

**Florida Department of Health  
Division of Medical Quality Assurance**

**BOARD OF PHARMACY  
4052 Bald Cypress Way, Bin #C-04  
Tallahassee, FL 32399-3258**



**Chapter 465, Florida Statutes  
Rules 64B16, Florida Administrative Code**

## INTRODUCTION

The purpose of this booklet is to provide a central location for the Florida laws and rules, of which the Board of Pharmacy, the Department of Health, and Florida licensed pharmacy professionals must adhere.

All of the Florida statutes and administrative rules mentioned in this introduction are not included in this booklet but may be easily provided upon request. (Those in bold are included.)

**Chapter 465**, Florida Statutes, is the law which governs the practice of pharmacy in the State of Florida. In addition to the law, the Board promulgates rules to further define the mandate of the law.

**Chapter 64B16**, Florida Administrative Code, includes the rules promulgated by the Board of Pharmacy. The Board is required by law to promulgate certain rules to implement specific mandates with Chapters 465, 456, and 120, Florida Statutes. From these statutes, the Board has been delegated specific authority to promulgate other rules so long as the rules are consistent with the laws.

Chapter 456, Florida Statutes, is the law that governs the Department of Health. Within Chapter 456, the Department's and the Board's scopes interrelate and intertwine. The Board must/may promulgate rules for the purposes of carrying out the mandates set forth in Chapter 456.

Chapter 120, Florida Statutes, is the Administrative Procedures Act. The purpose of the act is to ensure that the general public has access to information regarding the functions and duties of administrative bodies, e.g. Board of Pharmacy and Department of Health, whose actions may affect the interests of private citizens.

Under Chapter 120, The Administration Commission (the Governor and Cabinet) has adopted model rules (Chapter 28) by which agencies are required to abide when dealing with rulemaking and hearing procedures to the extent that each agency does not adopt a specific rule of procedure covering the subject matter material contained in the model rules applicable to that agency.

Complaints against a licensee.....(850) 245-4339

Address for Board of Pharmacy:

Department of Health  
Board of Pharmacy  
4052 Bald Cypress Way, Bin C-04  
Tallahassee, FL 32399  
Telephone: (850) 245-4474  
Facsimile: (850) 921-5389  
Email: [info@floridaspharmacy.gov](mailto:info@floridaspharmacy.gov)  
Website: [www.floridaspharmacy.gov](http://www.floridaspharmacy.gov)

**BOARD OF PHARMACY**  
www.floridaspharmacy.gov

**TABLE OF CONTENTS**

<b>DESCRIPTION</b>	<b>PAGE</b>
• <b>Chapter 465, Pharmacy.....</b>	<b>1</b>
• <b>Division 64B16, Board of Pharmacy.....</b>	<b>36</b>
○ <b>64B16-25, Organization and Purpose.....</b>	<b>37</b>
○ <b>64B16-26, Pharmacists Licensure.....</b>	<b>38</b>
○ <b>64B16-27, Pharmacy Practice.....</b>	<b>66</b>
○ <b>64B16-28, General Requirements – Permits.....</b>	<b>90</b>
○ <b>64B16-29, Animal Control Shelter Permits.....</b>	<b>140</b>
○ <b>64B16-30, Disciplinary Guidelines.....</b>	<b>143</b>
○ <b>64B16-32, Nonresident Pharmacies.....</b>	<b>163</b>

## Chapter 465 Pharmacy

- 465.001 Short Title.
- 465.002 Legislative findings; intent.
- 465.003 Definitions.
- 465.004 Board of Pharmacy.
- 465.005 Authority to make rules.
- 465.006 Disposition of fees; expenditures.
- 465.007 Licensure by examination.
- 465.0075 Licensure by endorsement; requirements; fee.
- 465.008 Renewal of license.
- 465.009 Continuing professional pharmaceutical education.
- 465.012 Reactivation of license; continuing education.
- 465.0125 Consultant pharmacist license; application, renewal, fees; responsibilities; rules.
- 465.0126 Nuclear pharmacist license; application, renewal, fees.
- 465.013 Registration of pharmacy interns.
- 465.014 Pharmacy technician.
- 465.015 Violations and penalties.
- 465.0155 Standards of practice.
- 465.0156 Registration of nonresident pharmacies.
- 465.0157 International export pharmacy permit.
- 465.0158 Nonresident sterile compounding permit.
- 465.016 Disciplinary actions.
- 465.0161 Distribution of medicinal drugs without a permit.
- 465.017 Authority to inspect; disposal.
- 465.018 Community pharmacies; permits.
- 465.0181 Community pharmacy permit required to dispense Schedule II or Schedule III controlled substances.
- 465.019 Institutional pharmacies; permits.
- 465.0193 Nuclear pharmacy permits.
- 465.0196 Special pharmacy permits.
- 465.0197 Internet pharmacy permits.
- 465.022 Pharmacies; general requirements; fees.
- 465.023 Pharmacy permittee; disciplinary action.
- 465.0235 Automated pharmacy systems used by long-term care facilities, hospices, or state correctional institutions.
- 465.024 Promoting sale of certain drugs prohibited.
- 465.0244 Information disclosure.
- 465.025 Substitution of drugs.
- 465.0251 Generic drugs; removal from formulary under specified circumstances.
- 465.0252 Substitution of interchangeable biosimilar products.
- 465.0255 Expiration date of medicinal drugs; display; related use and storage instructions.
- 465.026 Filling of certain prescriptions.
- 465.0265 Centralized prescription filling.
- 465.0266 Common database.
- 465.027 Exceptions.
- 465.0275 Emergency prescription refill.
- 465.0276 Dispensing practitioner.

- 465.035 Dispensing of medicinal drugs pursuant to facsimile of prescription.
- 465.185 Rebates prohibited; penalties.
- 465.186 Pharmacist's order for medicinal drugs; dispensing procedure; development of formulary.
- 465.187 Sale of medicinal drugs.
- 465.188 Medicaid audits of pharmacies.
- 465.1885 Pharmacy audits; rights.
- 465.189 Administration of vaccines and epinephrine autoinjection.
- 465.1893 Administration of antipsychotic medication by injection.
- 465.1901 Practice of orthotics and pedorthics.

**465.001 Short Title.**—This chapter shall be known as the "Florida Pharmacy Act."

**History.**—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

**465.002 Legislative findings; intent.**—The Legislature finds that the practice of pharmacy is a learned profession. The sole legislative purpose for enacting this chapter is to ensure that every pharmacist practicing in this state and every pharmacy meet minimum requirements for safe practice. It is the legislative intent that pharmacists who fall below minimum competency or who otherwise present a danger to the public shall be prohibited from practicing in this state.

**History.**—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 1, 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

**465.003 Definitions.**—As used in this chapter, the term:

- (1) "Administration" means the obtaining and giving of a single dose of medicinal drugs by a legally authorized person to a patient for her or his consumption.
- (2) "Board" means the Board of Pharmacy.
- (3) "Consultant pharmacist" means a pharmacist licensed by the department and certified as a consultant pharmacist pursuant to s. 465.0125.
- (4) "Data communication device" means an electronic device that receives electronic information from one source and transmits or routes it to another, including, but not limited to, any such bridge, router, switch, or gateway.
- (5) "Department" means the Department of Health.
- (6) "Dispense" means the transfer of possession of one or more doses of a medicinal drug by a pharmacist to the ultimate consumer or her or his agent. As an element of dispensing, the pharmacist shall, prior to the actual physical transfer, interpret and assess the prescription order for potential adverse reactions, interactions, and dosage regimen she or he deems appropriate in the exercise of her or his professional judgment, and the pharmacist shall certify that the medicinal drug called for by the prescription is ready for transfer. The pharmacist shall also provide counseling on proper drug usage, either orally or in writing, if in the exercise of her or his professional judgment counseling is necessary. The actual sales transaction and delivery of such drug shall not be considered dispensing. The administration shall not be considered dispensing.
- (7) "Institutional formulary system" means a method whereby the medical staff evaluates, appraises, and selects those medicinal drugs or proprietary preparations which in the medical staff's clinical judgment are most useful in patient care, and which are available for dispensing by a practicing pharmacist in a Class II or Class III institutional pharmacy.
- (8) "Medicinal drugs" or "drugs" means those substances or preparations commonly known as "prescription" or "legend" drugs which are required by federal or state law to be dispensed only on a prescription, but shall not include patents or proprietary preparations as hereafter defined.
- (9) "Patent or proprietary preparation" means a medicine in its unbroken, original package which is sold to the public by, or under the authority of, the manufacturer or primary distributor thereof and which is not misbranded under the provisions of the Florida Drug and Cosmetic Act.

- (10) "Pharmacist" means any person licensed pursuant to this chapter to practice the profession of pharmacy.
- (11)(a) "Pharmacy" includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, and an Internet pharmacy.
1. The term "community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.
  2. The term "institutional pharmacy" includes every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility, hereinafter referred to as "health care institutions," where medicinal drugs are compounded, dispensed, stored, or sold.
  3. The term "nuclear pharmacy" includes every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term "nuclear pharmacy" does not include hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.
  4. The term "special pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in this subsection.
  5. The term "Internet pharmacy" includes locations not otherwise licensed or issued a permit under this chapter, within or outside this state, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Any act described in this definition constitutes the practice of pharmacy as defined in subsection (13).
- (b) The pharmacy department of any permittee shall be considered closed whenever a Florida licensed pharmacist is not present and on duty. The term "not present and on duty" shall not be construed to prevent a pharmacist from exiting the prescription department for the purposes of consulting or responding to inquiries or providing assistance to patients or customers, attending to personal hygiene needs, or performing any other function for which the pharmacist is responsible, provided that such activities are conducted in a manner consistent with the pharmacist's responsibility to provide pharmacy services.
- (12) "Pharmacy intern" means a person who is currently registered in, and attending, a duly accredited college or school of pharmacy, or who is a graduate of such a school or college of pharmacy, and who is duly and properly registered with the department as provided for under its rules.
- (13) "Practice of the profession of pharmacy" includes compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; consulting concerning therapeutic values and interactions of patent or proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders; and conducting other pharmaceutical services. For purposes of this subsection, "other pharmaceutical services" means the monitoring of the patient's drug therapy and assisting the patient in the management of his or her drug therapy, and includes review of the patient's drug therapy and communication with the patient's prescribing health care provider as licensed under chapter 458, chapter 459, chapter 461, or chapter 466, or similar statutory provision in another jurisdiction, or such provider's agent or such other persons as specifically authorized by the patient, regarding the drug therapy. However, nothing in this subsection may be interpreted to permit an alteration of a prescriber's directions, the diagnosis or treatment of any disease, the initiation of any drug therapy, the practice of medicine, or the practice of osteopathic medicine, unless otherwise permitted by law. "Practice of the profession of pharmacy" also includes any other act, service, operation, research, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training, and shall expressly permit a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients. The practice of the profession of pharmacy also includes the administration of vaccines to adults pursuant to s. 465.189 and the preparation of prepackaged drug products in facilities holding Class III institutional pharmacy permits.
- (14) "Prescription" includes any order for drugs or medicinal supplies written or transmitted by any means of communication by a duly licensed practitioner authorized by the laws of the state to prescribe such drugs or medicinal supplies and intended to be dispensed by a pharmacist. The term also includes an orally transmitted order by the lawfully designated agent of such practitioner. The term also includes an order written or transmitted by a practitioner licensed to practice in a jurisdiction other than this state, but only if the pharmacist called upon to dispense such order determines, in the exercise of her or his professional judgment, that the order is valid and necessary for the treatment of a chronic or recurrent illness. The term "prescription" also includes a

pharmacist's order for a product selected from the formulary created pursuant to s. 465.186. Prescriptions may be retained in written form or the pharmacist may cause them to be recorded in a data processing system, provided that such order can be produced in printed form upon lawful request.

(15) "Nuclear pharmacist" means a pharmacist licensed by the department and certified as a nuclear pharmacist pursuant to s. 465.0126.

(16) "Centralized prescription filling" means the filling of a prescription by one pharmacy upon request by another pharmacy to fill or refill the prescription. The term includes the performance by one pharmacy for another pharmacy of other pharmacy duties such as drug utilization review, therapeutic drug utilization review, claims adjudication, and the obtaining of refill authorizations.

(17) "Automated pharmacy system" means a mechanical system that delivers prescription drugs received from a Florida licensed pharmacy and maintains related transaction information.

(18) "Compounding" means combining, mixing, or altering the ingredients of one or more drugs or products to create another drug or product.

(19) "Outsourcing facility" means a single physical location registered as an outsourcing facility under the federal Drug Quality and Security Act, Pub. L. No. 113-54, at which sterile compounding of a drug or product is conducted.

(20) "Compounded sterile product" means a drug that is intended for parenteral administration, an ophthalmic or oral inhalation drug in aqueous format, or a drug or product that is required to be sterile under federal or state law or rule, which is produced through compounding, but is not approved by the United States Food and Drug Administration.

(21) "Central distribution facility" means a facility under common control with a hospital holding a Class III institutional pharmacy permit that may dispense, distribute, compound, or fill prescriptions for medicinal drugs; prepare prepackaged drug products; and conduct other pharmaceutical services.

(22) "Common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise.

**History.**—ss. 1, 7, ch. 79-226; s. 322, ch. 81-259; ss. 14, 15, ch. 81-302; ss. 2, 3, ch. 81-318; ss. 1, 2, ch. 82-179; s. 1, ch. 83-101; s. 36, ch. 83-216; s. 3, ch. 83-265; s. 29, ch. 83-329; s. 1, ch. 85-35; ss. 2, 26, 27, ch. 86-256; s. 1, ch. 88-172; s. 1, ch. 89-77; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 123, ch. 94-218; s. 239, ch. 97-103; s. 87, ch. 97-264; s. 118, ch. 99-397; s. 1, ch. 2002-182; s. 1, ch. 2004-25; s. 1, ch. 2004-387; s. 2, ch. 2007-152; s. 2, ch. 2012-60; s. 1, ch. 2014-148; s. 1, ch. 2018-95.

#### **465.004 Board of Pharmacy.—**

(1) The Board of Pharmacy is created within the department and shall consist of nine members to be appointed by the Governor and confirmed by the Senate.

(2) Seven members of the board must be licensed pharmacists who are residents of this state and who have been engaged in the practice of the profession of pharmacy in this state for at least 4 years and, to the extent practicable, represent the various pharmacy practice settings. Of the pharmacist members, two must be currently engaged in the practice of pharmacy in a community pharmacy; two must be currently engaged in the practice of pharmacy in a Class II, Modified Class II, or Class III institutional pharmacy; and three must be pharmacists licensed in this state irrespective of practice setting. The remaining two members must be residents of the state who have never been licensed as pharmacists and who are in no way connected with the practice of the profession of pharmacy. No person may be appointed as a consumer member who is in any way connected with a drug manufacturer or wholesaler. At least one member of the board must be 60 years of age or older. The Governor shall appoint members to the board in accordance with this subsection as members' terms expire or as a vacancy occurs until the composition of the board complies with the requirements of this subsection.

(3) As the terms of the members expire, the Governor shall appoint successors for terms of 4 years, and such members shall serve until their successors are appointed.

(4) All provisions of chapter 456 relating to activities of the board shall apply.

**History.**—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 3, 26, 27, ch. 86-256; s. 16, ch. 87-172; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 124, ch. 94-218; s. 88, ch. 97-264; s. 67, ch. 98-166; s. 124, ch. 2000-160; s. 1, ch. 2014-113; s. 2, ch. 2018-95.

**465.005 Authority to make rules.**—The Board of Pharmacy has authority to adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter conferring duties upon it.

**History.**—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 4, 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 126, ch. 98-200.

**465.006 Disposition of fees; expenditures.**—All moneys received under this chapter shall be deposited and expended pursuant to the provisions of s. 456.025. All expenditures for duties of the board authorized by this chapter shall be paid upon presentation of vouchers approved by the executive director of the board.

**History.**—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 68, ch. 98-166; s. 125, ch. 2000-160.

**465.007 Licensure by examination.**—

(1) Any person desiring to be licensed as a pharmacist shall apply to the department to take the licensure examination. The department shall examine each applicant who the board certifies has:

(a) Completed the application form and remitted an examination fee set by the board not to exceed \$100 plus the actual per applicant cost to the department for purchase of portions of the examination from the National Association of Boards of Pharmacy or a similar national organization. The fees authorized under this section shall be established in sufficient amounts to cover administrative costs.

(b) Submitted satisfactory proof that she or he is not less than 18 years of age and:

1. Is a recipient of a degree from a school or college of pharmacy accredited by an accrediting agency recognized and approved by the United States Office of Education; or

2. Is a graduate of a 4-year undergraduate pharmacy program of a school or college of pharmacy located outside the United States, has demonstrated proficiency in English by passing both the Test of English as a Foreign Language (TOEFL) and the Test of Spoken English (TSE), has passed the Foreign Pharmacy Graduate Equivalency Examination that is approved by rule of the board, and has completed a minimum of 500 hours in a supervised work activity program within this state under the supervision of a pharmacist licensed by the department, which program is approved by the board.

(c) Submitted satisfactory proof that she or he has completed an internship program approved by the board. No such board-approved program shall exceed 2,080 hours, all of which may be obtained prior to graduation.

(2) The department may permit an applicant who has satisfied all requirements of subsection (1), except those relating to age or the internship program, to take the written examination, but the passing of the examination shall confer no rights or privileges upon the applicant in connection with the practice of pharmacy in this state.

(3) Except as provided in subsection (2), the department shall issue a license to practice pharmacy to any applicant who successfully completes the examination in accordance with this section.

**History.**—ss. 1, 7, ch. 79-226; ss. 13, 15, 23, 25, 30, 34, 62, ch. 80-406; ss. 2, 3, ch. 81-318; s. 30, ch. 83-329; ss. 5, 26, 27, ch. 86-256; s. 13, ch. 88-205; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 240, ch. 97-103.

**465.0075 Licensure by endorsement; requirements; fee.**—

(1) The department shall issue a license by endorsement to any applicant who applies to the department and remits a nonrefundable fee of not more than \$100, as set by the board, and whom the board certifies:

(a) Has met the qualifications for licensure in s. 465.007(1)(b) and (c);

(b) Has obtained a passing score, as established by rule of the board, on the licensure examination of the National Association of Boards of Pharmacy or a similar nationally recognized examination, if the board certifies that the applicant has taken the required examination;

(c)1. Has submitted evidence of the active licensed practice of pharmacy, including practice in community or public health by persons employed by a governmental entity, in another jurisdiction for at least 2 of the immediately preceding 5 years or evidence of successful completion of board-approved postgraduate training or a board-approved clinical competency examination within the year immediately preceding application for licensure; or

2. Has completed an internship meeting the requirements of s. 465.007(1)(c) within the 2 years immediately preceding application; and



(d) Has obtained a passing score on the pharmacy jurisprudence portions of the licensure examination, as required by board rule.

(2) An applicant licensed in another state for a period in excess of 2 years from the date of application for licensure in this state shall submit a total of at least 30 hours of board-approved continuing education for the 2 calendar years immediately preceding application.

(3) The department may not issue a license by endorsement to any applicant who is under investigation in any jurisdiction for an act or offense that would constitute a violation of this chapter until the investigation is complete, at which time the provisions of s. 465.016 apply.

(4) The department may not issue a license by endorsement to any applicant whose license to practice pharmacy has been suspended or revoked in another state or who is currently the subject of any disciplinary proceeding in another state.

**History.**—s. 1, ch. 2001-166; s. 1, ch. 2008-216.

#### **465.008 Renewal of license.—**

(1) The department shall renew a license upon receipt of the renewal application, verification of compliance with s. 465.009, and receipt of a fee set by the board not to exceed \$250.

(2) The department shall adopt rules establishing a procedure for the biennial renewal of licenses.

(3) Any person licensed under this chapter for 50 years or more is exempt from the payment of the renewal or delinquent fee, and the department shall issue a lifetime license to such a person.

**History.**—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 6, 26, 27, ch. 86-256; s. 7, ch. 90-341; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 178, ch. 94-119; s. 32, ch. 2001-277.

#### **465.009 Continuing professional pharmaceutical education.—**

(1) No license renewal shall be issued by the department until the licensee submits proof satisfactory to the board that during the 2 years prior to her or his application for renewal the licensee has participated in not less than 30 hours of continuing professional pharmaceutical education in courses approved by the board.

(2) The board shall approve only those courses that build upon the basic courses offered in the curricula of accredited colleges or schools of pharmacy, and the board shall require that the provider meets the educational standards for the program design, administration, and evaluation established by the board.

(3) Upon initial licensure, the department may reduce the number of required hours consistent with the requirements of biennial renewal.

(4) The department may make exception from the requirements of this section in an emergency or hardship case.

(5) The board may adopt rules within the requirements of this section that are necessary for its implementation, including a rule creating a committee composed of equal representation from the board, the colleges of pharmacy in the state, and practicing pharmacists within the state, whose purpose shall be to approve the content of each course offered for continuing education credit prior to the time such course is offered.

(6) Notwithstanding subsections (1)-(5):

(a) Each pharmacist certified to administer a vaccine or epinephrine autoinjection under s. 465.189 must complete a 3-hour continuing education course, which shall be offered by a statewide professional association of physicians in this state accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award (AMA PRA) Category I credit, on the safe and effective administration of vaccines and epinephrine autoinjection as part of biennial relicensure or recertification. This course may be offered in a distance-learning format and must be included in the 30 hours of continuing professional pharmaceutical education specified in subsection (1).

(b) Each pharmacist must submit confirmation of having completed the course specified in paragraph (a) on a form provided by the board when submitting fees for license renewal.

(c) Failure to comply with paragraphs (a) and (b) results in the revocation of the authorization for a pharmacist to administer a vaccine or epinephrine autoinjection under s. 465.189. Such authorization may be restored upon completion of such requirements.

**History.**—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 7, 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 241, ch. 97-103; s. 1, ch. 2002-184; s. 3, ch. 2012-60.

**465.012 Reactivation of license; continuing education.—**

(1) The board shall prescribe by rule continuing education requirements as a condition of reactivating a license. The continuing education requirements for reactivating a license shall be at least 15 classroom hours for each year the license was inactive in addition to completion of the number of hours required for renewal on the date the license became inactive.

(2) The board shall adopt rules relating to application procedures for inactive status, to the biennial renewal of inactive licenses, and to the reactivation of licenses. The board shall prescribe by rule an application fee for inactive status, a renewal fee for inactive status, a delinquency fee, and a fee for the reactivation of a license. None of these fees may exceed the biennial renewal fee established by the board for an active license. The department may not reactivate a license unless the inactive or delinquent licensee has paid any applicable biennial renewal or delinquency fee, or both, and a reactivation fee.

**History.**—ss. 1, 7, ch. 79-226; s. 323, ch. 81-259; ss. 2, 3, ch. 81-318; ss. 2, 30, ch. 82-179; s. 3, ch. 83-265; ss. 8, 26, 27, ch. 86-256; s. 8, ch. 90-341; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 179, ch. 94-119.

**465.0125 Consultant pharmacist license; application, renewal, fees; responsibilities; rules.—**

(1) The department shall issue or renew a consultant pharmacist license upon receipt of an initial or renewal application which conforms to the requirements for consultant pharmacist initial licensure or renewal as promulgated by the board by rule and a fee set by the board not to exceed \$250. The consultant pharmacist shall be responsible for maintaining all drug records required by law and for establishing drug handling procedures for the safe handling and storage of drugs. The consultant pharmacist may also be responsible for ordering and evaluating any laboratory or clinical testing when, in the judgment of the consultant pharmacist, such activity is necessary for the proper performance of the consultant pharmacist's responsibilities. Such laboratory or clinical testing may be ordered only with regard to patients residing in a nursing home facility, and then only when authorized by the medical director of the nursing home facility. The consultant pharmacist must have completed such additional training and demonstrate such additional qualifications in the practice of institutional pharmacy as shall be required by the board in addition to licensure as a registered pharmacist.

(2) Notwithstanding the provisions of subsection (1), a consultant pharmacist or a doctor of pharmacy licensed in this state may also be responsible for ordering and evaluating any laboratory or clinical testing for persons under the care of a licensed home health agency when, in the judgment of the consultant pharmacist or doctor of pharmacy, such activity is necessary for the proper performance of his or her responsibilities and only when authorized by a practitioner licensed under chapter 458, chapter 459, chapter 461, or chapter 466. In order for the consultant pharmacist or doctor of pharmacy to qualify and accept this authority, he or she must receive 3 hours of continuing education relating to laboratory and clinical testing as established by the board.

(3) The board shall promulgate rules necessary to implement and administer this section.

**History.**—s. 31, ch. 83-329; s. 1, ch. 85-65; ss. 9, 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 1, ch. 93-231; s. 89, ch. 97-264.

**465.0126 Nuclear pharmacist license; application, renewal, fees.**—The department shall issue or renew a nuclear pharmacist license upon receipt of an initial or renewal application which conforms to the requirements for nuclear pharmacist initial licensure or biennial renewal as established by the board by rule and receipt of a fee established by the board by rule not to exceed \$250, which fee shall be in addition to the initial licensure or biennial renewal fee for pharmacists. The nuclear pharmacist shall be responsible for the compounding and the dispensing of nuclear pharmaceuticals, for maintaining all drug records required by law, for establishing drug handling procedures for the safe handling and storage of radiopharmaceuticals and medicinal drugs, for providing the security of the prescription department, and for complying with such other rules as relate to the practice of the profession of pharmacy. The nuclear pharmacist must have completed such additional training and must demonstrate such additional qualifications in the practice of nuclear pharmacy as is required by the board by rule in addition to licensure as a registered pharmacist. The board shall adopt rules necessary to implement and administer this section. The requirements of this section do not apply to hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.

**History.**—s. 2, ch. 88-172; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

**465.013 Registration of pharmacy interns.**—The department shall register as pharmacy interns persons certified by the board as being enrolled in an intern program at an accredited school or college of pharmacy or who are graduates of accredited schools or colleges of pharmacy and are not yet licensed in the state. The board may refuse to certify to the department or may revoke the registration of any intern for good cause, including grounds enumerated in this chapter for revocation of pharmacists' licenses.

**History.**—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

**465.014 Pharmacy technician.**—

(1) A person other than a licensed pharmacist or pharmacy intern may not engage in the practice of the profession of pharmacy, except that a licensed pharmacist may delegate to pharmacy technicians who are registered pursuant to this section those duties, tasks, and functions that do not fall within the purview of s. 465.003(13). All such delegated acts must be performed under the direct supervision of a licensed pharmacist who is responsible for all such acts performed by persons under his or her supervision. A registered pharmacy technician, under the supervision of a pharmacist, may initiate or receive communications with a practitioner or his or her agent, on behalf of a patient, regarding refill authorization requests. A licensed pharmacist may not supervise more than one registered pharmacy technician unless otherwise permitted by the guidelines adopted by the board. The board shall establish guidelines to be followed by licensees or permittees in determining the circumstances under which a licensed pharmacist may supervise more than one pharmacy technician.

(2) Any person who wishes to work as a pharmacy technician in this state must register by filing an application with the board on a form adopted by rule of the board. The board shall register each applicant who has remitted a registration fee set by the board, not to exceed \$50 biennially; has completed the application form and remitted a nonrefundable application fee set by the board, not to exceed \$50; is at least 17 years of age; and has completed a pharmacy technician training program approved by the Board of Pharmacy. Notwithstanding any requirements in this subsection, any registered pharmacy technician registered pursuant to this section before January 1, 2011, who has worked as a pharmacy technician for a minimum of 1,500 hours under the supervision of a licensed pharmacist or received certification as a pharmacy technician by certification program accredited by the National Commission for Certifying Agencies is exempt from the requirement to complete an initial training program for purposes of registration as required by this subsection.

(3) A person whose license to practice pharmacy has been denied, suspended, or restricted for disciplinary purposes is not eligible to register as a pharmacy technician.

(4) Notwithstanding the requirements of this section or any other provision of law, a pharmacy technician student who is enrolled in a pharmacy technician training program that is approved by the board may be placed in a pharmacy for the purpose of obtaining practical training. A pharmacy technician student shall wear identification that indicates his or her student status when performing the functions of a pharmacy technician, and registration under this section is not required.

(5) Notwithstanding the requirements of this section or any other provision of law, a person who is licensed by the state as a pharmacy intern may be employed as a registered pharmacy technician without paying a registration fee or filing an application with the board to register as a pharmacy technician.

(6) As a condition of registration renewal, a registered pharmacy technician shall complete 20 hours biennially of continuing education courses approved by the board or the Accreditation Council for Pharmacy Education, of which 4 hours must be via live presentation and 2 hours must be related to the prevention of medication errors and pharmacy law.

(7) The board shall adopt rules that require each registration issued by the board under this section to be displayed in such a manner as to make it available to the public and to facilitate inspection by the department. The board may adopt other rules as necessary to administer this section.

(8) If the board finds that an applicant for registration as a pharmacy technician or that a registered pharmacy technician has committed an act that constitutes grounds for discipline as set forth in s. 456.072(1) or has committed an act that constitutes grounds for denial of a license or disciplinary action as set forth in this chapter, including an act that constitutes a substantial violation of s. 456.072(1) or a violation of this chapter which

occurred before the applicant or registrant was registered as a pharmacy technician, the board may enter an order imposing any of the penalties specified in s. 456.072(2) against the applicant or registrant.

**History.**—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 10, 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 242, ch. 97-103; s. 192, ch. 97-264; s. 120, ch. 99-397; ss. 2, 3, 4, ch. 2008-216; s. 2, ch. 2014-113; s. 13, ch. 2016-145.

**465.015 Violations and penalties.—**

(1) It is unlawful for any person to own, operate, maintain, open, establish, conduct, or have charge of, either alone or with another person or persons, a pharmacy:

(a) Which is not registered under the provisions of this chapter.

(b) In which a person not licensed as a pharmacist in this state or not registered as an intern in this state or in which an intern who is not acting under the direct and immediate personal supervision of a licensed pharmacist fills, compounds, or dispenses any prescription or dispenses medicinal drugs.

(2) It is unlawful for any person:

(a) To make a false or fraudulent statement, either for herself or himself or for another person, in any application, affidavit, or statement presented to the board or in any proceeding before the board.

(b) To fill, compound, or dispense prescriptions or to dispense medicinal drugs if such person does not hold an active license as a pharmacist in this state, is not registered as an intern in this state, or is an intern not acting under the direct and immediate personal supervision of a licensed pharmacist.

(c) To sell or dispense drugs as defined in s. 465.003(8) without first being furnished with a prescription.

(d) To sell samples or complimentary packages of drug products.

(3) It is unlawful for any pharmacist to knowingly fail to report to the sheriff or other chief law enforcement agency of the county where the pharmacy is located within 24 hours after learning of any instance in which a person obtained or attempted to obtain a controlled substance, as defined in s. 893.02, or at the close of business on the next business day, whichever is later, that the pharmacist knew or believed was obtained or attempted to be obtained through fraudulent methods or representations from the pharmacy at which the pharmacist practiced pharmacy. Any pharmacist who knowingly fails to make such a report within 24 hours after learning of the fraud or attempted fraud or at the close of business on the next business day, whichever is later, commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. A sufficient report of the fraudulent obtaining of controlled substances under this subsection must contain, at a minimum, a copy of the prescription used or presented and a narrative, including all information available to the pharmacist concerning the transaction, such as the name and telephone number of the prescribing physician; the name, description, and any personal identification information pertaining to the person who presented the prescription; and all other material information, such as photographic or video surveillance of the transaction.

(4)(a) It is unlawful for any person other than a pharmacist licensed under this chapter to use the title "pharmacist" or "druggist" or otherwise lead the public to believe that she or he is engaged in the practice of pharmacy.

(b) It is unlawful for any person other than an owner of a pharmacy registered under this chapter to display any sign or to take any other action that would lead the public to believe that such person is engaged in the business of compounding, dispensing, or retailing any medicinal drugs. This paragraph shall not preclude a person not licensed as a pharmacist from owning a pharmacy.

(c) It is unlawful for a person, firm, or corporation that is not licensed or registered under this chapter to:

1. Use in a trade name, sign, letter, or advertisement any term, including "drug," "pharmacy," "prescription drugs," "Rx," or "apothecary," which implies that the person, firm, or corporation is licensed or registered to practice pharmacy in this state.

2. Hold himself or herself out to others as a person, firm, or corporation licensed or registered to practice pharmacy in this state.

(d) It is unlawful for a person who is not registered as a pharmacy technician under this chapter or who is not otherwise exempt from the requirement to register as a pharmacy technician, to perform the functions of a registered pharmacy technician, or hold himself or herself out to others as a person who is registered to perform the functions of a registered pharmacy technician in this state.

(5) Any person who violates any provision of subsection (1) or subsection (4) commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. Any person who violates any provision of subsection (2) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. In any warrant, information, or indictment, it shall not be necessary to negative any exceptions, and the burden of any exception shall be upon the defendant.

**History.**—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 11, 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 91, ch. 91-224; s. 4, ch. 91-429; s. 243, ch. 97-103; s. 121, ch. 99-397; s. 55, ch. 2000-318; s. 2, ch. 2004-25; s. 5, ch. 2008-216; s. 10, ch. 2011-141; s. 19, ch. 2016-145.

**465.0155 Standards of practice.—**

(1) Consistent with the provisions of this act, the board shall adopt by rule standards of practice relating to the practice of pharmacy which shall be binding on every state agency and shall be applied by such agencies when enforcing or implementing any authority granted by any applicable statute, rule, or regulation, whether federal or state.

(2)(a) Before dispensing a controlled substance to a person not known to the pharmacist, the pharmacist must require the person purchasing, receiving, or otherwise acquiring the controlled substance to present valid photographic identification or other verification of his or her identity. If the person does not have proper identification, the pharmacist may verify the validity of the prescription and the identity of the patient with the prescriber or his or her authorized agent. Verification of health plan eligibility through a real-time inquiry or adjudication system is considered to be proper identification.

(b) This subsection does not apply in an institutional setting or to a long-term care facility, including, but not limited to, an assisted living facility or a hospital to which patients are admitted.

(c) As used in this subsection, the term “proper identification” means an identification that is issued by a state or the Federal Government containing the person’s photograph, printed name, and signature or a document considered acceptable under 8 C.F.R. s. 274a.2(b)(1)(v)(A) and (B).

**History.**—ss. 12, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 6, ch. 2018-13.

**465.0156 Registration of nonresident pharmacies.—**

(1) Any pharmacy which is located outside this state and which ships, mails, or delivers, in any manner, a dispensed medicinal drug into this state shall be considered a nonresident pharmacy, shall be registered with the board, shall provide pharmacy services at a high level of protection and competence, and shall disclose to the board the following specific information:

(a) That it maintains at all times a valid, unexpired license, permit, or registration to operate the pharmacy in compliance with the laws of the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed;

(b) The location, names, and titles of all principal corporate officers and the pharmacist who serves as the prescription department manager for dispensing medicinal drugs to residents of this state. This disclosure shall be made within 30 days after any change of location, corporate officer, or pharmacist serving as the prescription department manager for dispensing medicinal drugs to residents of this state;

(c) That it complies with all lawful directions and requests for information from the regulatory or licensing agency of all states in which it is licensed as well as with all requests for information made by the board pursuant to this section. It shall respond directly to all communications from the board concerning emergency circumstances arising from errors in the dispensing of medicinal drugs to the residents of this state;

(d) That it maintains its records of medicinal drugs dispensed to patients in this state so that the records are readily retrievable from the other business records of the pharmacy and from the records of other medicinal drugs dispensed; and

(e) That during its regular hours of operation but not less than 6 days per week, for a minimum of 40 hours per week, a toll-free telephone service shall be provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient’s records. This toll-free number must be disclosed on the label affixed to each container of dispensed medicinal drugs.

(2) Applications for nonresident pharmacy registration under this section shall be made on a form furnished by the board. The board may require such information as the board deems reasonably necessary to carry out the

purposes of this section. The board may grant an exemption from the registration requirements of this section to any nonresident pharmacy which confines its dispensing activity to isolated transactions. The board may define by rule the term isolated transactions.

(3) The registration fee and the biennial renewal fee shall be the fee specified in s. 465.022.

(4) The board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy for failure to comply with s. 465.0158, s. 465.017(2), or s. 465.025, or with any requirement of this section in accordance with this chapter.

(5) In addition to the prohibitions of subsection (4) the board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy in accordance with this chapter for conduct which causes or could cause serious bodily or psychological injury to a human or serious bodily injury to a nonhuman animal in this state.

(6) A nonresident pharmacy is subject to s. 456.0635.

(7) It is unlawful for any nonresident pharmacy which is not registered pursuant to this section to advertise its services in this state, or for any person who is a resident of this state to advertise the pharmacy services of a nonresident pharmacy which has not registered with the board, with the knowledge that the advertisement will or is likely to induce members of the public in this state to use the pharmacy to fill prescriptions.

(8) This section does not apply to Internet pharmacies required to be permitted under s. 465.0197.

(9) Notwithstanding s. 465.003(10), for purposes of this section, the registered pharmacy and the pharmacist designated by the registered pharmacy as the prescription department manager or the equivalent must be licensed in the state of location in order to dispense into this state.

**History.**—ss. 13, 27, ch. 86-256; s. 3, ch. 89-218; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 31, ch. 95-144; s. 90, ch. 97-264; s. 2, ch. 2004-387; s. 2, ch. 2014-148.

#### **465.0157 International export pharmacy permit.—**

(1) To participate as an exporter of prescription drugs into this state under the International Prescription Drug Importation Program established in s. 499.0285, a pharmacy located outside of the United States must hold an international export pharmacy permit.

(2) An international export pharmacy shall maintain at all times an active and unencumbered license or permit to operate the pharmacy in compliance with the laws of the jurisdiction in which the dispensing facility is located and from which the prescription drugs will be exported. Such jurisdiction must be in a country with which the United States has a current mutual recognition agreement, cooperation agreement, memorandum of understanding, or other federal mechanism recognizing the country's adherence to current good manufacturing practices for pharmaceutical products.

(3) An application for an international export pharmacy permit must be submitted on a form developed and provided by the board. The board may require an applicant to provide any information it deems reasonably necessary to carry out the purposes of this section.

(4) An applicant shall submit the following to the board to obtain an initial permit, or to the department to renew a permit:

(a) Proof of an active and unencumbered license or permit to operate the pharmacy in compliance with the laws of the jurisdiction in which the dispensing facility is located and from which the prescription drugs will be exported.

(b) Documentation demonstrating that the country in which the pharmacy operates has a current mutual recognition agreement, cooperation agreement, memorandum of understanding, or other federal mechanism recognizing the country's adherence to current good manufacturing practices for pharmaceutical products.

(c) The location, names, and titles of all principal corporate officers and the pharmacist who serves as the prescription department manager for prescription drugs exported into this state under the International Prescription Drug Importation Program.

(d) Written attestation by an owner or officer of the applicant, and by the applicant's prescription department manager, that:

1. The attestor has read and understands the laws and rules governing the manufacture, distribution, and dispensing of prescription drugs in this state.

2. A prescription drug shipped, mailed, or delivered into this state meets or exceeds this state's standards for safety and efficacy.
3. A prescription drug product shipped, mailed, or delivered into this state must not have been, and may not be, manufactured or distributed in violation of the laws and rules of the jurisdiction in which the applicant is located and from which the prescription drugs shall be exported.
  - (e) A current inspection report from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which the applicant is located. The inspection report must reflect compliance with this section. An inspection report is current if the inspection was conducted within 6 months before the date of submitting the application for the initial permit or within 1 year before the date of submitting an application for permit renewal. If the applicant is unable to submit a current inspection report conducted by the regulatory or licensing agency of the jurisdiction in which the applicant is located and from which the prescription drugs will be exported, due to acceptable circumstances, as established by rule, or if an inspection has not been performed, the department must:
    1. Conduct, or contract with an entity to conduct, an onsite inspection, with all related costs borne by the applicant;
    2. Accept a current and satisfactory inspection report, as determined by rule, from an entity approved by the board; or
    3. Accept a current inspection report from the United States Food and Drug Administration conducted pursuant to the federal Drug Quality and Security Act, Pub. L. No. 113-54.
  - (5) The department shall adopt rules governing the financial responsibility of the pharmacy permittee. The rules must establish, at a minimum, financial reporting requirements, standards for financial capability to perform the functions governed by the permit, and requirements for ensuring permittees and their contractors can be held accountable for the financial consequences of any act of malfeasance or misfeasance or fraudulent or dishonest act or acts committed by the permittee or its contractors.

**History.**—s. 2, ch. 2019-99.

<sup>1</sup>**Note.**—Section 11, ch. 2019-99, provides in part that “[i]mplementation of sections 2 through 10 of this act is contingent upon authorization granted under federal law, rule, or approval.” Section 11, ch. 2019-99, was codified as s. 499.02851.

**465.0158 Nonresident sterile compounding permit.—**

- (1) In order to ship, mail, deliver, or dispense, in any manner, a compounded sterile product into this state, a nonresident pharmacy registered under s. 465.0156, or an outsourcing facility, must hold a nonresident sterile compounding permit.
- (2) An application for a nonresident sterile compounding permit shall be submitted on a form furnished by the board. The board may require such information as it deems reasonably necessary to carry out the purposes of this section. The fee for an initial permit and biennial renewal of the permit shall be set by the board pursuant to s. 465.022(14).
- (3) An applicant must submit the following to the board to obtain an initial permit, or to the department to renew a permit:
  - (a) Proof of registration as an outsourcing facility with the Secretary of the United States Department of Health and Human Services if the applicant is eligible for such registration pursuant to the federal Drug Quality and Security Act, Pub. L. No. 113-54.
  - (b) Proof of registration as a nonresident pharmacy, pursuant to s. 465.0156, unless the applicant is an outsourcing facility and not a pharmacy, in which case the application must include proof of an active and unencumbered license, permit, or registration issued by the state, territory, or district in which the outsourcing facility is physically located which allows the outsourcing facility to engage in compounding and to ship, mail, deliver, or dispense a compounded sterile product into this state.
  - (c) Written attestation by an owner or officer of the applicant, and by the applicant's prescription department manager or pharmacist in charge, that:
    1. The attestor has read and understands the laws and rules governing sterile compounding in this state.
    2. A compounded sterile product shipped, mailed, delivered, or dispensed into this state meets or exceeds this state's standards for sterile compounding.

3. A compounded sterile product shipped, mailed, delivered, or dispensed into this state must not have been, and may not be, compounded in violation of the laws and rules of the state, territory, or district in which the applicant is located.

(d) The applicant's existing policies and procedures for sterile compounding, which must comply with pharmaceutical standards in chapter 797 of the United States Pharmacopoeia and any standards for sterile compounding required by board rule or current good manufacturing practices for an outsourcing facility.

(e) A current inspection report from an inspection conducted by the regulatory or licensing agency of the state, territory, or district in which the applicant is located. The inspection report must reflect compliance with this section. An inspection report is current if the inspection was conducted within 6 months before the date of submitting the application for the initial permit or within 1 year before the date of submitting an application for permit renewal. If the applicant is unable to submit a current inspection report conducted by the regulatory or licensing agency of the state, territory, or district in which the applicant is located, due to acceptable circumstances, as established by rule, or if an inspection has not been performed, the department shall:

1. Conduct, or contract with an entity to conduct, an onsite inspection for which all costs shall be borne by the applicant;
2. Accept a current and satisfactory inspection report, as determined by rule, from an entity approved by the board; or
3. Accept a current inspection report from the United States Food and Drug Administration conducted pursuant to the federal Drug Quality and Security Act, Pub. L. No. 113-54.

(4) A permittee may not ship, mail, deliver, or dispense a compounded sterile product into this state if the product was compounded in violation of the laws or rules of the state, territory, or district in which the permittee is located or does not meet or exceed this state's sterile compounding standards.

(5) In accordance with this chapter, the board may deny, revoke, or suspend the permit of; fine; or reprimand a permittee for:

- (a) Failure to comply with this section;
- (b) A violation listed under s. 456.0635, s. 456.065, or s. 456.072, except s. 456.072(1)(s) or (1)(u);
- (c) A violation under s. 465.0156(5); or
- (d) A violation listed under s. 465.016.

(6) A nonresident pharmacy registered under s. 465.0156 which ships, mails, delivers, or dispenses a compounded sterile product into this state may continue to do so if the product meets or exceeds the standards for sterile compounding in this state; the product is not compounded in violation of any law or rule of the state, territory, or district where the pharmacy is located; and the pharmacy is issued a permit under this section on or before February 28, 2015.

(7) An applicant registering on or after October 1, 2014, as a nonresident pharmacy under s. 465.0156 may not ship, mail, deliver, or dispense a compounded sterile product into this state until the applicant is registered as a nonresident pharmacy and is issued a permit under this section.

(8) The board shall adopt rules as necessary to administer this section, including rules for:

- (a) Submitting an application for the permit required by this section.
- (b) Determining how, when, and under what circumstances an inspection of a nonresident sterile compounding permittee must be conducted.
- (c) Evaluating and approving entities from which a satisfactory inspection report will be accepted in lieu of an onsite inspection by the department or an inspection by the licensing or regulatory agency of the state, territory, or district where the applicant is located.

**History.**—s. 3, ch. 2014-148; s. 22, ch. 2016-224.

#### **465.016 Disciplinary actions.—**

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

- (a) Obtaining a license by misrepresentation or fraud or through an error of the department or the board.
- (b) Procuring or attempting to procure a license for any other person by making or causing to be made any false representation.



- (c) Permitting any person not licensed as a pharmacist in this state or not registered as an intern in this state, or permitting a registered intern who is not acting under the direct and immediate personal supervision of a licensed pharmacist, to fill, compound, or dispense any prescriptions in a pharmacy owned and operated by such pharmacist or in a pharmacy where such pharmacist is employed or on duty.
- (d) Being unfit or incompetent to practice pharmacy by reason of:
1. Habitual intoxication.
  2. The misuse or abuse of any medicinal drug appearing in any schedule set forth in chapter 893.
  3. Any abnormal physical or mental condition which threatens the safety of persons to whom she or he might sell or dispense prescriptions, drugs, or medical supplies or for whom she or he might manufacture, prepare, or package, or supervise the manufacturing, preparation, or packaging of, prescriptions, drugs, or medical supplies.
- (e) Violating chapter 499; 21 U.S.C. ss. 301-392, known as the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse Prevention and Control Act; or chapter 893.
- (f) Having been convicted or found guilty, regardless of adjudication, in a court of this state or other jurisdiction, of a crime which directly relates to the ability to practice pharmacy or to the practice of pharmacy. A plea of nolo contendere constitutes a conviction for purposes of this provision.
- (g) Using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed, except as authorized in s. 465.019(6) or s. 465.025.
- (h) Having been disciplined by a regulatory agency in another state for any offense that would constitute a violation of this chapter.
- (i) Compounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy. For purposes of this paragraph, it shall be legally presumed that the compounding, dispensing, or distributing of legend drugs in excessive or inappropriate quantities is not in the best interests of the patient and is not in the course of the professional practice of pharmacy.
- (j) Making or filing a report or record which the licensee knows to be false, intentionally or negligently failing to file a report or record required by federal or state law, willfully impeding or obstructing such filing, or inducing another person to do so. Such reports or records include only those which the licensee is required to make or file in her or his capacity as a licensed pharmacist.
- (k) Failing to make prescription fee or price information readily available by failing to provide such information upon request and upon the presentation of a prescription for pricing or dispensing. Nothing in this section shall be construed to prohibit the quotation of price information on a prescription drug to a potential consumer by telephone.
- (l) Placing in the stock of any pharmacy any part of any prescription compounded or dispensed which is returned by a patient; however, in a hospital, nursing home, correctional facility, or extended care facility in which unit-dose medication is dispensed to inpatients, each dose being individually sealed and the individual unit dose or unit-dose system labeled with the name of the drug, dosage strength, manufacturer's control number, and expiration date, if any, the unused unit dose of medication may be returned to the pharmacy for redispensing. Each pharmacist shall maintain appropriate records for any unused or returned medicinal drugs.
- (m) Being unable to practice pharmacy with reasonable skill and safety by reason of illness, use of drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition. A pharmacist affected under this paragraph shall at reasonable intervals be afforded an opportunity to demonstrate that she or he can resume the competent practice of pharmacy with reasonable skill and safety to her or his customers.
- (n) Violating a rule of the board or department or violating an order of the board or department previously entered in a disciplinary hearing.
- (o) Failing to report to the department any licensee under chapter 458 or under chapter 459 who the pharmacist knows has violated the grounds for disciplinary action set out in the law under which that person is licensed and who provides health care services in a facility licensed under chapter 395, or a health maintenance organization certificated under part I of chapter 641, in which the pharmacist also provides services. However, a person who the licensee knows is unable to practice medicine or osteopathic medicine with reasonable skill and safety to patients by reason of illness or use of alcohol, drugs, narcotics, chemicals, or any other type of material, or as a result of a mental or physical condition, may be reported to a consultant operating an impaired practitioner program as described in s. 456.076 rather than to the department.

- (p) Failing to notify the Board of Pharmacy in writing within 20 days of the commencement or cessation of the practice of the profession of pharmacy in Florida when such commencement or cessation of the practice of the profession of pharmacy in Florida was a result of a pending or completed disciplinary action or investigation in another jurisdiction.
- (q) Using or releasing a patient's records except as authorized by this chapter and chapter 456.
- (r) Violating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto.
- (s) Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship.
- (t) Committing an error or omission during the performance of a specific function of prescription drug processing, which includes, for purposes of this paragraph:
1. Receiving, interpreting, or clarifying a prescription.
  2. Entering prescription data into the pharmacy's record.
  3. Verifying or validating a prescription.
  4. Performing pharmaceutical calculations.
  5. Performing prospective drug review as defined by the board.
  6. Obtaining refill and substitution authorizations.
  7. Interpreting or acting on clinical data.
  8. Performing therapeutic interventions.
  9. Providing drug information concerning a patient's prescription.
  10. Providing patient counseling.
- (2) The board may enter an order denying licensure or imposing any of the penalties in s. 456.072(2) against any applicant for licensure or licensee who is found guilty of violating any provision of subsection (1) of this section or who is found guilty of violating any provision of s. 456.072(1).
- (3) The board shall not reinstate the license of a pharmacist, or cause a license to be issued to a person it has deemed unqualified, until such time as it is satisfied that she or he has complied with all the terms and conditions set forth in the final order and that such person is capable of safely engaging in the practice of pharmacy.
- (4) The board shall by rule establish guidelines for the disposition of disciplinary cases involving specific types of violations. Such guidelines may include minimum and maximum fines, periods of supervision or probation, or conditions of probation or reissuance of a license.
- History.**—ss. 1, 7, ch. 79-226; ss. 13, 15, 24, 25, 30, 34, 62, ch. 80-406; s. 324, ch. 81-259; ss. 2, 3, ch. 81-318; s. 3, ch. 83-101; s. 37, ch. 83-216; ss. 32, 119, ch. 83-329; s. 1, ch. 84-364; ss. 26, 27, ch. 86-256; s. 41, ch. 88-1; s. 20, ch. 88-277; s. 2, ch. 89-77; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 45, ch. 92-149; s. 32, ch. 95-144; s. 244, ch. 97-103; s. 91, ch. 97-264; s. 119, ch. 99-397; s. 126, ch. 2000-160; s. 33, ch. 2001-277; s. 3, ch. 2004-387; s. 10, ch. 2005-240; s. 5, ch. 2008-184; s. 11, ch. 2011-141; s. 20, ch. 2016-145; s. 16, ch. 2017-41.

**465.0161 Distribution of medicinal drugs without a permit.**—An Internet pharmacy that distributes a medicinal drug to any person in this state without being permitted as a pharmacy under this chapter commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

**History.**—s. 4, ch. 2004-387.

**465.017 Authority to inspect; disposal.**—

- (1) Duly authorized agents and employees of the department may inspect in a lawful manner at all reasonable hours any pharmacy, hospital, clinic, wholesale establishment, manufacturer, physician's office, or any other place in the state in which drugs and medical supplies are compounded, manufactured, packed, packaged, made, stored, sold, offered for sale, exposed for sale, or kept for sale for the purpose of:
- (a) Determining if any provision of this chapter or any rule adopted under its authority is being violated;
  - (b) Securing samples or specimens of any drug or medical supply after paying or offering to pay for such sample or specimen; or
  - (c) Securing such other evidence as may be needed for prosecution under this chapter.

<sup>1</sup>(2) Duly authorized agents and employees of the department may inspect a nonresident pharmacy registered under s. 465.0156 or a nonresident sterile compounding permittee under s. 465.0158 pursuant to this section. The costs of such inspections shall be borne by such pharmacy or permittee.

(3) Except as permitted by this chapter, and chapters 406, 409, 456, 499, and 893, records maintained in a pharmacy relating to the filling of prescriptions and the dispensing of medicinal drugs may be furnished only to the patient for whom the drugs were dispensed, or her or his legal representative, or to the department pursuant to existing law, or, if the patient is incapacitated or unable to request such records, her or his spouse except upon the written authorization of such patient.

(a) Such records may be furnished in any civil or criminal proceeding, upon the issuance of a subpoena from a court of competent jurisdiction and proper notice to the patient or her or his legal representative by the party seeking such records.

(b) The board shall adopt rules establishing practice guidelines for pharmacies to dispose of records maintained in a pharmacy relating to the filling of prescriptions and the dispensing of medicinal drugs. Such rules must be consistent with the duty to preserve the confidentiality of such records in accordance with applicable state and federal law.

**History.**—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 1, 2, ch. 85-151; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 125, ch. 94-218; s. 245, ch. 97-103; s. 127, ch. 2000-160; s. 1, ch. 2003-166; s. 4, ch. 2014-148; s. 3, ch. 2019-99.

**Note.**—Section 11, ch. 2019-99, which was codified as s. 499.02851, provides in part that “[i]mplementation of sections 2 through 10 of this act is contingent upon authorization granted under federal law, rule, or approval.” If the contingency occurs, subsection (2), as amended by s. 3, ch. 2019-99, will read:

(2) Duly authorized agents and employees of the department may inspect a nonresident pharmacy registered under s. 465.0156, an international export pharmacy permittee under s. 465.0157, or a nonresident sterile compounding permittee under s. 465.0158 pursuant to this section. The costs of such inspections shall be borne by such pharmacy or permittee.

#### **465.018 Community pharmacies; permits.—**

(1) Any person desiring a permit to operate a community pharmacy shall apply to the department.

(2) If the board office certifies that the application complies with the laws of the state and the rules of the board governing pharmacies, the department shall issue the permit. No permit shall be issued unless a licensed pharmacist is designated as the prescription department manager.

(3) The board may suspend or revoke the permit of, or may refuse to issue a permit to:

(a) Any person who has been disciplined or who has abandoned a permit or allowed a permit to become void after written notice that disciplinary proceedings had been or would be brought against the permit;

(b) Any person who is an officer, director, or person interested directly or indirectly in a person or business entity that has had a permit disciplined or abandoned or become void after written notice that disciplinary proceedings had been or would be brought against the permit; or

(c) Any person who is or has been an officer of a business entity, or who was interested directly or indirectly in a business entity, the permit of which has been disciplined or abandoned or become null and void after written notice that disciplinary proceedings had been or would be brought against the permit.

(4) In addition to any other remedies provided by law, the board may deny the application or suspend or revoke the license, registration, or certificate of any entity regulated or licensed by it if the applicant, licensee, registrant, or licenseholder, or, in the case of a corporation, partnership, or other business entity, if any officer, director, agent, or managing employee of that business entity or any affiliated person, partner, or shareholder having an ownership interest equal to 5 percent or greater in that business entity, has failed to pay all outstanding fines, liens, or overpayments assessed by final order of the department, unless a repayment plan is approved by the department, or has failed to comply with any repayment plan.

(5) In reviewing any application requesting a change of ownership or a change of licensee or registrant, the transferor shall, before board approval of the change, repay or make arrangements to repay any amounts owed to the department. If the transferor fails to repay or make arrangements to repay the amounts owed to the department, the license or registration may not be issued to the transferee until repayment or until arrangements for repayment are made.

(6) Passing an onsite inspection is a prerequisite to the issuance of an initial permit or a permit for a change of location. The department must make the inspection within 90 days before issuance of the permit.

(7) Community pharmacies that dispense controlled substances must maintain a record of all controlled substance dispensing consistent with the requirements of s. 893.07 and must make the record available to the department and law enforcement agencies upon request.

**History.**—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 26, 27, ch. 86-256; s. 3, ch. 88-172; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 12, ch. 2011-141.

**465.0181 Community pharmacy permit required to dispense Schedule II or Schedule III controlled substances.**—In order to dispense controlled substances listed in Schedule II or Schedule III, as provided in s. 893.03, on or after July 1, 2012, a community pharmacy permittee must be permitted pursuant to this chapter, as amended by this act, and any rules adopted thereunder.

**History.**—s. 13, ch. 2011-141.

**465.019 Institutional pharmacies; permits.**—

(1) Any institution desiring to operate an institutional pharmacy shall apply to the department. If the board certifies that the application complies with the laws of the state and the rules of the board governing pharmacies, the department shall issue the permit.

(2) The following classes of institutional pharmacies are established:

(a) “Class I institutional pharmacies” are those institutional pharmacies in which all medicinal drugs are administered from individual prescription containers to the individual patient and in which medicinal drugs are not dispensed on the premises, except that nursing homes licensed under part II of chapter 400 may purchase medical oxygen for administration to residents. No medicinal drugs may be dispensed in a Class I institutional pharmacy.

(b) “Class II institutional pharmacies” are those institutional pharmacies which employ the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, shall provide dispensing and consulting services on the premises to patients of that institution, for use on the premises of that institution. However, an institutional pharmacy located in an area or county included in an emergency order or proclamation of a state of emergency declared by the Governor may provide dispensing and consulting services to individuals who are not patients of the institution. However, a single dose of a medicinal drug may be obtained and administered to a patient on a valid physician’s drug order under the supervision of a physician or charge nurse, consistent with good institutional practice procedures. The obtaining and administering of such single dose of a medicinal drug shall be pursuant to drug-handling procedures established by a consultant pharmacist. Medicinal drugs may be dispensed in a Class II institutional pharmacy, but only in accordance with the provisions of this section.

(c) “Modified Class II institutional pharmacies” are those institutional pharmacies in short-term, primary care treatment centers that meet all the requirements for a Class II permit, except space and equipment requirements.

(d)1. “Class III institutional pharmacies” are those institutional pharmacies, including central distribution facilities, affiliated with a hospital that provide the same services that are authorized by a Class II institutional pharmacy permit. Class III institutional pharmacies may also:

- a. Dispense, distribute, compound, and fill prescriptions for medicinal drugs.
- b. Prepare prepackaged drug products.
- c. Conduct other pharmaceutical services for the affiliated hospital and for entities under common control that are each permitted under this chapter to possess medicinal drugs.
- d. Provide the services in sub-subparagraphs a.-c. to an entity under common control which holds an active health care clinic establishment permit as required under s. 499.01(2)(r).

2. A Class III institutional pharmacy shall maintain policies and procedures addressing:

- a. The consultant pharmacist responsible for pharmaceutical services.
- b. Safe practices for the preparation, dispensing, prepackaging, distribution, and transportation of medicinal drugs and prepackaged drug products.

- c. Recordkeeping to monitor the movement, distribution, and transportation of medicinal drugs and prepackaged drug products.
- d. Recordkeeping of pharmacy staff responsible for each step in the preparation, dispensing, prepackaging, transportation, and distribution of medicinal drugs and prepackaged drug products.
- e. Medicinal drugs and prepackaged drug products that may not be safely distributed among Class III institutional pharmacies.

(3) Medicinal drugs shall be stocked, stored, compounded, dispensed, or administered in any health care institution only when that institution has secured an institutional pharmacy permit from the department.

(4) Medicinal drugs shall be dispensed in an institutional pharmacy to outpatients only when that institution has secured a community pharmacy permit from the department. However, an individual licensed to prescribe medicinal drugs in this state may dispense up to a 24-hour supply of a medicinal drug to any patient of an emergency department of a hospital that operates a Class II or Class III institutional pharmacy, provided that the physician treating the patient in such hospital's emergency department determines that the medicinal drug is warranted and that community pharmacy services are not readily accessible, geographically or otherwise, to the patient. Such dispensing from the emergency department must be in accordance with the procedures of the hospital. For any such patient for whom a medicinal drug is warranted for a period to exceed 24 hours, an individual licensed to prescribe such drug must dispense a 24-hour supply of such drug to the patient and must provide the patient with a prescription for such drug for use after the initial 24-hour period. The board may adopt rules necessary to carry out the provisions of this subsection.

(5) All institutional pharmacies shall be under the professional supervision of a consultant pharmacist, and the compounding and dispensing of medicinal drugs shall be done only by a licensed pharmacist. Every institutional pharmacy that employs or otherwise uses registered pharmacy technicians shall have a written policy and procedures manual specifying those duties, tasks, and functions that a registered pharmacy technician is allowed to perform.

(6) In a Class II or Class III institutional pharmacy, an institutional formulary system may be adopted with approval of the medical staff for the purpose of identifying those medicinal drugs, proprietary preparations, biologics, biosimilars, and biosimilar interchangeables that may be dispensed by the pharmacists employed in such institution. A facility with a Class II or Class III institutional pharmacy permit which is operating under the formulary system shall establish policies and procedures for the development of the system in accordance with the joint standards of the American Hospital Association and American Society of Hospital Pharmacists for the utilization of a hospital formulary system, which formulary shall be approved by the medical staff.

**History.**—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; s. 2, ch. 83-101; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 29, ch. 93-211; s. 244, ch. 98-166; s. 36, ch. 99-397; s. 79, ch. 2001-277; s. 6, ch. 2008-216; s. 1, ch. 2013-102; s. 3, ch. 2018-95.

**465.0193 Nuclear pharmacy permits.**—Any person desiring a permit to operate a nuclear pharmacy shall apply to the department. If the board certifies that the application complies with applicable law, the department shall issue the permit. No permit shall be issued unless a duly licensed and qualified nuclear pharmacist is designated as being responsible for activities described in s. 465.0126. The permittee shall notify the department within 10 days of any change of the licensed pharmacist responsible for the compounding and dispensing of nuclear pharmaceuticals.

**History.**—ss. 33, 118, ch. 83-329; ss. 15, 26, 27, ch. 86-256; s. 4, ch. 88-172; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

**465.0196 Special pharmacy permits.**—Any person desiring a permit to operate a special pharmacy shall apply to the department for a special pharmacy permit. If the board certifies that the application complies with the applicable laws and rules of the board governing the practice of the profession of pharmacy, the department shall issue the permit. A permit may not be issued unless a licensed pharmacist is designated to undertake the professional supervision of the compounding and dispensing of all drugs dispensed by the pharmacy. The licensed pharmacist shall be responsible for maintaining all drug records and for providing for the security of the area in the facility in which the compounding, storing, and dispensing of medicinal drugs occurs. The permittee shall notify the department within 10 days after any change of the licensed pharmacist responsible for such duties. Each permittee that employs or otherwise uses registered pharmacy technicians shall have a written policy

and procedures manual specifying those duties, tasks, and functions that a registered pharmacy technician is allowed to perform.

**History.**—ss. 34, 118, ch. 83-329; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 92, ch. 97-264; s. 122, ch. 99-397; s. 80, ch. 2001-277; s. 5, ch. 2004-387; s. 7, ch. 2008-216.

**465.0197 Internet pharmacy permits.—**

(1) Any person desiring a permit to operate an Internet pharmacy shall apply to the department for an Internet pharmacy permit. If the board certifies that the application complies with the applicable laws and rules of the board governing the practice of the profession of pharmacy, the department shall issue the permit. A permit may not be issued unless a licensed pharmacist is designated as the prescription department manager for dispensing medicinal drugs to persons in this state. The licensed pharmacist shall be responsible for maintaining all drug records and for providing for the security of the area in the facility in which the compounding, storing, and dispensing of medicinal drugs to persons in this state occurs. The permittee shall notify the department within 30 days after any change of the licensed pharmacist responsible for such duties. A permittee that employs or otherwise uses registered pharmacy technicians shall have a written policy and procedures manual specifying those duties, tasks, and functions that a registered pharmacy technician is allowed to perform.

(2) An Internet pharmacy must obtain a permit under this section to sell medicinal drugs to persons in this state.

(3) An Internet pharmacy shall provide pharmacy services at a high level of protection and competence and shall disclose to the board the following specific information:

(a) That it maintains at all times a valid, unexpired license, permit, or registration to operate the pharmacy in compliance with the laws of the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed.

(b) The location, names, and titles of all principal corporate officers and the pharmacist who serves as the prescription department manager for dispensing medicinal drugs to persons in this state. This disclosure shall be made within 30 days after any change of location, principal corporate officer, or pharmacist serving as the prescription department manager for dispensing medicinal drugs to persons in this state.

(c) That it complies with all lawful directions and requests for information from the regulatory or licensing agency of all states in which it is licensed as well as with all requests for information made by the board pursuant to this section. It shall respond directly to all communications from the board concerning emergency circumstances arising from errors in the dispensing of medicinal drugs to persons in this state.

(d) That it maintains its records of medicinal drugs dispensed to patients in this state so that the records are readily retrievable from the other business records of the pharmacy and from the records of other medicinal drugs dispensed.

(e) That during its regular hours of operation but not less than 6 days per week, for a minimum of 40 hours per week, a toll-free telephone service shall be provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number must be disclosed on the label affixed to each container of dispensed medicinal drugs.

(4) Notwithstanding s. 465.003(10), for purposes of this section, the Internet pharmacy and the pharmacist designated by the Internet pharmacy as the prescription department manager or the equivalent must be licensed in the state of location in order to dispense into this state.

**History.**—s. 6, ch. 2004-387; s. 8, ch. 2008-216.

**465.022 Pharmacies; general requirements; fees.—**

(1) The board shall adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter. Such rules shall include, but shall not be limited to, rules relating to:

(a) General drug safety measures.

(b) Minimum standards for the physical facilities of pharmacies.

(c) Safe storage of floor-stock drugs.

(d) Functions of a pharmacist in an institutional pharmacy, consistent with the size and scope of the pharmacy.

(e) Procedures for the safe storage and handling of radioactive drugs.

(f) Procedures for the distribution and disposition of medicinal drugs distributed pursuant to s. 499.028.

- (g) Procedures for transfer of prescription files and medicinal drugs upon the change of ownership or closing of a pharmacy.
- (h) Minimum equipment which a pharmacy shall at all times possess to fill prescriptions properly.
- (i) Procedures for the dispensing of controlled substances to minimize dispensing based on fraudulent representations or invalid practitioner-patient relationships.
- (2) A pharmacy permit may be issued only to a natural person who is at least 18 years of age, to a partnership comprised of at least one natural person and all of whose partners are at least 18 years of age, to a governmental agency, or to a business entity that is properly registered with the Secretary of State, if required by law, and has been issued a federal employer tax identification number. Permits issued to business entities may be issued only to entities whose affiliated persons, members, partners, officers, directors, and agents, including persons required to be fingerprinted under subsection (3), are not less than 18 years of age.
- (3) Any person or business entity, before engaging in the operation of a pharmacy, shall file with the board a sworn application on forms provided by the department. For purposes of this section, any person required to provide fingerprints under this subsection is an affiliated person within the meaning of s. 465.023(1).
- (a) An application for a pharmacy permit must include a set of fingerprints from each person having an ownership interest of 5 percent or greater and from any person who, directly or indirectly, manages, oversees, or controls the operation of the applicant, including officers and members of the board of directors of an applicant that is a corporation. The applicant must provide payment in the application for the cost of state and national criminal history records checks.
1. For corporations having more than \$100 million of business taxable assets in this state, in lieu of these fingerprint requirements, the department shall require the prescription department manager or consultant pharmacist of record who will be directly involved in the management and operation of the pharmacy to submit a set of fingerprints.
  2. A representative of a corporation described in subparagraph 1. satisfies the requirement to submit a set of his or her fingerprints if the fingerprints are on file with the department or the Agency for Health Care Administration, meet the fingerprint specifications for submission by the Department of Law Enforcement, and are available to the department.
- (b) The department shall annually submit the fingerprints provided by the applicant to the Department of Law Enforcement for a state criminal history records check. The Department of Law Enforcement shall annually forward the fingerprints to the Federal Bureau of Investigation for a national criminal history records check. The department shall report the results of annual criminal history records checks to wholesale distributors permitted under chapter 499 for the purposes of s. 499.0121(15).
- (c) In addition to those documents required by the department or board, each applicant having any financial or ownership interest greater than 5 percent in the subject of the application must submit a signed affidavit disclosing any financial or ownership interest greater than 5 percent in any pharmacy permitted in the past 5 years, which pharmacy has closed voluntarily or involuntarily, has filed a voluntary relinquishment of its permit, has had its permit suspended or revoked, or has had an injunction issued against it by a regulatory agency. The affidavit must disclose the reason such entity was closed, whether voluntary or involuntary.
- (4) An application for a pharmacy permit must include the applicant's written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships. The board must review the policies and procedures and may deny a permit if the policies and procedures are insufficient to reasonably prevent such dispensing. The department may phase in the submission and review of policies and procedures over one 18-month period beginning July 1, 2011.
- (5) The department or board shall deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant:
- (a) Has obtained a permit by misrepresentation or fraud.
  - (b) Has attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation.
  - (c) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy.

- (d) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud.
- (e) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, since July 1, 2009.
- (f) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009.
- (g) Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5-year period.
- (h) Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5-year period and the termination occurred at least 20 years before the date of the application.
- (i) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.
- (j) Has dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.
- For felonies in which the defendant entered a plea of guilty or nolo contendere in an agreement with the court to enter a pretrial intervention or drug diversion program, the department shall deny the application if upon final resolution of the case the licensee has failed to successfully complete the program.
- (6) The department or board may deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant has violated or failed to comply with any provision of this chapter; chapter 499, the Florida Drug and Cosmetic Act; chapter 893; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug Abuse Prevention and Control Act; or any rules or regulations promulgated thereunder unless the violation or noncompliance is technical.
- (7) After the application has been filed with the board and the permit fee provided in this section has been received, the board shall cause the application to be fully investigated, both as to the qualifications of the applicant and the prescription department manager or consultant pharmacist designated to be in charge and as to the premises and location described in the application.
- (8) The Board of Pharmacy shall have the authority to determine whether a bona fide transfer of ownership is present and that the sale of a pharmacy is not being accomplished for the purpose of avoiding an administrative prosecution.
- (9) Upon the completion of the investigation of an application, the board shall approve or deny the application. If approved, the permit shall be issued by the department.
- (10) A permittee must notify the department, on a form approved by the board, within 10 days after any change in prescription department manager or consultant pharmacist of record.
- (11) A permittee must notify the department of the identity of the prescription department manager within 10 days after employment. The prescription department manager must comply with the following requirements:
- (a) The prescription department manager of a permittee must obtain and maintain all drug records required by any state or federal law to be obtained by a pharmacy, including, but not limited to, records required by or under this chapter, chapter 499, or chapter 893. The prescription department manager must ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.
- (b) The prescription department manager must ensure the security of the prescription department. The prescription department manager must notify the board of any theft or significant loss of any controlled substances within 1 business day after discovery of the theft or loss.
- (c) A registered pharmacist may not serve as the prescription department manager in more than one location unless approved by the board.



(12) The board shall adopt rules that require the keeping of such records of prescription drugs as are necessary for the protection of public health, safety, and welfare.

(a) All required records documenting prescription drug distributions shall be readily available or immediately retrievable during an inspection by the department.

(b) The records must be maintained for 4 years after the creation or receipt of the record, whichever is later.

(13) Permits issued by the department are not transferable.

(14) The board shall set the fees for the following:

(a) Initial permit fee not to exceed \$250.

(b) Biennial permit renewal not to exceed \$250.

(c) Delinquent fee not to exceed \$100.

(d) Change of location fee not to exceed \$100.

**History.**—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; s. 36, ch. 82-225; ss. 16, 26, 27, ch. 86-256; s. 6, ch. 88-172; s. 14, ch. 88-205; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 127, ch. 98-200; s. 27, ch. 2009-223; s. 14, ch. 2011-141; s. 21, ch. 2016-145.

#### **465.023 Pharmacy permittee; disciplinary action.—**

(1) The department or the board may revoke or suspend the permit of any pharmacy permittee, and may fine, place on probation, or otherwise discipline any pharmacy permittee if the permittee, or any affiliated person, partner, officer, director, or agent of the permittee, including a person fingerprinted under s. 465.022(3), has:

(a) Obtained a permit by misrepresentation or fraud or through an error of the department or the board;

(b) Attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation;

(c) Violated any of the requirements of this chapter or any of the rules of the Board of Pharmacy; of chapter 499, known as the "Florida Drug and Cosmetic Act"; of 21 U.S.C. ss. 301-392, known as the "Federal Food, Drug, and Cosmetic Act"; of 21 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse Prevention and Control Act; or of chapter 893;

(d) Been convicted or found guilty, regardless of adjudication, of a felony or any other crime involving moral turpitude in any of the courts of this state, of any other state, or of the United States;

(e) Been convicted or disciplined by a regulatory agency of the Federal Government or a regulatory agency of another state for any offense that would constitute a violation of this chapter;

(f) Been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy;

(g) Been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud; or

(h) Dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

(2) If a pharmacy permit is revoked or suspended, the owner, manager, or proprietor shall cease to operate the establishment as a pharmacy as of the effective date of such suspension or revocation. In the event of such revocation or suspension, the owner, manager, or proprietor shall remove from the premises all signs and symbols identifying the premises as a pharmacy. The period of such suspension shall be prescribed by the Board of Pharmacy, but in no case shall it exceed 1 year. In the event that the permit is revoked, the person owning or operating the establishment shall not be entitled to make application for a permit to operate a pharmacy for a period of 1 year from the date of such revocation. Upon the effective date of such revocation, the permittee shall advise the Board of Pharmacy of the disposition of the medicinal drugs located on the premises. Such disposition shall be subject to continuing supervision and approval by the Board of Pharmacy.

**History.**—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; s. 38, ch. 83-216; ss. 35, 119, ch. 83-329; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 33, ch. 95-144; s. 7, ch. 2004-387; s. 6, ch. 2008-184; s. 28, ch. 2009-223; s. 22, ch. 2016-145.

**465.0235 Automated pharmacy systems used by long-term care facilities, hospices, or state correctional institutions.—**

- (1) A pharmacy may provide pharmacy services to a long-term care facility or hospice licensed under chapter 400 or chapter 429 or a state correctional institution operated under chapter 944 through the use of an automated pharmacy system that need not be located at the same location as the pharmacy.
- (2) Medicinal drugs stored in bulk or unit of use in an automated pharmacy system servicing a long-term care facility, hospice, or correctional institution are part of the inventory of the pharmacy providing pharmacy services to that facility, hospice, or institution, and drugs delivered by the automated pharmacy system are considered to have been dispensed by that pharmacy.
- (3) The operation of an automated pharmacy system must be under the supervision of a Florida-licensed pharmacist. To qualify as a supervisor for an automated pharmacy system, the pharmacist need not be physically present at the site of the automated pharmacy system and may supervise the system electronically. The Florida-licensed pharmacist shall be required to develop and implement policies and procedures designed to verify that the medicinal drugs delivered by the automated dispensing system are accurate and valid and that the machine is properly restocked.
- (4) The Legislature does not intend this section to limit the current practice of pharmacy in this state. This section is intended to allow automated pharmacy systems to enhance the ability of a pharmacist to provide pharmacy services in locations that do not employ a full-time pharmacist. This section does not limit or replace the use of a consultant pharmacist.
- (5) The board shall adopt rules governing the use of an automated pharmacy system by January 1, 2005, which must specify:
  - (a) Recordkeeping requirements;
  - (b) Security requirements; and
  - (c) Labeling requirements that permit the use of unit-dose medications if the facility, hospice, or institution maintains medication-administration records that include directions for use of the medication and the automated pharmacy system identifies:
    1. The dispensing pharmacy;
    2. The prescription number;
    3. The name of the patient; and
    4. The name of the prescribing practitioner.

**History.**—s. 3, ch. 2004-25; s. 92, ch. 2006-197.

**465.024 Promoting sale of certain drugs prohibited.—**

- (1) It is declared that the unrestricted use of certain controlled substances, causing abnormal reactions that may interfere with the user's physical reflexes and judgments, may create hazardous circumstances which may cause accidents to the user and to others, thereby affecting the public health, safety, and welfare. It is further declared to be in the public interest to limit the means of promoting the sale and use of these drugs. All provisions of this section shall be liberally construed to carry out these objectives and purposes.
- (2) No pharmacist, owner, or employee of a retail drug establishment shall use any communication media to promote or advertise the use or sale of any controlled substance appearing in any schedule in chapter 893.
- (3) This section shall not prohibit the advertising of any medicinal drugs, other than those controlled substances specified in chapter 893, or any patent or proprietary preparation, provided the advertising is not false, misleading, or deceptive.

**History.**—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

**465.0244 Information disclosure.—**

- (1) Every pharmacy shall make available on its website a hyperlink to the health information that is disseminated by the Agency for Health Care Administration pursuant to s. 408.05(3) and shall place in the area where customers receive filled prescriptions notice that such information is available electronically and the address of its Internet website.

(2) In addition to the requirements of s. 465.025, a pharmacist or her or his authorized employee must inform customers of a less expensive, generically equivalent drug product for her or his prescription and whether the cost-sharing obligation to the customer exceeds the retail price of the prescription in the absence of prescription drug coverage.

**History.**—s. 39, ch. 2004-297; s. 14, ch. 2006-261; s. 16, ch. 2016-234; s. 1, ch. 2018-91.

**465.025 Substitution of drugs.—**

(1) As used in this section:

(a) “Brand name” means the registered trademark name given to a drug product by its manufacturer, labeler, or distributor.

(b) “Generically equivalent drug product” means a drug product with the same active ingredient, finished dosage form, and strength.

(c) “Prescriber” means any practitioner licensed to prescribe medicinal drugs.

(2) A pharmacist who receives a prescription for a brand name drug shall, unless requested otherwise by the purchaser, substitute a less expensive, generically equivalent drug product that is:

(a) Distributed by a business entity doing business, and subject to suit and service of legal process, in the United States; and

(b) Listed in the formulary of generic and brand name drug products as provided in subsection (5) for the brand name drug prescribed, unless the prescriber writes the words “MEDICALLY NECESSARY,” in her or his own handwriting, on the face of a written prescription; unless, in the case of an oral prescription, the prescriber expressly indicates to the pharmacist that the brand name drug prescribed is medically necessary; or unless, in the case of a prescription that is electronically generated and transmitted, the prescriber makes an overt act when transmitting the prescription to indicate that the brand name drug prescribed is medically necessary. When done in conjunction with the electronic transmission of the prescription, the prescriber’s overt act indicates to the pharmacist that the brand name drug prescribed is medically necessary.

(3)(a) Any pharmacist who substitutes any drug as provided in subsection (2) shall notify the person presenting the prescription of such substitution, together with the existence and amount of the retail price difference between the brand name drug and the drug substituted for it, and shall inform the person presenting the prescription that such person may refuse the substitution as provided in subsection (2).

(b) Any pharmacist substituting a less expensive drug product shall pass on to the consumer the full amount of the savings realized by such substitution.

(4) Each pharmacist shall maintain a record of any substitution of a generically equivalent drug product for a prescribed brand name drug as provided in this section.

(5) Each community pharmacy shall establish a formulary of generic and brand name drug products which, if selected as the drug product of choice, would not pose a threat to the health and safety of patients receiving prescription medication. In compiling the list of generic and brand name drug products for inclusion in the formulary, the pharmacist shall rely on drug product research, testing, information, and formularies compiled by other pharmacies, by states, by the United States Department of Health, Education, and Welfare, by the United States Department of Health and Human Services, or by any other source which the pharmacist deems reliable. Each community pharmacy shall make such formulary available to the public, the Board of Pharmacy, or any physician requesting same. This formulary shall be revised following each addition, deletion, or modification of said formulary.

(6) The Board of Pharmacy and the Board of Medicine shall establish by rule a formulary of generic drug type and brand name drug products which are determined by the boards to demonstrate clinically significant biological or therapeutic inequivalence and which, if substituted, would pose a threat to the health and safety of patients receiving prescription medication.

(a) The formulary may be added to or deleted from as the Board of Pharmacy and the Board of Medicine deem appropriate. Any person who requests any inclusion, addition, or deletion of a generic drug type or brand name drug product to the formulary shall have the burden of proof to show cause why such inclusion, addition, or deletion should be made.

(b) Upon adoption of the formulary required by this subsection, and upon each addition, deletion, or modification to the formulary, the Board of Pharmacy shall mail a copy to each manager of the prescription department of each community pharmacy licensed by the state, each nonresident pharmacy registered in the state, and each board regulating practitioners licensed by the laws of the state to prescribe drugs shall incorporate such formulary into its rules. No pharmacist shall substitute a generically equivalent drug product for a prescribed brand name drug product if the brand name drug product or the generic drug type drug product is included in the said formulary.

(7) Every community pharmacy shall display in a prominent place that is in clear and unobstructed public view, at or near the place where prescriptions are dispensed, a sign in block letters not less than 1 inch in height which shall read: "CONSULT YOUR PHARMACIST CONCERNING THE AVAILABILITY OF A LESS EXPENSIVE GENERICALLY EQUIVALENT DRUG AND THE REQUIREMENTS OF FLORIDA LAW."

(8) The standard of care to be applied to the acts of any pharmacist performing professional services in compliance with this section when a substitution is made by said pharmacist shall be that which would apply to the performance of professional services in the dispensing of a prescription order prescribing a drug by generic name. In no event when a pharmacist substitutes a drug shall the prescriber be liable in any action for loss, damage, injury, or death to any person occasioned by or arising from the use or nonuse of the substituted drug, unless the original drug was incorrectly prescribed.

**History.**—ss. 1, 7, ch. 79-226; s. 325, ch. 81-259; ss. 2, 3, ch. 81-318; ss. 26, 27, ch. 86-256; s. 4, ch. 89-218; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 20, ch. 91-220; s. 4, ch. 91-429; s. 246, ch. 97-103; s. 4, ch. 2006-271.

**465.0251 Generic drugs; removal from formulary under specified circumstances.—**

(1) The Board of Pharmacy and the Board of Medicine shall remove any generic named drug product from the formulary established by s. 465.025(6), if every commercially marketed equivalent of that drug product is "A" rated as therapeutically equivalent to a reference listed drug or is a reference listed drug as referred to in "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book) published by the United States Food and Drug Administration.

(2) Nothing in this act shall alter or amend s. 465.025 as to existing law providing for the authority of physicians to prohibit generic drug substitution by writing "medically necessary" on the prescription.

**History.**—ss. 1, 2, ch. 2001-146.

**465.0252 Substitution of interchangeable biosimilar products.—**

(1) As used in this section, the terms "biological product," "biosimilar," and "interchangeable" have the same meanings as defined in s. 351 of the federal Public Health Service Act, 42 U.S.C. s. 262.

(2) A pharmacist may only dispense a substitute biological product for the prescribed biological product if:

(a) The United States Food and Drug Administration has determined that the substitute biological product is biosimilar to and interchangeable for the prescribed biological product.

(b) The prescribing health care provider does not express a preference against substitution in writing, verbally, or electronically.

(c) The pharmacist notifies the person presenting the prescription of the substitution in the same manner as provided in s. 465.025(3)(a).

(d) The pharmacist retains a written or electronic record of the substitution for at least 2 years.

(3) A pharmacist who practices in a Class II, Modified Class II, or Class III institutional pharmacy shall comply with the notification provisions of paragraph (2)(c) by entering the substitution in the institution's written medical record system or electronic medical record system.

(4) The board shall maintain on its public website a current list of biological products that the United States Food and Drug Administration has determined are biosimilar and interchangeable as provided in paragraph (2)(a).

**History.**—s. 2, ch. 2013-102; s. 4, ch. 2018-95.

**465.0255 Expiration date of medicinal drugs; display; related use and storage instructions.—**

(1) The manufacturer, repackager, or other distributor of any medicinal drug shall display the expiration date of each drug in a readable fashion on the container and on its packaging. The term "readable" means conspicuous and bold.

(2) Each pharmacist for a community pharmacy dispensing medicinal drugs and each practitioner dispensing medicinal drugs on an outpatient basis shall display on the outside of the container of each medicinal drug dispensed, or in other written form delivered to the purchaser:

(a) The expiration date when provided by the manufacturer, repackager, or other distributor of the drug; or

(b) An earlier beyond-use date for expiration, which may be up to 1 year after the date of dispensing.

The dispensing pharmacist or practitioner must provide information concerning the expiration date to the purchaser upon request and must provide appropriate instructions regarding the proper use and storage of the drug.

(3) This section does not impose liability on the dispensing pharmacist or practitioner for damages related to, or caused by, a medicinal drug that loses its effectiveness prior to the expiration date displayed by the dispensing pharmacist or practitioner.

(4) The provisions of this section are intended to notify the patient receiving a medicinal drug of the information required by this section, and the dispensing pharmacist or practitioner shall not be liable for the patient's failure to heed such notice or to follow the instructions for storage.

**History.**—ss. 1, 2, ch. 93-44; s. 8, ch. 2004-387.

**465.026 Filling of certain prescriptions.**—Nothing contained in this chapter shall be construed to prohibit a pharmacist licensed in this state from filling or refilling a valid prescription which is on file in a pharmacy located in this state or in another state and has been transferred from one pharmacy to another by any means, including any electronic means, under the following conditions:

(1) Prior to dispensing any transferred prescription, the dispensing pharmacist must, either verbally or by any electronic means, do all of the following:

(a) Advise the patient that the prescription on file at the other pharmacy must be canceled before it may be filled or refilled.

(b) Determine that the prescription is valid and on file at the other pharmacy and that the prescription may be filled or refilled, as requested, in accordance with the prescriber's intent expressed on the prescription.

(c) Notify the pharmacist or pharmacy where the prescription is on file that the prescription must be canceled.

(d) Record in writing, or by any electronic means, the prescription order, the name of the pharmacy at which the prescription was on file, the prescription number, the name of the drug and the original amount dispensed, the date of original dispensing, and the number of remaining authorized refills.

(e) Obtain the consent of the prescriber to the refilling of the prescription when the prescription, in the dispensing pharmacist's professional judgment, so requires. Any interference with the professional judgment of the dispensing pharmacist by any pharmacist or pharmacy permittee, or its agents or employees, shall be grounds for discipline.

(2) Upon receipt of a prescription transfer request, if the pharmacist is satisfied in her or his professional judgment that the request is valid, or if the request has been validated by any electronic means, the pharmacist or pharmacy must do all of the following:

(a) Transfer the information required by paragraph (1)(d) accurately and completely.

(b) Record on the prescription, or by any electronic means, the requesting pharmacy and pharmacist and the date of request.

(c) Cancel the prescription on file by electronic means or by recording the word "void" on the prescription record. No further prescription information shall be given or medication dispensed pursuant to the original prescription.

(3) If a transferred prescription is not dispensed within a reasonable time, the pharmacist shall, by any means, so notify the transferring pharmacy. Such notice shall serve to revalidate the canceled prescription. The pharmacist who has served such notice shall then cancel the prescription in the same manner as set forth in paragraph (2)(c).

(4) In the case of a prescription to be transferred from or to a pharmacy located in another state, it shall be the responsibility of the pharmacist or pharmacy located in the State of Florida to verify, whether by electronic means

or otherwise, that the person or entity involved in the transfer is a licensed pharmacist or pharmacy in the other state.

(5) Electronic transfers of prescriptions are permitted regardless of whether the transferor or transferee pharmacy is open for business.

(6) The transfer of a prescription for medicinal drugs listed in Schedules III, IV, and V appearing in chapter 893 for the purpose of refill dispensing is permissible, subject to the requirements of this section and federal law. Compliance with federal law shall be deemed compliance with the requirements of this section.

**History.**—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; s. 1, ch. 85-71; ss. 17, 26, 27, ch. 86-256; s. 1, ch. 90-2; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 247, ch. 97-103; s. 93, ch. 97-264; s. 4, ch. 2004-25; s. 9, ch. 2004-387; s. 1, ch. 2006-243.

#### **465.0265 Centralized prescription filling.—**

(1) A pharmacy licensed under this chapter may perform centralized prescription filling for another pharmacy, provided that the pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which the pharmacies will comply with federal and state laws, rules, and regulations.

(2) Each pharmacy performing or contracting for the performance of centralized prescription filling pursuant to this section must maintain a policy and procedures manual, which shall be made available to the board or its agent upon request. The policy and procedures manual shall include the following information:

(a) A description of how each pharmacy will comply with federal and state laws, rules, and regulations.

(b) The procedure for maintaining appropriate records to identify the pharmacist responsible for dispensing the prescription and counseling the patient.

(c) The procedure for tracking the prescription during each stage of the filling and dispensing process.

(d) The procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription.

(e) The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information.

(f) The procedure to be used by the pharmacy in implementing and operating a quality assurance program designed to objectively and systematically monitor, evaluate, and improve the quality and appropriateness of patient care.

(3) The filling, delivery, and return of a prescription by one pharmacy for another pursuant to this section shall not be construed as the filling of a transferred prescription as described in s. 465.026 or as a wholesale distribution as defined in s. 499.003.

(4) The board shall adopt rules pursuant to ss. 120.536(1) and 120.54 necessary to implement this section.

**History.**—s. 2, ch. 2002-182; s. 40, ch. 2008-207; s. 38, ch. 2010-161; s. 34, ch. 2014-89.

**465.0266 Common database.**—Nothing contained in this chapter shall be construed to prohibit the dispensing by a pharmacist licensed in this state or another state of a prescription contained in a common database, and such dispensing shall not constitute a transfer as defined in s. 465.026(1)-(6), provided that the following conditions are met:

(1) All pharmacies involved in the transactions pursuant to which the prescription is dispensed are under common ownership and utilize a common database.

(2) All pharmacies involved in the transactions pursuant to which the prescription is dispensed and all pharmacists engaging in dispensing functions are properly licensed, permitted, or registered in this state or another state.

(3) The common database maintains a record of all pharmacists involved in the process of dispensing a prescription.

(4) The owner of the common database maintains a policy and procedures manual that governs its participating pharmacies, pharmacists, and pharmacy employees and that is available to the board or its agent upon request. The policy and procedures manual shall include the following information:

(a) A best practices model detailing how each pharmacy and each pharmacist accessing the common database will comply with applicable federal and state laws, rules, and regulations.

(b) The procedure for maintaining appropriate records for regulatory oversight for tracking a prescription during each stage of the filling and dispensing process, identifying the pharmacists involved in filling and dispensing the prescription and counseling the patient, and responding to any requests for information made by the board under s. 465.0156.

(c) The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information.

(d) A quality assurance program designed to objectively and systematically monitor, evaluate, and improve the quality and appropriateness of patient care through the use of the common database.

Any pharmacist dispensing a prescription has at all times the right and obligation to exercise his or her independent professional judgment. Notwithstanding other provisions in this section, no pharmacist licensed in this state participating in the dispensing of a prescription pursuant to this section shall be responsible for the acts and omissions of another person participating in the dispensing process provided such person is not under the direct supervision and control of the pharmacist licensed in this state.

**History.**—s. 2, ch. 2006-243.

#### **465.027 Exceptions.—**

(1) This chapter shall not be construed to prohibit the sale of home remedies or preparations commonly known as patents or proprietary preparations when sold only in original or unbroken packages, nor shall this chapter be construed to prevent businesses from engaging in the sale of sundries or patents or proprietary preparations.

(2) This chapter does not apply to a manufacturer, or its agent, holding an active manufacturer or third-party logistics provider permit under chapter 499, to the extent the manufacturer, or its agent, is engaged in the manufacture or distribution of dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure, if the dialysate, drugs, or devices are:

(a) Approved or cleared by the United States Food and Drug Administration; and

(b) Delivered in the original, sealed packaging after receipt of a physician's order to dispense to:

1. A patient with chronic kidney failure, or the patient's designee, for the patient's self-administration of the dialysis therapy; or

2. A health care practitioner or an institution for administration or delivery of the dialysis therapy to a patient with chronic kidney failure.

**History.**—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 18, 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 23, ch. 2016-230; s. 1, ch. 2018-50.

#### **465.0275 Emergency prescription refill.—**

(1) In the event a pharmacist receives a request for a prescription refill and the pharmacist is unable to readily obtain refill authorization from the prescriber, the pharmacist may dispense:

(a) A one-time emergency refill of up to a 72-hour supply of the prescribed medication; or

(b) A one-time emergency refill of one vial of insulin to treat diabetes mellitus.

(2) If the Governor issues an emergency order or proclamation of a state of emergency, the pharmacist may dispense up to a 30-day supply in the areas or counties affected by the order or proclamation, provided that:

(a) The prescription is not for a medicinal drug listed in Schedule II appearing in chapter 893.

(b) The medication is essential to the maintenance of life or to the continuation of therapy in a chronic condition.

(c) In the pharmacist's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences or may cause physical or mental discomfort.

(d) The dispensing pharmacist creates a written order containing all of the prescription information required by this chapter and chapters 499 and 893 and signs that order.

(e) The dispensing pharmacist notifies the prescriber of the emergency dispensing within a reasonable time after such dispensing.

**History.**—ss. 19, 27, ch. 86-256; s. 3, ch. 89-77; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 30, ch. 93-211; s. 24, ch. 2016-230.

#### **465.0276 Dispensing practitioner.—**

- (1)(a) A person may not dispense medicinal drugs unless licensed as a pharmacist or otherwise authorized under this chapter to do so, except that a practitioner authorized by law to prescribe drugs may dispense such drugs to her or his patients in the regular course of her or his practice in compliance with this section.
- (b) A practitioner registered under this section may not dispense a controlled substance listed in Schedule II or Schedule III as provided in s. 893.03. This paragraph does not apply to:
1. The dispensing of complimentary packages of medicinal drugs which are labeled as a drug sample or complimentary drug as defined in s. 499.028 to the practitioner's own patients in the regular course of her or his practice without the payment of a fee or remuneration of any kind, whether direct or indirect, as provided in subsection (4).
  2. The dispensing of controlled substances in the health care system of the Department of Corrections.
  3. The dispensing of a controlled substance listed in Schedule II or Schedule III in connection with the performance of a surgical procedure.
    - a. For an opioid drug listed as a Schedule II controlled substance in s. 893.03 or 21 U.S.C. s. 812:
      - (I) For the treatment of acute pain, the amount dispensed pursuant to this subparagraph may not exceed a 3-day supply, or a 7-day supply if the criteria in s. 456.44(5)(a) are met.
      - (II) For the treatment of pain other than acute pain, a practitioner must indicate "NONACUTE PAIN" on a prescription.
      - (III) For the treatment of pain related to a traumatic injury with an Injury Severity Score of 9 or greater, a practitioner must concurrently prescribe an emergency opioid antagonist, as defined in s. 381.887(1).
    - b. For a controlled substance listed in Schedule III, the amount dispensed pursuant to this subparagraph may not exceed a 14-day supply.
    - c. The exception in this subparagraph does not allow for the dispensing of a controlled substance listed in Schedule II or Schedule III more than 14 days after the performance of the surgical procedure.
    - d. For purposes of this subparagraph, the term "surgical procedure" means any procedure in any setting which involves, or reasonably should involve:
      - (I) Perioperative medication and sedation that allows the patient to tolerate unpleasant procedures while maintaining adequate cardiorespiratory function and the ability to respond purposefully to verbal or tactile stimulation and makes intra- and postoperative monitoring necessary; or
      - (II) The use of general anesthesia or major conduction anesthesia and preoperative sedation.
  4. The dispensing of a controlled substance listed in Schedule II or Schedule III pursuant to an approved clinical trial. For purposes of this subparagraph, the term "approved clinical trial" means a clinical research study or clinical investigation that, in whole or in part, is state or federally funded or is conducted under an investigational new drug application that is reviewed by the United States Food and Drug Administration.
  5. The dispensing of methadone in a facility licensed under s. 397.427 where medication-assisted treatment for opiate addiction is provided.
  6. The dispensing of a controlled substance listed in Schedule II or Schedule III to a patient of a facility licensed under part IV of chapter 400.
  7. The dispensing of controlled substances listed in Schedule II or Schedule III which have been approved by the United States Food and Drug Administration for the purpose of treating opiate addictions, including, but not limited to, buprenorphine and buprenorphine combination products, by a practitioner authorized under 21 U.S.C. s. 823, as amended, to the practitioner's own patients for the medication-assisted treatment of opiate addiction.
    - (2) A practitioner who dispenses medicinal drugs for human consumption for fee or remuneration of any kind, whether direct or indirect, must:
      - (a) Register with her or his professional licensing board as a dispensing practitioner and pay a fee not to exceed \$100 at the time of such registration and upon each renewal of her or his license. Each appropriate board shall establish such fee by rule.
      - (b) Comply with and be subject to all laws and rules applicable to pharmacists and pharmacies, including, but not limited to, this chapter and chapters 499 and 893 and all federal laws and federal regulations.
      - (c) Before dispensing any drug, give the patient a written prescription and orally or in writing advise the patient that the prescription may be filled in the practitioner's office or at any pharmacy.
      - (d)1. Before dispensing a controlled substance to a person not known to the dispenser, require the person purchasing, receiving, or otherwise acquiring the controlled substance to present valid photographic identification



or other verification of his or her identity. If the person does not have proper identification, the dispenser may verify the validity of the prescription and the identity of the patient with the prescriber or his or her authorized agent. Verification of health plan eligibility through a real-time inquiry or adjudication system is considered to be proper identification.

2. This paragraph does not apply in an institutional setting or to a long-term care facility, including, but not limited to, an assisted living facility or a hospital to which patients are admitted.

3. As used in this paragraph, the term "proper identification" means an identification that is issued by a state or the Federal Government containing the person's photograph, printed name, and signature or a document considered acceptable under 8 C.F.R. s. 274a.2(b)(1)(v)(A) and (B).

(3) The registration of any practitioner who has been found by her or his respective board to have dispensed medicinal drugs in violation of this chapter shall be subject to suspension or revocation.

(4) A practitioner who confines her or his activities to the dispensing of complimentary packages of medicinal drugs to the practitioner's own patients in the regular course of her or his practice, without the payment of fee or remuneration of any kind, whether direct or indirect, and who herself or himself dispenses such drugs is not required to register pursuant to this section. The practitioner must dispense such drugs in the manufacturer's labeled package with the practitioner's name, patient's name, and date dispensed, or, if such drugs are not dispensed in the manufacturer's labeled package, they must be dispensed in a container which bears the following information:

(a) Practitioner's name;

(b) Patient's name;

(c) Date dispensed;

(d) Name and strength of drug; and

(e) Directions for use.

(5) This chapter and the rules adopted thereunder do not prohibit a veterinarian licensed under chapter 474 from administering a compounded drug to a patient, as defined in s. 474.202, or dispensing a compounded drug to the patient's owner or caretaker. This subsection does not affect the regulation of the practice of pharmacy as set forth in this chapter.

**History.**—ss. 20, 27, ch. 86-256; s. 1, ch. 88-159; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 95, ch. 92-149; s. 248, ch. 97-103; s. 11, ch. 2010-211; s. 15, ch. 2011-141; s. 1, ch. 2015-127; s. 21, ch. 2016-105; s. 25, ch. 2016-230; s. 7, ch. 2018-13.

#### **465.035 Dispensing of medicinal drugs pursuant to facsimile of prescription.—**

(1) Notwithstanding any other provision of this chapter, it is lawful for a pharmacy to dispense medicinal drugs, including controlled substances authorized under subsection (2), based on reception of an electronic facsimile of the original prescription if all of the following conditions are met:

(a) In the course of the transaction the pharmacy complies with laws and administrative rules relating to pharmacies and pharmacists.

(b) Except in the case of the transmission of a prescription by a person authorized by law to prescribe medicinal drugs:

1. The facsimile system making the transmission provides the pharmacy receiving the transmission with audio communication via telephonic, electronic, or similar means with the person presenting the prescription.

2. At the time of the delivery of the medicinal drugs, the pharmacy has in its possession the original prescription for the medicinal drug involved.

3. The recipient of the prescription shall sign a log and shall indicate the name and address of both the recipient and the patient for whom the medicinal drug was prescribed.

(2) Controlled substances listed in Schedule II as defined in s. 893.03(2) may be dispensed as provided in this section to the extent allowed by 21 C.F.R. s. 1306.11.

**History.**—s. 5, ch. 90-341; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 8, ch. 91-201; s. 4, ch. 91-429; s. 94, ch. 97-264; s. 5, ch. 99-186.

#### **465.185 Rebates prohibited; penalties.—**

- (1) It is unlawful for any person to pay or receive any commission, bonus, kickback, or rebate or engage in any split-fee arrangement in any form whatsoever with any physician, surgeon, organization, agency, or person, either directly or indirectly, for patients referred to a pharmacy registered under this chapter.
- (2) The department shall adopt rules which assess administrative penalties for acts prohibited by subsection (1). In the case of an entity licensed by the department, such penalties may include any disciplinary action available to the department under the appropriate licensing laws. In the case of an entity not licensed by the department, such penalties may include:
  - (a) A fine not to exceed \$1,000.
  - (b) If applicable, a recommendation by the department to the appropriate regulatory agency that disciplinary action be taken.

**History.**—s. 2, ch. 79-106; s. 326, ch. 81-259; s. 2, ch. 81-318; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 125, ch. 92-149.

#### **465.186 Pharmacist's order for medicinal drugs; dispensing procedure; development of formulary.—**

- (1) There is hereby created a committee composed of two members of the Board of Medicine licensed under chapter 458 chosen by said board, one member of the Board of Osteopathic Medicine licensed under chapter 459 chosen by said board, three members of the Board of Pharmacy licensed under this chapter and chosen by said board, and one additional person with a background in health care or pharmacology chosen by the committee. The committee shall establish a formulary of medicinal drug products and dispensing procedures which shall be used by a pharmacist when ordering and dispensing such drug products to the public. Dispensing procedures may include matters related to reception of patient, description of his or her condition, patient interview, patient physician referral, product selection, and dispensing and use limitations. In developing the formulary of medicinal drug products, the committee may include products falling within the following categories:
  - (a) Any medicinal drug of single or multiple active ingredients in any strengths when such active ingredients have been approved individually or in combination for over-the-counter sale by the United States Food and Drug Administration.
  - (b) Any medicinal drug recommended by the United States Food and Drug Administration Advisory Panel for transfer to over-the-counter status pending approval by the United States Food and Drug Administration.
  - (c) Any medicinal drug containing any antihistamine or decongestant as a single active ingredient or in combination.
  - (d) Any medicinal drug containing fluoride in any strength.
  - (e) Any medicinal drug containing lindane in any strength.
  - (f) Any over-the-counter proprietary drug under federal law that has been approved for reimbursement by the Florida Medicaid Program.
  - (g) Any topical anti-infectives excluding eye and ear topical anti-infectives.However, any drug which is sold as an over-the-counter proprietary drug under federal law shall not be included in the formulary or otherwise affected by this section.
- (2) The Board of Pharmacy, the Board of Medicine, and the Board of Osteopathic Medicine shall adopt by rule a formulary of medicinal drugs and dispensing procedures as established by the committee. A pharmacist may order and dispense a product from the formulary pursuant to the established dispensing procedure, as adopted by the boards, for each drug in conjunction with its inclusion in the formulary. Any drug product ordered by a pharmacist shall be selected and dispensed only by the pharmacist so ordering, and said order shall not be refilled, nor shall another medicinal drug be ordered for the same condition unless such act is consistent with dispensing procedures established by the committee. Appropriate referral to another health care provider is indicated under such circumstances. On each occasion of such dispensing, the pharmacist shall create and maintain a prescription record in the form required by law.
- (3) Affixed to the container containing a medicinal drug dispensed pursuant to this section shall be a label bearing the following information:
  - (a) The name of the pharmacist ordering the medication.
  - (b) The name and address of the pharmacy from which the medication was dispensed.
  - (c) The date of dispensing.

- (d) The order number or other identification adequate to readily identify the order.
  - (e) The name of the patient for whom the medicinal drug was ordered.
  - (f) The directions for use of the medicinal drug ordered.
  - (g) A clear, concise statement that the order may not be refilled.
  - (4) Any pharmacist performing the services authorized by this section shall be eligible for reimbursement by third party prescription programs when so provided by contract or when otherwise provided by such program.
  - (5) Any person ordering or dispensing medicinal drugs in violation of this section shall be guilty of a misdemeanor of the first degree, and such violation shall be punishable as provided in s. 775.082 or s. 775.083.
- History.**—ss. 2, 3, ch. 85-35; ss. 26, 27, ch. 86-256; s. 56, ch. 87-225; s. 59, ch. 91-137; s. 21, ch. 91-140; s. 6, ch. 91-156; s. 21, ch. 91-220; s. 92, ch. 91-224; s. 4, ch. 91-429; s. 96, ch. 92-149; s. 249, ch. 97-103; s. 95, ch. 97-264.

**465.187 Sale of medicinal drugs.**—The sale of medicinal drugs dispensed upon the order of a practitioner pursuant to this chapter shall be entitled to the exemption from sales tax provided for in s. 212.08.

**History.**—ss. 21, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

**465.188 Medicaid audits of pharmacies.**—

- (1) Notwithstanding any other law, when an audit of the Medicaid-related records of a pharmacy licensed under chapter 465 is conducted, such audit must be conducted as provided in this section.
  - (a) The agency conducting the audit must give the pharmacist at least 1 week’s prior notice of the initial audit for each audit cycle.
  - (b) An audit must be conducted by a pharmacist licensed in this state.
  - (c) Any clerical or recordkeeping error, such as a typographical error, scrivener’s error, or computer error regarding a document or record required under the Medicaid program does not constitute a willful violation and is not subject to criminal penalties without proof of intent to commit fraud.
  - (d) A pharmacist may use the physician’s record or other order for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug.
  - (e) A finding of an overpayment or underpayment must be based on the actual overpayment or underpayment and may not be a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs.
  - (f) Each pharmacy shall be audited under the same standards and parameters.
  - (g) A pharmacist must be allowed at least 10 days in which to produce documentation to address any discrepancy found during an audit.
  - (h) The period covered by an audit may not exceed 1 calendar year.
  - (i) An audit may not be scheduled during the first 5 days of any month due to the high volume of prescriptions filled during that time.
  - (j) The audit report must be delivered to the pharmacist within 90 days after conclusion of the audit. A final audit report shall be delivered to the pharmacist within 6 months after receipt of the preliminary audit report or final appeal, as provided for in subsection (2), whichever is later.
  - (k) The audit criteria set forth in this section applies only to audits of claims submitted for payment subsequent to July 11, 2003. Notwithstanding any other provision in this section, the agency conducting the audit shall not use the accounting practice of extrapolation in calculating penalties for Medicaid audits.
- (2) The Agency for Health Care Administration shall establish a process under which a pharmacist may obtain a preliminary review of an audit report and may appeal an unfavorable audit report without the necessity of obtaining legal counsel. The preliminary review and appeal may be conducted by an ad hoc peer review panel, appointed by the agency, which consists of pharmacists who maintain an active practice. If, following the preliminary review, the agency or review panel finds that an unfavorable audit report is unsubstantiated, the agency shall dismiss the audit report without the necessity of any further proceedings.
- (3) This section does not apply to investigative audits conducted by the Medicaid Fraud Control Unit of the Department of Legal Affairs.

(4) This section does not apply to any investigative audit conducted by the Agency for Health Care Administration when the agency has reliable evidence that the claim that is the subject of the audit involves fraud, willful misrepresentation, or abuse under the Medicaid program.

**History.**—s. 1, ch. 2003-277; s. 11, ch. 2004-344.

**465.1885 Pharmacy audits; rights.—**

- (1) If an audit of the records of a pharmacy licensed under this chapter is conducted directly or indirectly by a managed care company, an insurance company, a third-party payor, a pharmacy benefit manager, or an entity that represents responsible parties such as companies or groups, referred to as an “entity” in this section, the pharmacy has the following rights:
- (a) To be notified at least 7 calendar days before the initial onsite audit for each audit cycle.
  - (b) To have the onsite audit scheduled after the first 3 calendar days of a month unless the pharmacist consents otherwise.
  - (c) To have the audit period limited to 24 months after the date a claim is submitted to or adjudicated by the entity.
  - (d) To have an audit that requires clinical or professional judgment conducted by or in consultation with a pharmacist.
  - (e) To use the written and verifiable records of a hospital, physician, or other authorized practitioner, which are transmitted by any means of communication, to validate the pharmacy records in accordance with state and federal law.
  - (f) To be reimbursed for a claim that was retroactively denied for a clerical error, typographical error, scrivener’s error, or computer error if the prescription was properly and correctly dispensed, unless a pattern of such errors exists, fraudulent billing is alleged, or the error results in actual financial loss to the entity.
  - (g) To receive the preliminary audit report within 120 days after the conclusion of the audit.
  - (h) To produce documentation to address a discrepancy or audit finding within 10 business days after the preliminary audit report is delivered to the pharmacy.
  - (i) To receive the final audit report within 6 months after receiving the preliminary audit report.
  - (j) To have recoupment or penalties based on actual overpayments and not according to the accounting practice of extrapolation.
- (2) The rights contained in this section do not apply to:
- (a) Audits in which suspected fraudulent activity or other intentional or willful misrepresentation is evidenced by a physical review, review of claims data or statements, or other investigative methods;
  - (b) Audits of claims paid for by federally funded programs; or
  - (c) Concurrent reviews or desk audits that occur within 3 business days of transmission of a claim and where no chargeback or recoupment is demanded.
- (3) An entity that audits a pharmacy located within a Health Care Fraud Prevention and Enforcement Action Team (HEAT) Task Force area designated by the United States Department of Health and Human Services and the United States Department of Justice may dispense with the notice requirements of paragraph (1)(a) if such pharmacy has been a member of a credentialed provider network for less than 12 months.

**History.**—s. 1, ch. 2014-85.

**465.189 Administration of vaccines and epinephrine autoinjection.—**

- (1) In accordance with guidelines of the Centers for Disease Control and Prevention for each recommended immunization or vaccine, a pharmacist, or a registered intern under the supervision of a pharmacist who is certified under subsection (6), may administer the following vaccines to an adult within the framework of an established protocol under a supervising physician licensed under chapter 458 or chapter 459:
- (a) Immunizations or vaccines listed in the Adult Immunization Schedule as of February 1, 2015, by the United States Centers for Disease Control and Prevention. The board may authorize, by rule, additional immunizations or vaccines as they are added to the Adult Immunization Schedule.
  - (b) Immunizations or vaccines recommended by the United States Centers for Disease Control and Prevention for international travel as of July 1, 2015. The board may authorize, by rule, additional immunizations or vaccines

as they are recommended by the United States Centers for Disease Control and Prevention for international travel.

(c) Immunizations or vaccines approved by the board in response to a state of emergency declared by the Governor pursuant to s. 252.36.

A registered intern who administers an immunization or vaccine under this subsection must be supervised by a certified pharmacist at a ratio of one pharmacist to one registered intern.

(2) In order to address any unforeseen allergic reaction, a pharmacist may administer epinephrine using an autoinjector delivery system within the framework of an established protocol under a supervising physician licensed under chapter 458 or chapter 459.

(3) A pharmacist may not enter into a protocol unless he or she maintains at least \$200,000 of professional liability insurance and has completed training in administering vaccines authorized under this section.

(4) A pharmacist administering vaccines under this section shall maintain and make available patient records using the same standards for confidentiality and maintenance of such records as those that are imposed on health care practitioners under s. 456.057. These records shall be maintained for a minimum of 5 years.

(5) The decision by a supervising physician licensed under chapter 458 or chapter 459 to enter into a protocol under this section is a professional decision on the part of the practitioner, and a person may not interfere with a physician's decision as to entering into such a protocol. A pharmacist may not enter into a protocol that is to be performed while acting as an employee without the written approval of the owner of the pharmacy. Pharmacists shall forward vaccination records to the department for inclusion in the state registry of immunization information.

(6) Any pharmacist or registered intern seeking to administer vaccines to adults under this section must be certified to administer such vaccines pursuant to a certification program approved by the Board of Pharmacy in consultation with the Board of Medicine and the Board of Osteopathic Medicine. The certification program shall, at a minimum, require that the pharmacist attend at least 20 hours of continuing education classes approved by the board and the registered intern complete at least 20 hours of coursework approved by the board. The program shall have a curriculum of instruction concerning the safe and effective administration of such vaccines, including, but not limited to, potential allergic reactions to such vaccines.

(7) The written protocol between the pharmacist and supervising physician under this section must include particular terms and conditions imposed by the supervising physician upon the pharmacist relating to the administration of vaccines by the pharmacist pursuant to this section. The written protocol shall include, at a minimum, specific categories and conditions among patients for whom the supervising physician authorizes the pharmacist to administer such vaccines. The terms, scope, and conditions set forth in the written protocol between the pharmacist and the supervising physician must be appropriate to the pharmacist's training and certification for administering such vaccines. Pharmacists who have been delegated the authority to administer vaccines under this section by the supervising physician under the protocol shall provide evidence of current certification by the Board of Pharmacy to the supervising physician. A supervising physician shall review the administration of such vaccines by the pharmacist pursuant to the written protocol between them, and this review shall take place as outlined in the written protocol. The process and schedule for the review shall be outlined in the written protocol between the pharmacist and the supervising physician.

(8) The pharmacist shall submit to the Board of Pharmacy a copy of his or her protocol or written agreement to administer vaccines under this section.

**History.**—s. 3, ch. 2007-152; s. 1, ch. 2012-60; s. 3, ch. 2014-113; s. 1, ch. 2015-108.

#### **465.1893 Administration of antipsychotic medication by injection.—**

(1)(a) A pharmacist, at the direction of a physician licensed under chapter 458 or chapter 459, may administer a long-acting antipsychotic medication approved by the United States Food and Drug Administration by injection to a patient if the pharmacist:

1. Is authorized by and acting within the framework of an established protocol with the prescribing physician.
2. Practices at a facility that accommodates privacy for nondeltoid injections and conforms with state rules and regulations regarding the appropriate and safe disposal of medication and medical waste.
3. Has completed the course required under subsection (2).

(b) A separate prescription from a physician is required for each injection administered by a pharmacist under this subsection.

(2)(a) A pharmacist seeking to administer a long-acting antipsychotic medication by injection must complete an 8-hour continuing education course offered by:

1. A statewide professional association of physicians in this state accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award (AMA PRA) Category 1 Credit or the American Osteopathic Association (AOA) Category 1-A continuing medical education (CME) credit; and
2. A statewide association of pharmacists.

(b) The course may be offered in a distance learning format and must be included in the 30 hours of continuing professional pharmaceutical education required under s. 465.009(1). The course shall have a curriculum of instruction that concerns the safe and effective administration of behavioral health and antipsychotic medications by injection, including, but not limited to, potential allergic reactions to such medications.

**History.**—s. 5, ch. 2017-134.

**465.1901 Practice of orthotics and pedorthics.**—The provisions of chapter 468 relating to orthotics or pedorthics do not apply to any licensed pharmacist or to any person acting under the supervision of a licensed pharmacist. The practice of orthotics or pedorthics by a pharmacist or any of the pharmacist's employees acting under the supervision of a pharmacist shall be construed to be within the meaning of the term "practice of the profession of pharmacy" as set forth in s. 465.003(13), and shall be subject to regulation in the same manner as any other pharmacy practice. The Board of Pharmacy shall develop rules regarding the practice of orthotics and pedorthics by a pharmacist. Any pharmacist or person under the supervision of a pharmacist engaged in the practice of orthotics or pedorthics is not precluded from continuing that practice pending adoption of these rules.

**History.**—s. 3, ch. 2009-202; s. 14, ch. 2016-145.

**Division 64B16, Board of Pharmacy**

64B16-25	ORGANIZATION AND PURPOSE
64B16-26	PHARMACISTS LICENSURE
64B16-27	PHARMACY PRACTICE
64B16-28	GENERAL REQUIREMENTS - PERMITS
64B16-29	ANIMAL CONTROL SHELTER PERMITS
64B16-30	DISCIPLINARY GUIDELINES
64B16-32	NONRESIDENT PHARMACIES

**CHAPTER 64B16-25  
ORGANIZATION AND PURPOSE**

64B16-25.130	Executive Director (Repealed)
64B16-25.170	Probable Cause Panel
64B16-25.340	Meetings and Workshops

**64B16-25.130 Executive Director.**

*Rulemaking Authority 465.005 FS. Law Implemented 48.111(2), 456.004, 456.009 FS. History—New 10-17-79, Formerly 21S-8.04, 21S-8.004, Amended 7-30-91, Formerly 21S-25.130, 61F10-25.130, 59X-25.130, Amended 10-29-97, 11-2-03, Repealed 3-28-12.*

**64B16-25.170 Probable Cause Panel.**

(1) The determination as to whether probable cause exists to believe that a violation of Chapter 456, Part II, 465, 499 or 893, F.S., or of the rules promulgated thereunder, has occurred shall be made by the probable cause panel. The panel shall meet as necessary.

(2) The probable cause panel shall be composed of two (2) persons, either current or former board members appointed by the chairman of the Board. One appointee must be a current board member. The panel must include a former or current board member who is a licensed pharmacist. An appointee may be a former board member.

*Rulemaking Authority 465.005 FS. Law Implemented 456.073 FS. History—New 10-17-79, Formerly 21S-8.08, 21S-8.008, 21S-25.170, 61F10-25.170, 59X-25.170, Amended 11-24-09.*

**64B16-25.340 Meetings and Workshops.**

The following are considered to be official meetings of the Board:

(1) Board Meetings.

(2) Examination Committee Meetings.

(3) Tripartite Continuing Education Committee Meeting.

(4) Meetings of committees set out in the official minutes of the Board where statutory authority is given by the practice act.

(5) Meetings of a Board member with Department staff or contractors of the Department at the Department's or Board's request. Any participation or meeting of members noticed or unnoticed will be on file in the Board office.

(6) Where a Board member has been requested by the State Surgeon General to participate in a meeting.

(7) Probable Cause Panel meetings.

(8) All activity of Board members, if authorized by the Board, when grading, proctoring or reviewing examinations given by the Department.

(9) All participation in Board authorized meetings with professional associations of which the Board is a member or invitee. This would include all meetings of the National Association of Boards of Pharmacy of which the Board is a member as well as Board authorized participation in meetings of national or professional associations or organizations involved in educating, regulating and reviewing the profession over which the Board has statutory authority.

(10) Any and all other activities which are Board approved and which are necessary for Board members to attend in order to further protect the public health, safety and welfare, through the regulation of which the Board has statutory authority.

*Rulemaking Authority 456.011(4) FS. Law Implemented 456.011(4) FS. History—New 9-30-81, Amended 11-13-81, 12-31-81, Formerly 21S-10.05, 21S-10.005, Amended 7-30-91, Formerly 21S-25.340, 61F10-25.340, 59X-25.340, Amended 2-18-08*



**CHAPTER 64B16-26**  
**PHARMACISTS LICENSURE**

64B16-26.100	Pharmacists Newly Licensed (Repealed)
64B16-26.101	Fees and License Renewal Application
64B16-26.1001	Examination and Application Fees
64B16-26.1002	Initial License Fees
64B16-26.1003	Active License Renewal Fees
64B16-26.1004	Inactive License Election; Renewal; Fees
64B16-26.1005	Retired License Election; Renewal; Fees.
64B16-26.1012	Approved Continuing Education Provider Renewal Fee
64B16-26.102	Inactive License Renewal (Repealed)
64B16-26.1021	Delinquent License Reversion; Reinstatement; Fees
64B16-26.1022	Permit Fees
64B16-26.103	Continuing Education Credits; Renewal
64B16-26.1031	Vaccine Certification Program
64B16-26.1032	Immunization Administration Certification Application and Information
64B16-26.104	Exemptions for Members of the Armed Forces; Spouses
64B16-26.105	Consultant Pharmacists Initial Registration Fee and Renewal Fee (Repealed)
64B16-26.106	Nuclear Pharmacists Initial Registration Fee and Renewal Fee (Repealed)
64B16-26.107	Inactive Nuclear Pharmacist License Renewal (Repealed)
64B16-26.200	Examination Requirements; Passing Scores
64B16-26.201	Reexamination (Repealed)
64B16-26.202	Examination Review Procedure (Repealed)
64B16-26.203	Pharmacist Licensure by Examination (U.S. Graduates); Application
64B16-26.2031	Licensure by Examination (Foreign Graduates); Application
64B16-26.2032	Application for Pharmacy Intern Registration
64B16-26.2033	Approved Pharmacy Internship Programs
64B16-26.2035	Examination Fees (Repealed)
64B16-26.204	Pharmacist Licensure by Endorsement; Application
64B16-26.205	Requirements for Foreign Pharmacy Graduates to Be Admitted to the Pharmacist Licensure Examination (Repealed)
64B16-26.300	Consultant Pharmacist Licensure
64B16-26.301	Subject Matter for Consultant Pharmacist Training Program
64B16-26.302	Subject Matter for Consultant Pharmacist Licensure Renewal Continuing Education
64B16-26.303	Nuclear Pharmacist Licensure
64B16-26.304	Subject Matter for Nuclear Pharmacist License Renewal Continuing Education Programs
64B16-26.320	Subject Matter for Continuing Education to Order and Evaluate Laboratory Tests
64B16-26.350	Requirements for Pharmacy Technician Registration
64B16-26.351	Standards for Approval of Registered Pharmacy Technician Training Programs
64B16-26.355	Subject Matter for Registered Pharmacy Technician Continuing Education
64B16-26.400	Pharmacy Interns; Registration; Employment
64B16-26.401	Requirements for an Internship Program Sufficient to Qualify an Applicant for Licensure by Examination (Repealed)
64B16-26.600	Tripartite Continuing Education Committee
64B16-26.601	Standards for Approval of Courses and Providers
64B16-26.6012	Guidelines for Board Ordered Disciplinary Continuing Education Courses
64B16-26.602	Recommendation by the Tripartite Continuing Education Committee (Repealed)

- 64B16-26.603 Continuing Education Records Requirements (Repealed)
- 64B16-26.606 Number of Required Hours (Repealed)

**64B16-26.100 Pharmacists Newly Licensed.**

*Rulemaking Authority 456.013(2), 465.005 FS. Law Implemented 456.013(2), 465.008 FS. History–New 3-19-79, Formerly 21S-6.04, Amended 1-7-87, 12-29-88, 10-16-90, Formerly 21S-6.004, Amended 1-10-93, Formerly 21S-26.100, 61F10-26.100, 59X-26.100, Amended 4-17-01, Repealed 3-10-05.*

**64B16-26.101 Fees and License Renewal Application.**

*Rulemaking Authority 465.005 FS. Law Implemented 456.036, 456.064, 465.008 FS. History–New 3-19-79, Formerly 21S-6.05, Amended 1-7-87, 4-21-87, 12-29-88, Formerly 21S-6.005, Amended 7-31-91, 1-10-93, Formerly 21S-26.101, 61F10-26.101, Amended 3-10-96, Formerly 59X-26.101, Amended 12-31-97, 12-3-00, 3-18-01, 10-15-01, Repealed 3-10-05.*

**64B16-26.1001 Examination and Application Fees.**

- (1) The examination fee for licensure by examination shall be \$100, payable to the Board. Examination fees for the National Practice Examination and jurisprudence examination are payable to the examination vendor.
- (2) The non-refundable application fee licensure by endorsement shall be \$100, payable to the Board.
- (3) The application fee for a continuing education provider seeking approved provider status shall be \$150, payable to the Board.
- (4) The application fee for the Immunization Administration Certification shall be \$55 for pharmacists and no fee for pharmacy interns, payable to the Board.
- (5) The non-refundable application fee for registered pharmacy technicians shall be \$50, payable to the Board.

*Rulemaking Authority 456.025, 465.005, 465.077(1)(a), 465.0075(1), 465.009, 465.014(2) FS. Law Implemented 456.025(7), 465.007, 465.0075, 465.009, 465.014, 465.189 FS. History–New 1-11-05, Amended 10-30-07, 11-15-09, 7-7-10, 3-14-16.*

**64B16-26.1002 Initial License Fees.**

- (1) The initial license fee for a pharmacist license shall be \$190 plus a \$5 unlicensed activity fee pursuant to section 456.065(3), F.S.
- (2) The initial license fee for a consultant pharmacist license shall be \$50 plus a \$5 unlicensed activity fee pursuant to section 456.065(3), F.S.
- (3) The initial license fee for a nuclear pharmacist license shall be \$50 plus a \$5 unlicensed activity fee pursuant to section 456.065(3), F.S.
- (4) The initial registration fee for a registered pharmacy technician shall be \$50 plus a \$5 unlicensed activity fee pursuant to section 456.065(3), F.S.

*Rulemaking Authority 465.005, 465.0125, 465.0126 FS. Law Implemented 456.013(2), 456.065(3), 465.0125, 465.0126, 465.014 FS. History–New 1-11-05, Amended 11-24-09.*

**64B16-26.1003 Active License Renewal Fees.**

- (1) The biennial license renewal fee for an active pharmacist license shall be \$200 plus a \$5 unlicensed activity fee pursuant to section 456.065(3), F.S.
- (2) The biennial license renewal fee for a consultant pharmacist active license shall be \$100 plus a \$5 unlicensed activity fee pursuant to section 456.065(3), F.S.
- (3) The biennial license renewal fee for a nuclear pharmacist active license shall be \$100 plus a \$5 unlicensed activity fee pursuant to section 456.065(3), F.S.
- (4) The biennial registration renewal fee for a registered pharmacy technician shall be \$50 plus \$5 unlicensed activity fee pursuant to section 456.065(3), F.S.

*Rulemaking Authority 456.036, 465.005, 465.008, 465.0125, 465.0126 FS. Law Implemented 456.036, 456.065(3), 465.008, 465.0125, 465.0126, 465.014 FS. History—New 1-11-05, Amended 2-24-10, 2-1-12.*

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

(1) A pharmacist licensee may elect:

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

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

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

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

(2) A consultant pharmacist licensee may elect:

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

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

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

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

(3) A nuclear pharmacist licensee may elect:

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

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

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

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

\$25 and the difference between the inactive status renewal fee and the active status renewal fee, if any exists.

(4) A registered pharmacy technician may elect:

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

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

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

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

*Rulemaking Authority 456.036, 465.005, 465.012, 465.0125, 465.0126 FS. Law Implemented 456.036, 456.065(3), 465.012, 465.0125, 465.0126 FS. History—New 1-11-05, Amended 10-30-07, 10-27-09.*

#### **64B16-26.1005 Retired License Election; Renewal; Fees.**

(1) A licensee may elect to place his or her license on retired status.

(a) At the time of license renewal, to place the license on retired status, the licensee must submit a written request with the board for retired status and submit the retired status fee of \$50.00 pursuant to section 456.036(4)(b), F.S., and the current unlicensed activity fee.

(b) At a time other than license renewal, to place the license on retired status, the licensee must submit a written request to the Board for the retired status plus submit the retired status fee of \$50.00 pursuant to section 456.036(4)(b), F.S., plus a change of status fee of \$25.00, plus the current unlicensed activity fee.

(c) Before the license of a retired status licensee is reactivated, the licensee must meet the continuing education requirements in rule 64B16-26.103, F.A.C., and pay any renewal fees imposed on an active status licensee for all biennial licensure periods, plus the current unlicensed activity fee during which the licensee was on retired status.

(2) Any pharmacist applying for an active status license who has been on retired status for 5 years or more, or if licensed elsewhere, has not been active during the past 5 years, shall as a condition of licensure, demonstrate that he or she is able to practice with the care and skill sufficient to protect the health, safety, and welfare of the public by:

(a) If inactive for less than 5 years, the licensee must pass a jurisprudence examination;

(b) If inactive for 5 or more years, in addition to paragraph (a), the licensee must pass the NAPLEX.

*Rulemaking Authority 456.036(16) FS. Law Implemented 456.013, 456.036(4)(b) FS. History—New 11-29-06, Amended 12-22-09.*

#### **64B16-26.1012 Approved Continuing Education Provider Renewal Fee.**

The biennial fee to renew as an approved continuing education provider shall be \$150.

*Rulemaking Authority 456.013(9), 465.005 FS. Law Implemented 456.013(9), 465.009, 465.012 FS. History—New 1-11-05.*

#### **64B16-26.1021 Delinquent License Reversion; Reinstatement; Fees.**

(1) An active or inactive license that is not renewed by midnight of the expiration date of the license shall

automatically revert to delinquent status.

(2) A pharmacist may request that a delinquent license be reinstated to active or inactive status, provided the licensee meets the continuing education requirements of rule 64B16-26.103, F.A.C., for each biennium the license was on inactive status, and by submitting a reactivation fee of \$100 plus the current fee for an active status or inactive status license set forth in rule 64B16-26.1003 or 64B16-26.1004, F.A.C.

(3) A consultant pharmacist may request that a delinquent consultant pharmacist license be reinstated to an active or inactive status by submitting a delinquent fee of \$100 plus the current fee for an active or inactive status consultant pharmacist license set forth in rule 64B16-26.1003 or 64B16-26.1004, F.A.C.

(4) A nuclear pharmacist may request that a delinquent nuclear pharmacist license be reinstated to an active or inactive license status by submitting a delinquent fee of \$100 plus the current fee for an active or inactive nuclear pharmacist license set forth in rule 64B16-26.1003 or 64B16-26.1004, F.A.C.

(5) A registered pharmacy technician may request that a delinquent registered pharmacy technician registration be reinstated to an active or inactive status provided the registered pharmacy technician meets the continuing education requirements of rule 64B16-26.103, F.A.C., for each biennium the registration was on inactive status, and by submitting a reactivation fee of \$25 plus the current fee for an active or inactive status registered pharmacy technician registration set forth in rule 64B16-26.1003 or 64B16-26.1004, F.A.C.

(6) A license in delinquent status that is not renewed prior to midnight of the expiration date of the current licensure cycle shall be rendered null without any further action by the Department. Any subsequent license shall be the result of applying for and meeting all requirements imposed on an applicant for new licensure.

*Rulemaking Authority 456.036, 465.005, 465.012 FS. Law Implemented 456.036, 465.012 FS. History—New 1-11-05, Amended 10-27-09.*

#### **64B16-26.102 Inactive License Renewal.**

*Rulemaking Authority 465.005 FS. Law Implemented 465.008, 465.012 FS. History—New 3-19-79, Formerly 21S-6.06, Amended 1-7-87, 12-29-88, Formerly 21S-6.006, Amended 7-31-91, 1-10-93, Formerly 21S-26.102, 61F10-26.102, Amended 3-10-96, Formerly 59X-26.102, Amended 3-18-01, Repealed 3-10-05.*

#### **64B16-26.1022 Permit Fees.**

(1) The initial permit fee for a pharmacy, as provided by section 465.022(14)(a), F.S., shall be \$250.00.

(2) The biennial permit renewal fee for a pharmacy, as provided by section 465.022(14)(b), F.S., shall be \$250.00.

(3) The change of location fee for a pharmacy, as provided by section 465.022(14)(d), F.S., shall be \$100.00.

(4) The delinquent fee for a pharmacy permit, as provided by section 465.022(14)(c), F.S., shall be \$100.00.

*Rulemaking Authority 465.005, 465.022(8) FS. Law Implemented 465.022(8) FS. History—New 1-11-05.*

#### **64B16-26.103 Continuing Education Credits; Renewal.**

(1) Prior to biennial 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 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 24 month period prior to the expiration date of the pharmacy technician registration.

(a) Upon a pharmacy technician's first renewal, 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 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 technician registration occurs 12 months or more after the initial licensure, then 12 hours of registered pharmacy 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 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 20 hours must be obtained either at a live seminar, a live video teleconference, or through an interactive computer-based application.

*Rulemaking Authority 456.033, 465.009 FS. Law Implemented 456.013(7), (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.*

#### **64B16-26.1031 Vaccine Certification Program.**

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

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

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



- (b) Immunization Schedules;
- (c) Immunization screening questions, provision of risk/benefit information, informed consent, recordkeeping, and electronic reporting into the statewide immunization registry;
- (d) Vaccine storage and handling;
- (e) Bio-Hazardous waste disposal and sterile techniques;
- (f) Entering, negotiating and performing pursuant to physician oversight protocols;
- (g) Community immunization resources and programs;
- (h) Identifying, managing and responding to adverse incidents including but not limited to potential allergic reactions associated with vaccine administration;
- (i) Procedures and policies for reporting adverse events to the Vaccine Adverse Event Reporting System (VAERS);
- (j) Reimbursement procedures and vaccine coverage by federal, state and local governmental jurisdictions and private third party payors;
- (k) Administration techniques;
- (l) Administration of epinephrine using an autoinjector delivery system;
- (m) The immunization and vaccine guidelines in the February 1, 2015, Adult Immunization Schedule by the United States Centers for Disease Control and Prevention, entitled "Recommended Adult Immunization Schedule – United States – 2015," which is hereby incorporated by reference. The Schedule may be obtained from <http://www.flrules.org/Gateway/reference.asp?No=Ref-06808>, and the Board office at the address in subsection (1);
- (n) The immunizations or vaccines recommended by the United States Centers for Disease Control and Prevention for international travel as of July 1, 2015, which may be found in the CDC Health Information for International Travel (2014 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.

*Rulemaking Authority 465.005 FS. Law Implemented 465.189 FS. History–New 3-20-08, Amended 8-30-10, 7-29-13, 5-29-16.*

**64B16-26.1032 Immunization Administration Certification Application and Information.**

All applications for immunization certification shall be made on board approved form DH-MQA 1125, "Immunization Administration Certification Application and Information," 04/17, which is hereby incorporated by reference. To obtain an application, 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 Department of Health's website at <http://floridaspharmacy.gov/Applications/immunization-administration-certification-application.pdf>, or at <http://www.flrules.org/Gateway/reference.asp?No=Ref-08566>. The application must be accompanied with a non-refundable application fee, if applicable, as set forth in rule 64B16-26.1001, F.A.C.

*Rulemaking Authority 465.005 FS. Law Implemented 465.189 FS. History–New 9-21-10, Amended 8-13-13, 4-4-16, 8-20-17.*

**64B16-26.104 Exemptions for Members of the Armed Forces; Spouses.**

(1) Any pharmacist or registered pharmacy technician on active duty with the Armed Forces of the United States who at the time of becoming a member of the Armed Forces of the United States was in good standing with the Board and was entitled to practice the profession of pharmacy or registered as a pharmacy technician in Florida

shall be exempt from all license renewal provisions so long as the licensee is on active duty with the Armed Forces and for a period of six months after discharge so long as the licensee is not engaged in the practice of pharmacy in the private sector for profit.

(2) A pharmacist or registered pharmacy technician who is a spouse of a member of the Armed Forces of the United States and who was caused to be absent from the State of Florida because of the spouse's duties with the Armed Forces shall be exempt from all license renewal provisions.

*Rulemaking Authority 465.005 FS. Law Implemented 456.024 FS. History–New 3-19-79, Amended 4-30-85, Formerly 21S-6.09, 21S-6.009, Amended 7-31-91, Formerly 21S-26.104, 61F10-26.104, 59X-26.104, Amended 1-11-05, 10-27-09.*

#### **64B16-26.105 Consultant Pharmacists Initial Registration Fee and Renewal Fee.**

*Rulemaking Authority 465.005, 465.008, 465.0125 FS. Law Implemented 456.036, 465.0125 FS. History–New 10-26-83, Amended 2-21-84, Formerly 21S-6.10, 21S-6.010, 21S-26.105, 61F10-26.105, Amended 3-28-95, Formerly 59X-26.105, Repealed 3-10-05.*

#### **64B16-26.106 Nuclear Pharmacists Initial Registration Fee and Renewal Fee**

*Rulemaking Authority 465.005, 465.0126 FS. Law Implemented 456.036, 465.0126 FS. History–New 12-29-88, Formerly 21S-6.011, 21S-26.106, 61F10-26.106, Amended 6-26-95, 3-11-96, Formerly 59X-26.106, Repealed 3-10-05.*

#### **64B16-26.107 Inactive Nuclear Pharmacist License Renewal.**

*Rulemaking Authority 465.005, 465.008, 465.012, 465.022(8) FS. Law Implemented 465.008, 465.012, 465.022(8) FS. History–New 6-26-95, Formerly 59X-26.107, Repealed 3-10-05.*

#### **64B16-26.200 Examination Requirements; Passing Scores.**

(1) The examination provided in Section 465.007, F.S., shall be as follows:

(a) Part A – North American Pharmacist Licensure Examination (NAPLEX).

(b) Part B – Multistate Pharmacy Jurisprudence Examination (MPJE) – Florida Version.

(2) Passing Scores. The minimum passing scaled score for the NAPLEX shall be seventy-five percent (75%). The minimum passing scaled score for the MPJE shall be seventy-five percent (75%).

*Rulemaking Authority 456.017(1), 465.005, 465.0075(1) FS. Law Implemented 456.017(1)(b), (6), 465.007(3), 465.0075 FS. History–New 10-17-79, Amended 2-8-81, 6-22-82, 8-16-84, 4-30-85, Formerly 21S-12.01, Amended 5-6-86, Formerly 21S-12.001, Amended 1-10-93, Formerly 21S-26.200, 61F10-26.200, Amended 7-1-97, Formerly 59X-26.200, Amended 3-22-99, 1-11-05, 4-4-17, 5-14-18.*

#### **64B16-26.201 Reexamination.**

*Rulemaking Authority 456.017, 465.005 FS. Law Implemented 456.017 FS. History–New 10-17-79, Amended 2-8-81, 11-27-84, 4-30-85, Formerly 21S-12.02, Amended 5-6-86, Formerly 21S-12.002, 21S-26.201, 61F10-26.201, 59X-26.201, Repealed 3-10-05.*

#### **64B16-26.202 Examination Review Procedure.**

*Rulemaking Authority 456.017(2) FS. Law Implemented 456.017(2) FS. History–New 10-17-79, Amended 12-27-82, Formerly 21S-12.03, Amended 12-24-89, Formerly 21S-12.003, 21S-26.202, 61F10-26.202, 59X-26.202, Repealed 3-10-05.*

#### **64B16-26.203 Pharmacist Licensure by Examination (U.S. Graduates); Application.**

Applicants who are at least eighteen (18) years of age and a recipient of a degree from a school or college of

pharmacy accredited by an accrediting agency recognized and approved by the United States Department of Education may apply to take the licensure examination.

(1) All applications for licensure by examination must be made on board approved form DHMQA 101, Pharmacist Examination Application for U.S. 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-07403>, 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-pharmacist-exam-us-pr-grad.pdf>. 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 completion of an internship program provided by either an accredited school or college of pharmacy or a state board of pharmacy or jointly by both, provided that the program meets the requirements of rule 64B16-26.2033, F.A.C.

(3) An applicant must reapply if all requirements for licensure are not met within one (1) year of the receipt of the application.

(4) Passing examination scores may be used upon reapplication only if the examination was completed within three (3) years of the reapplication.

*Rulemaking Authority 456.013(1), 465.005 FS. Law Implemented 456.013(1), 456.025(3), 465.007 FS. History—New 10-17-79, Formerly 21S-12.04, 21S-12.004, Amended 7-31-91, 10-14-91, Formerly 21S-26.203, 61F10-26.203, Amended 7-1-97, Formerly 59X-26.203, Amended 8-17-99, 10-15-01, 1-2-02, 1-12-03, 1-11-05, 2-18-08, 5-26-09, 5-11-10, 9-15-16.*

#### **64B16-26.2031 Licensure by Examination (Foreign 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. 07/16), Pharmacist Examination Application For Foreign Graduates and Instructions, which is hereby incorporated by reference, and which can be obtained from <http://www.flrules.org/Gateway/reference.asp?No=Ref-07404>, 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-pharmacist-exam-foreign-grad.pdf>. 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.

*Rulemaking Authority 456.013(1), 465.005 FS. Law Implemented 456.013(1), 456.025(3), 465.007(1) FS. History—New 1-11-05, Amended 8-8-07, 6-10-09, 5-27-10, 9-12-16.*

#### **64B16-26.2032 Application for Pharmacy Intern Registration.**

(l)(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 for Pharmacy Education (ACPE) shall apply for pharmacy intern registration on form DH-MQA 104, Pharmacy Intern Application for ACPE Accredited Students/Graduates and Instructions, 10/16, which is hereby incorporated by reference and which can be obtained from <http://www.flrules.org/Gateway/reference.asp?No=Ref-08026>, 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, 10/16, which is incorporated by reference and which can be obtained from <https://www.flrules.org/Gateway/reference.asp?No=Ref-07946>, 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), 456.0635, 465.003(12), (13), 465.007(1)(c), 465.0075(1)(c)2., 465.013 FS. History—New 4-1-07, Amended 7-7-10, 10-7-12, 3-15-17.*

#### **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., F.S., 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) 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, 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;

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;

5. Ensures that any intern who is a foreign pharmacy graduate is supervised at a ratio of one (1) pharmacist to one (1) intern; and,

6. Ensures that, for foreign pharmacy graduate interns, the program will afford the intern the experience and objectives required by the Foreign Graduate Registered Intern Work Activity Manual, form DH-MQA 1153, incorporated by reference in rule 64B16-26.2031, F.A.C.

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

3. 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;

4. 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,

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

6. Supervise no more than one (1) intern at any time, if such intern is a foreign pharmacy graduate.

(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." 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.

*Rulemaking Authority 465.005, 465.007(1)(c) FS. Law Implemented 456.013(1), 465.002, 465.003(12), (13), 465.007(1)(c), 465.0075(1)(c)2., 465.013, 465.015(1)(b), (2)(b) FS. History—New 5-27-10, Amended 3-15-17.*

#### **64B16-26.2035 Examination Fees.**

*Rulemaking Authority 465.005 FS. Law Implemented 465.007 FS. History—New 9-19-94, Amended 3-10-96, Formerly 59X-26.2035, Amended 3-22-99, 10-30-00, Repealed 3-10-05.*

#### **64B16-26.204 Pharmacist Licensure by Endorsement; Application.**

(1)(a) U.S. Graduates. All applications for licensure by endorsement for pharmacists who received a degree from a school or college of pharmacy accredited by an accrediting agency recognized and approved by the United States Department of Education shall be made on board approved form DOH-MQA100, 10/16. Pharmacist Licensure by Endorsement Application and Instructions (U.S. Graduates), which is hereby incorporated by reference, and which can be obtained from <http://www.flrules.org/Gateway/reference.asp?No=Ref-07752>, 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-pharmacist-endorse-uspr-grad.pdf>.

(b) Foreign Graduates. All applications for licensure by endorsement for pharmacists graduated from a pharmacy program of a school or college of pharmacy located outside of the United States shall be made on board approved form DOH-MQA 1196, 10/16, Pharmacist Licensure by Endorsement Application and Instructions (Foreign Graduates), which is hereby incorporated by reference, and which can be obtained from <http://www.flrules.org/Gateway/reference.asp?No=Ref-07753>, 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-pharmacist-endorse-foreign-grad-2013.pdf>.

(2) The application must be accompanied with a non-refundable application fee and initial licensure fee as set forth in rules 64B16-26.1001 and 64B16-26.1002, F.A.C., and in addition, the applicant must submit satisfactory proof of the following:

(a) Compliance with the requirements of sections 465.007(1)(b)1. or 2., and (1)(c), F.S.;

(b) Having obtained a passing score on a licensure examination as described in subsection 465.0075(1)(b), F.S.; and,

(c)1. Having two (2) years of active practice, as defined in section 465.0075(1)(c)1., F.S., within the immediately preceding five (5) years and have completed 30 hours of Board approved continuing education within the two (2) calendar years immediately preceding application. For purposes of this rule only, the Board defines "Board approved continuing education" as any continuing education course offered, sponsored, or approved by the Florida Board of Pharmacy, the Accreditation Council for Pharmacy Education (ACPE), or other state board of pharmacy which course was accepted by the other state board for licensure or licensure renewal purposes;

2. Successful completion of board-approved postgraduate training or a board-approved clinical competency examination within the year immediately preceding application; or

3. Successful completion of an internship meeting the requirements of section 465.007(1)(c), F.S., and rule 64B16-26.2033, F.A.C., within the two (2) years immediately preceding application.

(3) All requirements for licensure by endorsement must be met within one (1) year of the receipt of the application. Applicants failing to meet this requirement must reapply.

(4) Applicants shall cause the National Association of Boards of Pharmacy, or other similar organization to issue a Transfer of Pharmaceutical Licensure certificate showing examination date, examination results, states of licensure, disciplinary actions, and licensure status.

(5) Applicants deemed qualified for licensure by endorsement shall be required to complete the Multistate Pharmacy Jurisprudence Examination – Florida Version. Passing scores on this examination may be used upon

reapplication only if the examination was completed within three (3) years of the reapplication.

*Rulemaking Authority 456.013, 465.005, 465.0075 FS. Law Implemented 456.013(1), (2), 456.0635, 465.007, 465.0075 FS. History–New 11-8-01, Amended 1-11-05, 2-18-08, 5-26-09, 10-10-10, 1-10-17.*

**64B16-26.205 Requirements for Foreign Pharmacy Graduates to Be Admitted to the Pharmacist Licensure Examination.**

*Rulemaking Authority 465.005, 465.007 FS. Law Implemented 465.007 FS. History–New 4-18-84, Formerly 21S-12.06, Amended 9-17-87, Formerly 21S-12.006, Amended 7-31-91, 1-10-93, 4-8-93, Formerly 21S-26.205, 61F10-26.205, Amended 3-10-96, Formerly 59X-26.205, Amended 8-17-99, Repealed 3-10-05.*

**64B16-26.300 Consultant Pharmacist Licensure.**

(1) No person shall serve as consultant pharmacist as defined in Section 465.003(3), F.S., unless that person holds a license as a consultant pharmacist.

(2) Application for consultant pharmacist licensure shall be made on form DOH-MQA 1109, (Rev. 12/15), Consultant Pharmacist Application and Information, which is hereby incorporated by reference, and which can be obtained from <http://www.flrules.org/Gateway/reference.asp?No=Ref-06933> and the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or from the website located at <http://floridaspharmacy.gov/Applications/app-consultant-pharmacist.pdf>. The application shall be accompanied by an application fee.

(3) In order to be licensed as a consultant pharmacist, a person must meet the following requirements:

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

(b) Successfully complete a consultant pharmacist course of no fewer than twelve (12) hours, sponsored by an accredited college of pharmacy, and approved by the Florida Board of Pharmacy Tripartite Continuing Education Committee which is based on the Statement of the Competencies Required in Institutional Pharmacy Practice and subject matter set forth in rule 64B16-26.301, F.A.C. The course shall be instructionally designed to include a cognitive test on which the applicant must score a passing grade for certification of successful completion of the course.

(c) Successfully complete a period of assessment and evaluation under the supervision of a preceptor within one (1) year of completion of the course set forth in paragraph (b), above. This period of assessment and evaluation shall be completed over no more than three (3) consecutive months and shall include at least 40 hours of training in the following practice areas, 60% of which shall occur on-site at an institution that holds a pharmacy permit. The training shall include:

Minimum Skills Required	Percent of Time	Hours
Minimum of 40 Hours in Maximum of Three Months		
1. Regimen review, documentation and communication.	60%	24
a. Demonstrate ability to carry out process and understand documentation functions.		
b. Understand and perform drug regimen review. Communicate findings to appropriate individuals or groups.		
c. The applicant is responsible for learning other skills needed to perform in his/her type of facility where he/she is or will be the consultant Pharmacist of Record.		
2. Facility review.	20%	8
Demonstrate areas that should be evaluated, documentation, and reporting procedures.		
3. Committee and Reports.	5%	2
Review quarterly Quality of Care Committee minutes and preparation and delivery of pharmacist quarterly report.		
4. Policy and Procedures.	5%	2

Preparation, review, updating Policy and Methods.		
5. Principles of formulary management.	5%	2
Demonstrate ability to manage formulary.		
6. Professional Relationships.	5%	2
Knowledge and interaction of facility administration and professional staff.		

(4) In order to act as a preceptor, a person shall:

(a) Be a consultant pharmacist of record at an institutional pharmacy which is required to have a consultant pharmacist under the provisions of chapter 465, F.S., and these rules.

(b) Have a minimum of one (1) year of experience as a consultant pharmacist of record.

(c) Maintain all pharmacist licenses in good standing with the Board.

(d) Not act as a preceptor to more than two (2) applicants at the same time.

(5) Upon completion of the requirements set forth above, the applicant's preceptor shall confirm that the applicant's assessment and evaluation have met the requirements and that the applicant has successfully completed all required assignments under the preceptor's guidance and supervision.

(6) After licensure a consultant pharmacist's license shall be renewed biennially upon payment of the fee set forth in rule 64B16-26.1003, F.A.C., and upon completing twenty-four (24) hours of board approved continuing education based upon the provisions of rule 64B16-26.302, F.A.C.

(7) The number of hours earned in recertification programs by a consultant pharmacist, if applied to the twenty-four (24) hours required for consultant pharmacist license renewal, may not be used toward the thirty (30) hours of continued professional pharmaceutical education credits as set forth in rule 64B16-26.103, F.A.C.

(8) An applicant who applies for a consultant pharmacist license after the effective date of this rule shall be required to complete the assessment and evaluation required in paragraph (3)(c), prior to being licensed as a consultant pharmacist.

*Rulemaking Authority 456.013, 465.005, 465.0125 FS. Law Implemented 456.013, 465.0125 FS. History—New 5-19-72, Revised 4-19-74, Repromulgated 12-18-74, Amended 10-17-79, 4-8-80, 7-29-81, 7-1-83, 4-10-84, 4-30-85, Formerly 21S-1.26, 21S-1.026, Amended 7-31-91, 10-14-91, Formerly 21S-26.300, 61F10-26.300, Amended 9-19-94, 3-28-95, 3-10-96, Formerly 59X-26.300, Amended 5-22-01, 5-5-05, 11-29-06, 3-29-10, 6-23-16.*

#### **64B16-26.301 Subject Matter for Consultant Pharmacist Training Program.**

(1) Jurisprudence.

(a) Laws and regulations, state and federal, pertaining to institutional pharmacy and health care facilities.

(b) Laws and regulations, state and federal, pertaining to the safe and controlled storage of alcohol and other related substances, and relating to fire and health-hazard control.

(2) Policy and Procedures.

(a) Written procedures for outlining the medication system in effect.

1. Traditional systems.

2. Unit-dose systems.

a. Centralized.

b. Decentralized.

c. Automated medication systems.

3. Routine and emergency use of drugs.

4. After hours procedure for medication dispensing.

5. Managing drug shortages.

(b) Record keeping and reports.

1. Controlled substance control and record-of-usage.

2. Alcohol inventory and record-of-usage.

3. Patient drug use control and records.



- a. Recalls.
- b. Medication use evaluation.
- c. Medication errors.
- 4. Drug charges, methods, accountability, and reports.
- 5. Statistical reports of usage, volume, etc.
- (3) Administrative Responsibilities.
  - (a) Fiscal Control.
    - 1. Perpetual and traditional inventory systems.
    - 2. Application of EDP techniques.
  - (b) Personnel Management, orientation and training.
  - (c) Intra-professional relations pertaining to medication use.
  - (d) Inter-professional relations with other members of the institutional health care team.
    - 1. Pharmacy & Therapeutic Committee.
      - a. Rational drug therapy; review of medication use and prescribing.
      - b. Formulary development – evaluation, appraisal, selection, procurement, storage, distribution, medication safety, criteria for use development and safety.
      - c. Automatic stop orders on potent and dangerous drugs.
      - d. Controls on storage and use of investigational drugs.
    - 2. In-service education of nurses and other health-related personnel.
    - 3. Infectious Disease Committee.
  - (4) Professional Responsibilities.
    - (a) Drug information retrieval and methods of dispersal.
    - (b) Development of pharmacy practice.
    - (c) Development of an IV Admixture service.
    - (d) Procedures to enhance medication safety.
      - 1. Availability of equipment, technique, etc., to prepare special dosage forms for pediatric and geriatric patients.
      - 2. Preparation of sterile dosage forms.
      - 3. Proper writing, transcribing and initiating and/or transferring patient medication orders; development of physician's chart order copy system.
      - 4. Safety of patient self-medication and control of drugs at bedside.
      - 5. Reporting and trending adverse drug reactions.
      - 6. Screening for potential drug interactions.
      - 7. Development and maintenance of up-to-date emergency kits.
    - (e) Maintain drug quality and safe storage.
      - 1. Procedures for eliminating out-dated drugs.
      - 2. Requirements for safe and appropriate storage conditions.
    - (f) Maintain drug identity.
      - 1. Procedures for labeling, transferring of bulk medications, etc.
      - 2. Manufacturing and packaging procedures.
      - 3. Pre-packaging control and supervision.
  - (5) The Institutional Environment.
    - (a) The institution's pharmacy function and purpose.
    - (b) Interdepartmental relationships important to the institutional pharmacy.
    - (c) Understanding of scope of service and in-patient care mission of the institution.
    - (d) Special training with respect to the operation of nursing homes and Extended Care Facilities (ECF)/pharmacy relationship and special procurement procedures.
  - (6) Nuclear pharmacy.
    - (a) Procurement.

- (b) Compounding.
- (c) Quality control procedures.
- (d) Dispensing.
- (e) Distribution.
- (f) Basic radiation protection and practices.
- (g) Consultation and education to the nuclear medicine community; including patients, pharmacists, other health professionals, and the general public.
- (h) Research and development of new formulations.
- (i) Record keeping.
- (j) Reporting adverse drug reactions and medication errors.
- (k) Screening for potential drug interaction.

*Rulemaking Authority 465.005, 465.0125 FS. Law Implemented 465.0125 FS. History—New 5-19-72, Amended 12-18-74, 10-17-79, Formerly 21S-1.27, 21S-1.027, Amended 7-31-91, Formerly 21S-26.301, 61F10-26.301, 59X-26.301, Amended 5-5-05.*

**64B16-26.302 Subject Matter for Consultant Pharmacist Licensure Renewal Continuing Education.**

A Consultant Pharmacist License Renewal Continuing Education Program must contain at least three (3) hours of training in any of the subjects specified below. Duplicate courses are not acceptable.

- (1) Drug Therapy – Disease State. Patient Drug Therapy – management and monitoring.
  - (a) Drug, Disease State Information – In-depth disclosure of the drug or therapeutic class of drugs or disease state including pharmacology, side effects and interaction.
  - (b) New Therapeutic Modalities: Expansion of current drug therapy or treatment.
  - (c) Patient Assessment: Assessment techniques by consultant pharmacist to determine the need and effectiveness of indicated drug therapy along with identification and assessment of side effects on patient’s well-being.
  - (d) Pertinent Laboratory Tests.
  - (e) Therapeutic Dosing.
- (2) Administrative Responsibilities.
  - (a) Update on Administrative Responsibilities.
    1. Legal requirements including statutes, rules and regulation (Federal and State).
    2. The Joint Commission on the Accreditation of Healthcare Organizations.
    3. Personnel requirements.
    4. Health Insurance Portability and Accountability.
  - (b) Focus on Consultant Pharmacist Practice Issues/Concerns.
    1. How to get things accomplished in complex organizations.
    2. Key contacts to be effective as a consultant pharmacist.
    3. Considerations and preparation for site inspections.
  - (3) Consultant Pharmacist Facility Responsibilities. This segment details the requirements in one of the facility types for which a consultant pharmacist is required. Only one practice setting may be included in each program.
    - (a) Pharmacist-Medication Responsibilities – Assessment mechanism for delivery system, review procedures and monitoring processes.
    - (b) Pharmacist-Patient Responsibilities – Patient assessment, laboratory test monitoring and therapeutic dosing.
    - (c) Committee Responsibilities – Make-up and responsibilities for various facility committees.
    - (d) Reporting requirements.
  - (4) Compounding sterile or nonsterile human drugs, or both.

*Rulemaking Authority 465.005, 465.012, 465.0125 FS. Law Implemented 465.012, 465.0125 FS. History—New 10-14-91, Formerly 21S-26.302, 61F10-26.302, 59X-26.302, Amended 5-5-05, 7-21-09, 2-2-20.*

### **64B16-26.303 Nuclear Pharmacist Licensure.**

(1) A pharmacist licensed to practice pharmacy in this state who performs a radiopharmaceutical service shall, prior to engaging in such specialized practice, be actively licensed as a nuclear pharmacist.

(2) A pharmacist seeking licensure as a nuclear pharmacist in this state shall submit to the Board of Pharmacy the following:

(a) An application for nuclear pharmacist licensure, form DOH-MQA 104, (Rev. 12/15), Nuclear Pharmacist Application and Information, which is hereby incorporated by reference, and which can be obtained from <http://www.flrules.org/Gateway/reference.asp?No=Ref-06926>, and the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or from the website located at <http://floridaspharmacy.gov/Applications/app-nuclear-pharmacist-2013.pdf>;

(b) An application fee as specified by subsection 64B16-26.1002(3), F.A.C.;

(c) A course outline and certificate of training which document successful completion of the didactic training in compliance with subsection (3), below;

(d) Documentation of successful completion of on-the-job training and experience in compliance with subsection (5), below.

(3) All applicants must complete a minimum of 200 clock hours of formal didactic training from an accredited college of pharmacy or other program recognized by the Florida Department of Health and the Florida Board of Pharmacy as specified by subsection (4), below. All such formal training must include, at a minimum:

(a) Radiation physics and instrumentation (85 hours).

(b) Radiation protection (45 hours).

(c) Mathematics pertaining to the use and measurement of radioactivity (20 hours).

(d) Radiation biology (20 hours).

(e) Radiopharmaceutical chemistry (30 hours).

(4) Programs recognized by the Department and Board shall be determined to be comparable to those offered by accredited colleges of pharmacy for the training of nuclear pharmacists. Such academic training programs will be submitted to the Board of Pharmacy for approval by an accredited educational institution which operates under the auspices of or in conjunction with an accredited college of pharmacy.

(5) The minimum on-the-job training which shall be included in a radiopharmacy internship is 500 hours of training and experience in the handling of unsealed radioactive material under the supervision of a licensed nuclear pharmacist. The training and experience shall include but shall not be limited to the following:

(a) Ordering, receiving and unpackaging in a safe manner, radioactive material, including the performance of related radiation surveys.

(b) Calibrating dose calibrators, scintillation detectors, and radiation monitoring equipment.

(c) Calculating, preparing and verifying patient doses, including the proper use of radiation shields.

(d) Following appropriate internal control procedures to prevent mislabeling.

(e) Learning emergency procedures to safely handle and contain spilled materials, including related decontamination procedures and surveys.

(f) Eluting technetium-99m from generator systems, assaying the eluate for technetium-99m and for molybdenum-99 contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals.

(g) Clinical practice concepts.

(6) If the didactic and experiential training required in this section have not been completed within the last seven (7) years, the applicant must have been engaged in the lawful practice of nuclear pharmacy in another jurisdiction at least 1,080 hours during the last seven (7) years.

*Rulemaking Authority 465.005, 456.013, 465.0126 FS. Law Implemented 456.013, 465.0126 FS. History—New 1-18-05, Amended 6-7-16.*

### **64B16-26.304 Subject Matter for Nuclear Pharmacist License Renewal Continuing Education**

## **Programs.**

(1) A licensee completing the continuing education requirement for nuclear pharmacist license renewal pursuant to rule 64B16-26.103, F.A.C., shall complete twenty-four (24) additional hours per biennium of coursework each two year period by or through a Committee approved provider, instructionally designed to provide in-depth treatment of nuclear pharmacy practice with suggested subject matter set out in subsection (2) of this rule.

(2) Content of nuclear pharmacist continuing education program.

(a) Application of radiopharmaceutical theory in a practice or a research setting with respect to the drug products and their clinical application. Provision of drug and radiopharmaceutical information as it pertains to optimal handling and use of these products in a clinical setting.

(b) Effective communication skills in a multi-disciplinary environment with patients, nuclear medicine physicians, nuclear medicine technologists, radiation safety personnel and other nuclear pharmacists. The multi-faceted regulatory environment requires such skills in the preparation and maintenance of a radioactive by-product materials license, the identification and reporting of adverse reactions and misadministration, instances of poor product performance, environmental and personnel radiation safety.

(c) Application of the most rigorous and up-to-date principles of radiation safety and quality assurance in order to assure regulatory compendia, and operational standards for drug and radiopharmaceutical products and equipment. Recordkeeping and other documentation activities essential to procurement, storage, compounding, handling and use, distribution and disposal should be emphasized.

(d) Management of a nuclear pharmacy unit in accordance with regulatory and administrative agencies' requirements.

(e) Advances in drug, radiopharmaceutical or related technology (including, but not limited to: monoclonal antibodies, magnetic resonance imaging, computed tomography, positron-emission tomography, radioplaque and other contact enhancement agents, radioimmunoassay) with emphasis on paragraphs (a)-(d), above, for such new agents.

*Rulemaking Authority 465.005, 465.0126 FS. Law Implemented 465.0126 FS. History—New 1-18-05.*

### **64B16-26.320 Subject Matter for Continuing Education to Order and Evaluate Laboratory Tests.**

(1) Consultant pharmacists and pharmacists holding the Doctor of Pharmacy degree that wish to order and evaluate laboratory tests under the provisions of section 465.0125, F.S., shall successfully complete the requirements of a continuing education course set forth herein prior to such practice. Successful completion of the course will certify the pharmacist for this practice for two (2) years from date of completion.

(2) Providers of courses seeking approval under this section shall meet the procedures and standards provided for in rule 64B16-26.601, F.A.C. Courses approved under this section shall be at least three (3) hours in duration for initial certification and at least one (1) hour for recertification, and shall cover the following subjects:

(a) Requirements for monitoring laboratory values;

(b) Interpretation of laboratory values;

(c) Use of laboratory data to monitor and improve drug therapy;

(d) Legal aspects, restrictions, and requirements for obtaining laboratory studies;

(e) Use of laboratory data and therapeutic outcomes;

(f) Documentation of interventions; and,

(g) Laboratory studies as an element of complete patient care.

(3) A consultant pharmacist may apply the three (3) hour initial certification course and the one (1) hour recertification course toward the continuing education requirement for renewal of a consultant pharmacist license under rule 64B16-26.300, F.A.C., or may apply such continuing education hours toward the continuing education requirement for renewal of a pharmacist license under rule 64B16-26.103, F.A.C., but may not use the same continuing education hours to satisfy both requirements. A Doctor of Pharmacy who is not a consultant pharmacist may apply the three (3) hour initial certification course and the one (1) hour recertification course toward the continuing education requirement for renewal of a pharmacist license under rule 64B16-26.103, F.A.C.

*Rulemaking Authority 465.009, 465.0125(3) FS. Law Implemented 465.009, 465.0125(2) FS. History—New 2-23-98, Amended 6-15-98, 1-12-03, 3-10-05.*

**64B16-26.350 Requirements for Pharmacy Technician Registration.**

(1) As required by section 465.014, F.S., no person shall work as a Pharmacy Technician unless such person is at least seventeen (17) years of age and is registered by the Board or who is currently registered as a Pharmacy Intern.

(2) All applicants for registration as a pharmacy technician must be made on form DH-MQA-PH1183, "Pharmacy Technician Registration Application and Instructions," 07/16, which is incorporated herein by reference. Copies of the application may be obtained from the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254, (850)488-0595; the board's website at <http://floridaspharmacy.gov/Applications/app-pharm-tech.pdf> or from <http://www.flrules.org/Gateway/reference.asp?No=Ref-07398>. The application must be accompanied with a non-refundable application fee and an initial registration fee set forth in rules 64B16-26.1001 and 64B16-26.1002, F.A.C.

(3) In addition to the requirements of subsection (2), all applicants must submit proof of completion of a Board approved training course as outlined in rule 64B16-26.351, F.A.C.

*Rulemaking Authority 465.005, 465.014 FS. Law Implemented 456.0635, 456.013(1), (2), (3), 465.014 FS. History—New 8-5-10, Amended 9-1-16.*

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

Pursuant to section 465.014, F.S., in order to be registered as a pharmacy technician in Florida, an applicant must have completed a pharmacy technician training program approved by the Board. The standards for approval of a registered pharmacy technician training program are as follows.

(1) Preapproved pharmacy technician training programs. The standard for approval of Registered Pharmacy Technician Training programs provided or offered by accredited institutions or entities is whether the program or institution is, as of December 1, 2018,

(a) accredited by a regional or national accrediting agency; a regional or national institutional accrediting agency; or a specialized accrediting agency recognized by the Secretary of the United States Department of Education;

(b) accredited by an accrediting agency whose accreditation establishes eligibility to participate in the Title IV student financial assistance program administered by United States Department of Education; or

(c) Pharmacy technician training programs within the public-school system of the State of Florida that comply with the Florida Department of Education Curriculum Framework for Pharmacy Technician (2018-2019), program number H170500; which is incorporated herein by reference and which can be obtained at <https://www.flrules.org/Gateway/reference.asp?No=Ref-10356> or <http://www.fldoe.org/core/fileparse.php/18567/urlt/H170500-1819.rtf>.

(2) Federal Armed Services programs. The standard for approval of pharmacy technician training programs provided by a branch of the federal armed services shall be whether the curriculum of such course was developed on or before June 1, 2018.

(3) Other non-employer based programs. The standard for approval of all programs offered or accredited by an entity not listed in subsection (1) or (2), and which are not employer based programs, is whether the program:

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

(b) Offers 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) Applies directly to the Board of Pharmacy on approved form DH-MQA 1239 "Application for Registered Pharmacy Technician Training Programs." All applications must include the following information:

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

(d) Uses 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) Demonstrates 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) Employer sponsored training programs. All other pharmacy technician training programs not identified in subsections (1)-(3) must be employer sponsored by a Florida permitted pharmacy, or affiliated group of pharmacies under common ownership and, must:

(a) Meet the requirements of paragraphs (3)(b), (3)(d), and (3)(e), above;

(b) Be provided solely to employees of the permitted pharmacy or affiliated group;

(c) Contain a minimum of one hundred sixty (160) hours of training, which shall not exceed six (6) months.

Employer sponsored pharmacy technician training programs may request the program length exceed six (6) months in length under the following circumstances:

1. For programs containing a minimum of one hundred eighty (180) hours, the program length shall not exceed nine (9) months;

2. For programs containing a minimum of two hundred (200) hours, the program length shall not exceed twelve

(12) months.

3. In no event shall the total length of the training program exceed twelve (12) months.

For programs of any length, the Program Director may extend participation in the program for an individual employee. In no event shall an employee's training be extended more than six (6) months beyond the program's length.

(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.

(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.

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

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

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

(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.

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

(k) Apply directly to the Board of Pharmacy on approved form DH-MQA 1239 "Application for Registered Pharmacy Technician Training Programs."

(5) Reenrollment in employer-sponsored training programs. Any student who failed to complete an employer sponsored training program within the time periods established in paragraph (4)(c) must be terminated from the program. After termination, the Program Director may allow a student to reenroll in the program, at the Program Director's discretion and pursuant to the program's written policies and procedures. Reenrolled students must complete the entire program, including all required program hours, and no coursework or hours previously completed may be carried forward into the subsequent enrollment.

(6) All applications for approval of a Registered Pharmacy Technician Training Program shall be made on approved form DH-MQA 1239 "Application for Registered Pharmacy Technician Training Programs," 06/18, which is hereby incorporated by reference. Applications may be obtained from <https://www.flrules.org/Gateway/reference.asp?No=Ref-10116>, or the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254, (850)488-0595, or the board's website at <http://floridaspharmacy.gov/Applications/app-reg-pharm-tech-prog.pdf>, and must include the items required by subsection (3) or (4), above.

*Rulemaking Authority 465.005, 465.014(4), (7) FS. Law Implemented 465.014(2), (4) FS. History—New 6-23-10, Amended 11-17-11, 6-19-17, 6-14-18, 12-10-18, 4-4-19.*

#### **64B16-26.355 Subject Matter for Registered Pharmacy Technician Continuing Education.**

A Registered Pharmacy Technician Continuing Education Program must contain subject matter specifically designed to meet the objectives and the stated level and learning needs of the participants. The content shall be planned in logical order and reflect input from experts in the subject matter. Appropriate subject matter for continuing education offering shall reflect the professional educational needs for the learner in order to meet the health care needs of the consumer and consist of content from one or more of the following:

- (1) Pharmacy technician practice areas and special health care problems.
- (2) Biological, physical, behavioral and social sciences.

- (3) Legal aspects of health care.
- (4) Management/administration of health care personnel and patient care.
- (5) Teaching/learning process of health care personnel and patients.
- (6) Subjects which are taken at an accredited educational institution as verified by an official transcript, that meet any one of the criteria in rule 64B16-26.351, F.A.C., and are advanced beyond that completed for original registration shall be approved for continuing education under this rule.

*Rulemaking Authority 465.005, 465.014 FS. Law Implemented 465.014 FS. History–New 10-10-10.*

#### **64B16-26.400 Pharmacy Interns; Registration; Employment.**

(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) An applicant for pharmacy intern registration must submit proof 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 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 shall be considered a graduate of an accredited college or school of pharmacy. The internship experience allowed under this provision shall not count toward the 500-hours internship required subsequent to passage of the Foreign Pharmacy Graduate Equivalency Examination as mandated in section 465.007(1)(b)2., F.S., and as defined in rule 64B16-26.203, F.A.C.

(3) Upon the receipt of proof satisfactory to the Board that the intern applicant meets the requirements of either paragraph (a) or (b), of subsection (2), 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.

(4) 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.

(5) Within thirty (30) days of termination of enrollment in an intern program, or withdrawal of registration or attendance in an accredited school or college of pharmacy, all registered pharmacy interns shall report such change in enrollment, registration or attendance to the Board office. The notification may include a request, including full explanation and supported by accompanying documentation, if any, that the pharmacy intern registration not be cancelled pending the registered pharmacy intern's re-enrollment, re-registration, or re-attendance in an accredited intern program or accredited school or college of pharmacy.

*Rulemaking Authority 465.005 FS. Law Implemented 465.003(12), 465.013 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, 4-4-19.*

#### **64B16-26.401 Requirements for an Internship Program Sufficient to Qualify an Applicant for Licensure by Examination.**

*Rulemaking Authority 465.005 FS. Law Implemented 465.007 FS. History–New 8-20-83, Amended 5-19-72, 8-18-73, 12-18-74, 11-10-80, 10-25-84, Formerly 21S-1.22, 21S-1.022, Amended 7-31-91, Formerly 21S-26.401, Amended 12-27-93, Formerly 61F10-26.401, 59X-26.401, Amended 4-19-01, Repealed 3-10-05.*

#### **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.

(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.*

#### **64B16-26.601 Standards for Approval of Courses and Providers.**

(1) Each proposal for program or course approval submitted by a qualified provider must contain a detailed outline of the content of said program or course on forms which will be provided by the Board of Pharmacy upon request, and must build upon Standards of Practice and a basic course or courses offered in the curricula of accredited colleges or schools of pharmacy. Continuing education may consist of post-baccalaureate degree programs offered by accredited colleges or schools of pharmacy, post-graduate studies, institutes, seminars, lectures, conferences, workshops, correspondence courses, or other such committee-approved educational methods.

(2) All offerings must meet the following standards:

(a) Education Content Development.

1. Continuing education offerings shall involve advance planning that includes a statement of measurable educational goals and behavioral objectives.

2. Continuing education offerings shall be designed to reflect the educational needs of the pharmacist and build on the standards for practice and courses in the curricula of accredited colleges or schools of pharmacy.

3. Each continuing education offering shall be designed to explore one subject or a group of closely related subjects or standards.

(b) Methods of Delivery.

1. The method of delivery of a course shall be determined by giving appropriate consideration to such factors as educational content, objectives, and composition of the audience.

2. The method of delivery must encourage active participation and involvement on the part of the pharmacist.

(c) Program Faculty Qualifications.

1. The program faculty for a particular continuing education offering shall be competent in the subject matter and qualified by experience.

2. An appropriate number of program faculty for each activity shall be utilized.

3. There shall be adequate personnel to assist with administrative matters and personnel with competencies outside content areas in cases where the method of delivery requires technical or other special expertise.

(d) Facilities.

1. The facilities to be utilized shall be appropriate and adequate to the content, method of delivery, size of the audience and promote the attainment of the objectives of the offering.

(e) Evaluation. The provider must make provision for evaluation of the participants' attainment of the stated learner objectives through in-process activities that provide a measurable demonstration of the learner's achievement(s).

2. The provider must develop and employ an evaluation mechanism for the purpose of allowing the participant to assess his/her achievement of personal objectives.

3. The provider shall develop and employ an evaluation mechanism that will assess the effectiveness of the learning experiences, instructional methods, facilities, and resources used for the offering.

(f) Contact Hour Criteria. The number of contact hours or Continuing Education Units shall be determined by the provider in advance of the offering subject to approval by the committee and awarded upon the successful completion of the entire planned education experience.

(g) Record Keeping.

1. Records of individual offerings shall be maintained by the provider for inspection by the Board. The records shall be adequate to serve the needs of the participants and to permit the Board to monitor for adherence to the standards for continuing education offerings as outlined in the rules.

2. An individual certificate of attendance specifying title of offering, provider number, date of offering, and number of contact hours earned shall be furnished to each participant by the provider.

3. Records shall be maintained by the provider for a minimum of three (3) years.

(3) Providers seeking board approval shall meet each of the standards outlined herein:

(a) All continuing education offerings conducted by the provider shall meet the standards for continuing education offerings as outlined in these rules.

(b) There shall be a visible, continuous, and identifiable authority charged with administration of continuing education programs. The person or persons in whom the administrative function is vested shall be qualified by virtue of background and experience and approval by the committee.

(4) All programs approved by the Accreditation Council on Pharmacy Education (ACPE) for continuing education for pharmacists may be deemed approved by this Board for general continuing education hours for pharmacists.

(5) Entities or individuals who wish to become approved providers of continuing education must submit an initial approval fee of \$150 and provide information to demonstrate compliance with the requirements of this rule. A provider seeking to renew approved provider status shall pay a renewal fee of \$150.

(6) Entities or individuals applying for approval of an individual program shall submit a fee of \$50 and provide information to demonstrate compliance with this rule.

*Rulemaking Authority 465.005, 465.009 FS. Law Implemented 456.025(7), 465.009 FS. History—New 10-17-79, Amended 7-29-81, Formerly 21S-13.02, 21S-13.002, Amended 1-10-93, Formerly 21S-26.601, 61F10-26.601, 59X-26.601, Amended 1-29-03.*

**64B16-26.6012 Guidelines for Board Ordered Disciplinary Continuing Education Courses.**

Any continuing education course being taken as part of a disciplinary order, unless otherwise ordered by the Board, may be conducted by any method, including live, correspondence, or distant education.

(1) Laws and Rules courses shall be at least twelve (12) hours in length. The program shall include review and analysis of the laws regulating the profession of pharmacy in the State of Florida with discussion of recent changes to Florida Statutes and Board of Pharmacy rules. The remainder of the continuing education program shall be derived from the following areas:

(a) Federal laws related to:

1. Handling, management, and dispensing of controlled substances,
2. Protected patient information; and,
3. Medicare.

(b) Chapters 456, 499 and 893, F.S;

(c) Florida Medicaid program;

(d) Nursing home and Assisted Living Facility regulations;

(e) Prescriber laws and regulations;

(f) Pharmacy ethics;

(g) The Joint Commission (TJC) standards;

(h) Food and Drug Administration policies and procedures;

(i) Implementation of disaster and emergency preparedness plans by Florida pharmacists and pharmacy services providers; and,

(j) Occupational Safety and Health Administration (OSHA) and National Institute for Occupational Safety and Health (NIOSH) guidelines and requirements for pharmacy employers.

(2) Quality Related Event (QRE) courses shall be at least eight (8) hours in length.

(a) Course material shall include:

1. Pharmacy error detection,

2. Pharmacy error prevention; and,

3. Case studies of pharmacists who have made dosing calculation, checking/interpreting prescriptions, or dispensing errors.

(b) Course material shall include the following specific subject areas:

1. Common error types and causes,

2. Root cause analysis,

3. Process mapping and management,

4. System analysis,

5. Failure mode and effects analysis,

6. Human factors, cognitive and personality impacts,

7. Practice management and effective delegation tools,

8. Stress management,

9. Effective communication,

10. Continuous Quality Improvement (CQI) rules,

11. CQI implementation tools,

12. Individual self assessment, planning, and goal setting. The individual self assessment shall include a requirement that the pharmacist prepare a written report, in essay form, summarizing the impact of the course, what the pharmacist learned, and the changes that the pharmacist will implement in practice as a result of the course.

*Rulemaking Authority 456.072(2) 465.005, 465.016(4) FS. Law Implemented 456.072(2), 465.016(4) FS. History—New 7-21-09.*

**64B16-26.602 Recommendation by the Tripartite Continuing Education Committee.**

*Rulemaking Authority 465.005 FS. Law Implemented 465.009 FS. History–New 10-17-79, Amended 7-29-81, Formerly 21S-13.03, 21S-13.003, 21S-26.602, Amended 7-18-94, Formerly 61F10-26.602, 59X-26.602, Repealed 8-16-01.*

**64B16-26.603 Continuing Education Records Requirements.**

*Rulemaking Authority 465.005 FS. Law Implemented 465.009 FS. History–New 10-17-79, Formerly 21S-13.04, Amended 5-10-89, Formerly 21S-13.004, 21S-26.603, 61F10-26.603, 59X-26.603, Amended 1-11-05, Repealed 3-15-16.*

**64B16-26.606 Number of Required Hours.**

*Rulemaking Authority 465.005 FS. Law Implemented 465.009 FS. History–New 10-17-79, Formerly 21S-13.07, 21S-13.007, Amended 7-31-91, Formerly 21S-26.606, 61F10-26.606, 59X-26.606, Amended 2-23-98, 1-12-03, Repealed 3-10-05.*

**CHAPTER 64B16-27  
PHARMACY PRACTICE**

64B16-27.100	Proof of Licensure; Display of License; Pharmacist, Registered Pharmacy Intern and Registered Pharmacy Technician Identification
64B16-27.1001	Practice of Pharmacy
64B16-27.1003	Transmission of Prescription Orders (Repealed)
64B16-27.101	Counterfeit Drugs (Repealed)
64B16-27.103	Oral Prescriptions and Copies
64B16-27.104	Conduct Governing Pharmacists and Pharmacy Permittees
64B16-27.1042	Rebates Prohibited; Violations Defined
64B16-27.105	Transfer of Prescriptions (Repealed)
64B16-27.120	Ordering and Evaluation of Laboratory Tests
64B16-27.200	Purpose and Effect (Repealed)
64B16-27.210	General Terms and Conditions to Be Followed by a Pharmacist When Ordering and Dispensing Approved Medicinal Drug Products
64B16-27.211	Prescription Refills
64B16-27.220	Medicinal Drugs Which May Be Ordered by Pharmacists
64B16-27.230	Fluoride Containing Products
64B16-27.300	Standards of Practice – Continuous Quality Improvement Program
64B16-27.400	Practice of Pharmacy (Repealed)
64B16-27.4001	Delegation to and Supervision of Pharmacy Technicians; Responsibility of Supervising Pharmacist
64B16-27.410	Registered Pharmacy Technician to Pharmacist Ratio
64B16-27.420	Pharmacy Technician – Delegable and Non-Delegable Tasks
64B16-27.430	Responsibilities of the Pharmacist (Repealed)
64B16-27.440	Policies and Procedures (Repealed)
64B16-27.450	Prescription Department Managers
64B16-27.500	Negative Drug Formulary
64B16-27.510	Identification of Manufacturer (Repealed)
64B16-27.520	Positive Drug Formulary
64B16-27.530	Duty of Pharmacist to Inform Regarding Drug Substitution
64B16-27.615	Possession and Disposition of Sample Medicinal Drugs
64B16-27.620	Disposition of Complimentary or Sample Medicinal Drugs Which Are Unsuitable for Dispensing (Repealed)
64B16-27.630	Additional Immunizations or Vaccines Which May Be Administered
64B16-27.700	Definition of Compounding
64B16-27.797	The Standards of Practice for Compounding Sterile Products
64B16-27.800	Requirement for Patient Records
64B16-27.810	Prospective Drug Use Review
64B16-27.820	Patient Counseling
64B16-27.830	Standards of Practice – Drug Therapy Management
64B16-27.831	Standards of Practice for the Filling of Controlled Substance Prescriptions; Electronic Prescribing; Mandatory Continuing Education
64B16-27.850	Standards of Practice for Orthotics and Pedorthics
64B16-27.851	Record-Keeping for Orthotics and Pedorthics

**64B16-27.100 Proof of Licensure; Display of License; Pharmacist, Registered Pharmacy Intern**

**and Registered Pharmacy Technician Identification.**

(1) Proof of licensure. Every pharmacist, pharmacy intern, and registered pharmacy technician must maintain proof of current licensure such that it is readily retrievable upon request by any representative of the Department or the Board or any member of the public. The pharmacy may display the license or registration of each pharmacy employee or alternatively, may display a notice easily accessible to the public that the license or registration of each employee is available for viewing upon request.

(2) Identification. Every Pharmacist, Pharmacy Intern, or Registered Pharmacy Technician must be identified by means such as a clearly visible identification badge or monogrammed smock showing their name and if they are a pharmacist, pharmacy intern, or registered pharmacy technician. In addition, all registered pharmacy technicians shall state their names and verbally identify themselves as registered pharmacy technicians in the context of telephone or other forms of communication.

*Rulemaking Authority 456.072(1)(t), 465.005, 465.0155, 465.022 FS. Law Implemented 456.072(1)(t), 465.022 FS. History—Amended 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.06, 21S-1.006, Amended 7-30-91, Formerly 21S-27.100, 61F10-27.100, Amended 1-30-96, Formerly 59X-27.100, Amended 11-18-07, 1-1-10, 10-8-15, 11-7-17.*

**64B16-27.1001 Practice of Pharmacy.**

Those functions within the definition of the practice of the profession of pharmacy, as defined by Section 465.003(13), F.S., are specifically reserved to a pharmacist or a duly registered pharmacy intern in this state acting under the direct and immediate personal supervision of a pharmacist. The following subjects come solely within the purview of the pharmacist.

(1) A pharmacist or registered pharmacy intern must:

(a) Supervise and be responsible for the controlled substance inventory.

(b) Receive verbal prescriptions from a practitioner.

(c) Interpret and identify prescription contents.

(d) Engage in consultation with a practitioner regarding interpretation of the prescription and date in patient profile.

(e) Engage in professional communication with practitioners, nurses or other health professionals.

(f) Advise or consult with a patient, both as to the prescription and the patient profile record.

(2) When parenteral and bulk solutions of all sizes are prepared, regardless of the route of administration, the pharmacist must:

(a) Interpret and identify all incoming orders.

(b) Mix all extemporaneous compounding or be physically present and give direction to the registered pharmacy technician for reconstitution, for addition of additives, or for bulk compounding of the parenteral solution.

(c) Physically examine, certify to the accuracy of the final preparation, thereby assuming responsibility for the final preparation.

(d) Systemize all records and documentation of processing in such a manner that professional responsibility can be easily traced to a pharmacist.

(3) Only a pharmacist may make the final check of the completed prescription thereby assuming the complete responsibility for its preparation and accuracy.

(4) The pharmacist, as an integral aspect of dispensing, shall be directly and immediately available to the patient or the patient's agent for consultation and shall not dispense to a third party. No prescription shall be deemed to be properly dispensed unless the pharmacist is personally available.

(5) The pharmacist performing in this state any of the acts defined as "the practice of the profession of pharmacy" in Section 465.003(13), F.S., shall be actively licensed as a pharmacist in this state, regardless of whether the practice occurs in a permitted location (facility) or other location.

(6) The pharmacist may take a meal break, not to exceed 30 minutes in length, during which the pharmacy department of a permittee shall not be considered closed, under the following conditions:

(a) The pharmacist shall be considered present and on duty during any such meal break if a sign has been prominently posted in the pharmacy indicating the specific hours of the day during which meal breaks may be taken by the pharmacist and assuring patients that a pharmacist is available on the premises for consultation upon request during a meal break.

(b) The pharmacist shall be considered directly and immediately available to patients during such meal breaks if patients to whom medications are delivered during meal breaks are verbally informed that they may request that a pharmacist contact them at the pharmacist's earliest convenience after the meal break, and if a pharmacist is available on the premises during the meal break for consultation regarding emergency matters. Only prescriptions with the final certification by the pharmacist may be delivered.

(c) The activities of registered pharmacy technicians during such a meal break shall be considered to be under the direct and immediate personal supervision of a pharmacist if the pharmacist is available on the premises during the meal break to respond to questions by the technicians, and if at the end of the meal break the pharmacist certifies all prescriptions prepared by the registered pharmacy technicians during the meal break.

(7) The delegation of any duties, tasks or functions to registered pharmacy interns and registered pharmacy technicians must be performed subject to a continuing review and ultimate supervision of the pharmacist who instigated the specific task, so that a continuity of supervised activity is present between one pharmacist and one registered pharmacy technician. In every pharmacy, the pharmacist shall retain the professional and personal responsibility for any delegated act performed by registered pharmacy interns and registered pharmacy technicians in the licensee's employ or under the licensee's supervision.

*Rulemaking Authority 465.005, 465.0155 FS. Law Implemented 465.003(11)(b), (13), 465.014, 465.026 FS. History—New 11-18-07, Amended 1-1-10.*

#### **64B16-27.1003 Transmission of Prescription Orders.**

*Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.022, 465.026, 893.07 FS. History—New 11-18-07, Repealed 10-8-15.*

#### **64B16-27.101 Counterfeit Drugs.**

*Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.022 FS. History—Amended 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.15, 21S-1.015, Amended 7-30-91, Formerly 21S-27.101, 61F10-27.101, 59X-27.101, Repealed 10-8-15.*

#### **64B16-27.103 Oral Prescriptions and Copies.**

(1) Only a pharmacist or registered pharmacy intern acting under the supervision of a pharmacist may, in the State of Florida, accept an oral prescription of any nature.

(2) Only a pharmacist or registered pharmacy intern acting under the supervision of a pharmacist may, in the State of Florida, 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, and when said copy is given a notation shall be made upon the prescription that a copy has been given, the date given, and to whom given.

*Rulemaking Authority 465.005, 465.0155, 465.014, 465.022 FS. Law Implemented 465.003(13), 465.014, 465.022, 893.07(1)(b) FS. History—Amended 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.18, 21S-1.018, 21S-27.103, 61F10-27.103, Amended 9-19-94, Formerly 59X-27.103, Amended 10-15-01, 11-18-07.*

#### **64B16-27.104 Conduct Governing Pharmacists and Pharmacy Permittees.**

(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) Pursuant to Section 465.018, F.S., a permit for a community pharmacy may not be issued unless a licensed pharmacist is designated as the prescription department manager responsible for maintaining all drug records, providing for the security of the prescription department and following such other rules as relate to the practice of the profession of pharmacy. 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.

*Rulemaking 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.*

#### **64B16-27.1042 Rebates Prohibited; Violations Defined.**

As provided in Section 465.185(1), F.S., acts which will be considered as falling within the range of activities which would justify discipline against a pharmacist or permittee as provided in Section 465.016(1)(e) or 465.023(1)(c), F.S., shall include:

(1) Offering or providing cash, or goods, or entertainment (including, money, food or decorations) to a health care facility (as defined in Section 408.032(7), F.S.) or its representative in exchange for favorable consideration in obtaining or maintaining the business of the facility;

(2) Offering or providing supplies or equipment to a health care facility (as defined in Section 408.032(7), F.S.) at no charge or below market value when these items are not integral elements of the medication distribution system;

(3) Paying rent to a health care facility (as defined in Section 408.032(7), F.S.) for space that is not used or is unusable or paying a rental rate for space that is significantly greater than the usual and customary rental rate for similar space;

(4) Offering or providing computers, FAX machines, or other electronic devices to a health care facility (as defined in Section 408.032(7), F.S.) when that equipment is not an integral element in providing pharmacy or consultant services;

(5) Offering or providing a health care facility (as defined in Section 408.032(7), F.S.) consultant pharmacist services, or providing patient medical record systems, or any personnel services outside the practice of pharmacy, at no charge, below market value, or below cost in exchange for obtaining or maintaining the business of the facility.

*Rulemaking Authority 465.005, 465.0155 FS. Law Implemented 465.185, 465.0155 FS. History—New 3-9-94, Formerly 61F10-27.1042, 59X-27.1042.*

#### **64B16-27.105 Transfer of Prescriptions.**



*Rulemaking Authority 465.005, 465.0155 FS. Law Implemented 465.026 FS. History–New 1-3-79, Formerly 21S-1.33, 21S-1.033, Amended 7-30-91, Formerly 21S-27.105, 61F10-27.105, Amended 9-19-94, Formerly 59X-27.105, Amended 6-15-98, Repealed 10-8-15.*

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

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

*Rulemaking Authority 465.0125(3) FS. Law Implemented 465.0125(2) FS. History–New 2-23-98.*

**64B16-27.200 Purpose and Effect.**

*Rulemaking Authority 465.186(2) FS. Law Implemented 465.186 FS. History–New 5-1-86, Formerly 21S-18.001, 21S-27.200, 61F10-27.200, 59X-27.200, Repealed 10-8-15.*

**64B16-27.210 General Terms and Conditions to Be Followed by a Pharmacist When Ordering and Dispensing Approved Medicinal Drug Products.**

Pursuant to the authority of the Formulary Committee in Section 465.186, F.S., a pharmacist may order the medicinal drug products listed in Rule 64B16-27.220, F.A.C., subject to the following terms and limitations:

- (1) Injectable products shall not be ordered by the pharmacist.
- (2) No oral medicinal drugs shall be ordered by a pharmacist for a pregnant patient or nursing mother.
- (3) In any case of dispensing hereunder, the amount or quantity of drug dispensed shall not exceed a 34-day supply or standard course of treatment unless subject to the specific limitations in this rule. Patients shall be advised that they should seek the advice of an appropriate health care provider if their present condition, symptom, or complaint does not improve upon the completion of the drug regimen.
- (4) The directions for use of all prescribed medicinal drugs shall not exceed the manufacturer’s recommended dosage.
- (5) The pharmacist may only perform the acts of ordering and dispensing in a pharmacy which has been issued a permit by the Board of Pharmacy.
- (6) The pharmacist shall create a prescription when ordering and dispensing medicinal drug products which shall be maintained in the prescription files of the pharmacy. The pharmacist shall place the trade or generic name and the quantity dispensed on the prescription label, in addition to all other label requirements.
- (7) The pharmacist shall maintain patient profiles, separate from the prescription order, for all patients for whom the pharmacist orders and dispenses medicinal drug products and shall initial and date each profile entry. Such profiles shall be maintained at the pharmacy wherein the ordering and dispensing originated for a period of four (4) years.
- (8) In the patient profiles, the pharmacist shall record as a minimum the following information if a medicinal drug product is ordered and dispensed.
  - (a) Patient’s chief complaint or condition in the patient’s own words.
  - (b) A statement regarding the patient’s medical history.
  - (c) A statement regarding the patient’s current complaint which may include, onset, duration and frequency of the problem.
  - (d) The medicinal drug product ordered and dispensed.
  - (e) The pharmacist ordering and dispensing the medicinal drug product shall initial the profile.
  - (f) The prescription number shall be recorded in the patient’s profile.
  - (g) A medicinal drug product may be ordered, and dispensed only by the pharmacist so ordering.
  - (h) Only legend medicinal drugs may be prescribed by a pharmacist. Over-the-counter drugs are exempt from

the requirements of this rule and shall be recommended as over-the-counter products.

(11) Pharmacy interns and technicians may not be involved in the ordering of the medicinal drugs permitted in this rule.

*Rulemaking Authority 465.186(2) FS. Law Implemented 465.022, 465.186 FS. History—New 5-1-86, Formerly 21S-18.002, 21S-27.210, 61F10-27.210, 59X-27.210, Amended 11-18-07, 3-18-15.*

#### **64B16-27.211 Prescription Refills.**

No prescription may be filled or refilled in excess of one (1) year from the date of the original prescription was written. No prescription for a controlled substance listed in Schedule II may be refilled. No prescription for a controlled substance listed in Schedules III, IV, or V may be filled or refilled more than five (5) times within a period of six (6) months after the date on which the prescription was written.

*Rulemaking Authority 465.005, 465.016(1), 465.022(1)(a), 893.04 FS. Law Implemented 465.022 FS. History—New 11-18-07.*

#### **64B16-27.220 Medicinal Drugs Which May Be Ordered by Pharmacists.**

A Pharmacist may order and dispense from the following formulary, within their professional judgment, subject to the stated conditions.

(1) Oral analgesics for mild to moderate pain. The pharmacist may order these drugs for minor pain and menstrual cramps for patients with no history of peptic ulcer disease. The prescription shall be limited to a six (6) day supply for one treatment. If appropriate, the prescription shall be labeled to be taken with food or milk.

- (a) Magnesium salicylate/phenyltoloxamine citrate.
- (b) Acetylsalicylic acid (Zero order release, long acting tablets).
- (c) Choline salicylate and magnesium salicylate.
- (d) Naproxen sodium.
- (e) Naproxen.
- (f) Ibuprofen.

(2) Urinary analgesics. Phenazopyridine, not exceeding a two (2) day supply. The prescriptions shall be labeled about the tendency to discolor urine. If appropriate, the prescription shall be labeled to be taken after meals.

(3) Otic analgesics. Antipyrine 5.4%, benzocaine 1.4%, glycerin, if clinical signs or symptoms of tympanic membrane perforation do not exist. The product shall be labeled for use in the ear only.

(4) Anti-nausea preparations.

(a) Meclizine up to 25 mg., except for a patient currently using a central nervous system (CNS) depressant. The prescription shall be labeled to advise the patient of drowsiness and to caution against concomitant use with alcohol or other depressants.

(b) Scopolamine not exceeding 1.5 mg. per dermal patch. Patient shall be warned to seek appropriate medical attention if eye pain, redness or decreased vision develops.

(5) Antihistamines and decongestants. The following, including their salts, either as a single ingredient product or in combination, including nasal decongestants, may be ordered for a patient above 6 years of age.

(a) Antihistamines. The pharmacist shall warn the patient that an antihistamine should not be used by patients with bronchial asthma or other lower respiratory symptoms, glaucoma, cardiovascular disorders, hypertension, prostate conditions and urinary retention. An antihistamine shall be labeled to advise the patient of drowsiness and caution against the concomitant use with alcohol or other depressants.

1. Diphenhydramine.
2. Carbinoxamine.
3. Pyrilamine.
4. Dexchlorpheniramine.
5. Brompheniramine.

(b) Decongestants. The pharmacist shall not order an oral decongestant for use by a patient with coronary artery disease, angina, hyperthyroidism, diabetes, glaucoma, prostate conditions, hypertension, or a patient currently using a monoamine oxidase inhibitor.

1. Phenylephrine.
2. Azatadine.

(6) Topical antifungal/antibacterials. The pharmacist shall warn the patient that any of the products should not be used near deep or puncture wounds and contact with eyes or mucous membranes should be avoided. Iodochlorhydroxyquin preparations shall be labeled with staining potential.

- (a) Iodochlorhydroxyquin with 0.5% Hydrocortisone (not exceeding 20 grams).
- (b) Haloprogin 1%.
- (c) Clotrimazole topical cream and lotion.
- (d) Erythromycin topical.

(7) Topical anti-inflammatory. The pharmacist shall warn the patient that hydrocortisone should not be used on bacterial infections, viral infections, fungal infections, or by patients with impaired circulation. The prescription shall be labeled to advise the patient to avoid contact with eyes, mucous membranes or broken skin. Preparations containing hydrocortisone not exceeding 2.5%.

(8) Otic antifungal/antibacterial. Acetic acid 2% in aluminum acetate solution which shall be labeled for use in ears only.

(9) Keratolytics. Salicylic acid 16.7% and lactic acid 16.7% in flexible collodion, to be applied to warts, except for patients under two (2) years of age, and those with diabetes or impaired circulation. Prescriptions shall be labeled to avoid contact with normal skin, eyes and mucous membranes.

(10) Vitamins with fluoride (This does not include vitamins with folic acid in excess of 0.9 mg.).

(11) Medicinal drug shampoos containing Lindane. The pharmacist shall:

- (a) Limit the order to the treatment of head lice only;
- (b) Order no more than four (4) ounces per person; and,
- (c) Provide the patient with the appropriate instructions and precautions for use.

(12) Ophthalmics. Naphazoline 0.1% ophthalmic solution.

(13) Histamine H<sub>2</sub> antagonists. The pharmacist shall advise the patient to seek medical attention if symptom persist longer than 14 days while using the medication or if stools darken or contain blood.

- (a) Cimetidine.
- (b) Famotidine.
- (c) Ranitidine HCl.

(14) Acne products. Benzoyl Peroxide. The prescription shall be labeled to advise the patient to avoid use on the eye, eyelid, or mucous membranes.

(15) Topical Antiviral.

- (a) Acyclovir ointment may be ordered for the treatment of herpes simplex infections of the lips.
- (b) Penciclovir.

*Rulemaking Authority 465.186(2) FS. Law Implemented 465.186 FS. History--New 5-1-86, Amended 10-7-90, Formerly 21S-18.003, Amended 7-30-91, Formerly 21S-27.220, 61F10-27.220, Amended 3-12-97, Formerly 59X-27.220, Amended 6-15-98, 11-30-99, 11-18-07.*

### **64B16-27.230 Fluoride Containing Products That May Be Ordered by Pharmacists.**

Oral medicinal drug products containing fluoride may be ordered by pharmacists for their patients who do not have fluoride supplement in their drinking water, pursuant to the following limitations:

- (1) The fluoride content of drinking water does not exceed 0.5 ppm.
- (2) Once a fluoride treatment has been initiated with one specific fluoride medicinal drug product it should not be interchanged with a product of a different manufacturer for the course of the treatment.
- (3) If the fluoride content is less than 0.5 ppm then the following dosage schedule for oral usage shall be

followed.

- (a)1. For ages 0-6 months.
  - a. Less than 0.3 ppm in water – no supplementation,
  - b. 0.3-0.6 ppm in water – no supplementation,
  - c. 0.6 ppm in water – no supplementation,
2. For ages 6 months – 3 years,
  - a. Less than 0.3 ppm in water – supplement with 0.25 mg. F/day,
  - b. 0.3-0.6 ppm in water – no supplementation,
  - c. 0.6 ppm in water – no supplementation.
3. For ages 3-6 years.
  - a. Less than 0.3 ppm in water – supplement with 0.5 mg. F/day,
  - b. 0.3-0.6 ppm in water – supplement with 0.25 mg. F/day,
  - c. 0.6 ppm in water – no supplementation.
4. For ages 6-16 years.
  - a. Less than 0.3 ppm in water – supplement with 1.00 mg. F/day,
  - b. 0.3-0.6 ppm in water – supplement with 0.5 mg. F/day,
  - c. 0.6 ppm in water – no supplementation.

(b) No more than 264 mg. of sodium fluoride may be dispensed at any one time to a patient.

(c) Notwithstanding the provisions of subsection 64B16-27.210(3), F.A.C., a pharmacist may continue a course of therapy with fluoride products until appropriate referral to another health care practitioner is indicated or in no event shall the course of therapy be more than one (1) year.

*Rulemaking Authority 465.186(2) FS. Law Implemented 465.186 FS. History–New 5-1-86, Formerly 21S-18.004, 21S-27.230, 61F10-27.230, 59X-27.230, Amended 6-15-98.*

#### **64B16-27.300 Standards of Practice - Continuous Quality Improvement Program.**

(1) "Continuous Quality Improvement Program" means a system of standards and procedures to identify and evaluate quality-related events and improve patient care.

(2) "Quality-Related Event" means the inappropriate dispensing or administration of a prescribed medication including:

(a) A variation from the prescriber's prescription order, including, but not limited to:

1. Incorrect drug;
2. Incorrect drug strength;
3. Incorrect dosage form;
4. Incorrect patient; or
5. Inadequate or incorrect packaging, labeling, or directions.

(b) A failure to identify and manage:

1. Over-utilization or under-utilization;
2. Therapeutic duplication;
3. Drug-disease contraindications;
4. Drug-drug interactions;
5. Incorrect drug dosage or duration of drug treatment;
6. Drug-allergy interactions; or
7. Clinical abuse/misuse.

(3)(a) Each pharmacy shall establish a Continuous Quality Improvement Program which program shall be described in the pharmacy's policy and procedure manual and, at a minimum shall contain:

1. Provisions for a Continuous Quality Improvement Committee that may be comprised of staff members of the pharmacy, including pharmacists, registered pharmacy interns, registered pharmacy technicians, clerical staff, and other personnel deemed necessary by the prescription department manager or the consultant pharmacist of record,

2. Provisions for the prescription department manager or the consultant pharmacist of record to ensure that the committee conducts a review of Quality Related Events at least every three months.

3. A planned process to record, measure, assess, and improve the quality of patient care; and,

4. The procedure for reviewing Quality Related Events.

(b) As a component of its Continuous Quality Improvement Program, each pharmacy shall assure that, following a Quality-Related Event, all reasonably necessary steps have been taken to remedy any problem for the patient.

(c) At a minimum, the review shall consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.

(4) Each Quality-Related Event that occurs, or is alleged to have occurred, as the result of activities in a pharmacy, shall be documented in a written record or computer database created solely for that purpose. The Quality-Related Event shall be initially documented by the pharmacist to whom it is described, and it shall be recorded on the same day of its having been described to the pharmacist. Documentation of a Quality-Related Event shall include a description of the event that is sufficient to permit categorization and analysis of the event. Pharmacists shall maintain such records at least until the event has been considered by the committee and incorporated in the summary required in subsection (5), below.

(5) Records maintained as a component of a pharmacy Continuous Quality Improvement Program are confidential under the Health Insurance Portability and Accountability Act and are exempt from discovery pursuant to Section 766.101, F.S. In order to determine compliance the Department may review the policy and procedures and a Summarization of Quality-Related Events. The summarization document shall analyze remedial measures undertaken following a Quality-Related Event. No patient name or employee name shall be included in this summarization. The summarization shall be maintained for four (4) years. Records are considered peer-review documents and are not subject to discovery in civil litigation or administrative actions.

*Rulemaking Authority 465.0155 FS. Law Implemented 465.0155, 465.022 FS. History—New 7-15-99, Amended 1-2-02, 6-16-03, 11-18-07, 1-1-10, 3-18-15.*

#### **64B16-27.400 Practice of Pharmacy.**

*Rulemaking Authority 465.005, 465.0155 FS. Law Implemented 465.003(11)(b), (13), 465.014, 465.026 FS. History—New 2-14-77, Formerly 21S-4.01, 21S-4.001, Amended 7-30-91, Formerly 21S-27.400, 61F10-27.400, Amended 1-30-96, 10-1-96, Formerly 59X-27.400, Amended 4-13-00, Repealed 10-5-09.*

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

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

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

(b) Pharmacy Technicians in Training (PTT): are those technicians who are receiving practical (non-didactic) training in delegable tasks as part of employer-sponsored or non-employer sponsored board-approved pharmacy technician training programs who are not required to be duly registered with the board as pharmacy technicians.

(2) Supervision: Delegated tasks must be performed under the direct supervision of a pharmacist and pursuant to the following definitions and requirements:

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

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

*Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.014 FS. History—New 12-31-14, Amended 12-17-18.*

**64B16-27.410 Registered Pharmacy Technician to Pharmacist Ratio.**

(1) General Conditions. When the pharmacist delegates tasks to a registered pharmacy technician, such delegation must enhance the ability of the pharmacist to practice pharmacy to serve the patient population. A pharmacist shall not supervise more than one (1) registered pharmacy technician nor shall a pharmacy allow a supervision ratio of more than one (1) registered pharmacy technician to one (1) pharmacist (1:1), unless specifically authorized to do so pursuant to the provisions of this rule.

(2) Required Documentation. Regardless of the technician ratio, every pharmacy, pharmacist, Prescription Department Manager (PDM) and Consultant Pharmacist (CP) that employs or utilizes registered pharmacy technicians must comply with the following conditions:

(a) Establish and maintain a written Policy and Procedures Manual regarding the number of registered pharmacy technician positions and their utilization that includes the specific scope of delegable tasks of the technicians, job descriptions, and task protocols. The Policy and Procedures Manual or Manuals must include policies and the procedures for implementing the policies for each category enumerated below:

1. Supervision by a pharmacist;
2. Minimum qualifications of the registered pharmacy technician as established by statute and rule;
3. In-service education or on-going training and demonstration of competency specific to the practice site and job function;
4. General duties and responsibilities of the registered pharmacy technicians;
5. All functions related to prescription processing;
6. All functions related to prescription legend drug and controlled substance ordering and inventory control, including procedures for documentation and recordkeeping;
7. All functions related to retrieval of prescription files, patient files, patient profile information and other records pertaining to the practice of pharmacy;
8. All delegable tasks and non-delegable tasks as enumerated in Rule 64B16-27.420, F.A.C.;
9. Confidentiality and privacy laws and rules;
10. Prescription refill and renewal authorization;
11. Registered pharmacy technician functions related to automated pharmacy systems; and,
12. Continuous Quality Improvement Program.

(b) Establish and maintain documentation that is signed by the registered pharmacy technician acknowledging the technician has reviewed the Policy and Procedures Manual(s). Compliance with this paragraph must be achieved by April 7, 2015, or within ninety (90) days from the date the registered pharmacy technician is hired.

(c) Establish and maintain documentation that demonstrates the registered pharmacy technician has received training in the established job description, delegable tasks, task protocols, and policy and procedures in the specific pharmacy setting where the delegable tasks will be performed. Documentation shall consist of one of the following items:

1. Certification by the supervising licensee;
2. Certification by an instructor, trainer, or other similar person;
3. Training attendance logs or completion certificates, accompanied by an outline of the materials addressed;

or

4. Exam or written questionnaires.

(3) The Policy and Procedures Manual(s) required by paragraph (2)(a), must be maintained onsite where the pharmacy technician will perform the delegable tasks and must be available during a Department inspection or at the request of the Board of Pharmacy. However, any and all documentation required by paragraphs (2)(b) and (c), must be maintained and must be provided to the Board of Pharmacy or a Department inspector within 72 hours of a request.

(4) Three to One (3:1) Ratio: Any pharmacy or any pharmacist engaged in sterile compounding shall not exceed a ratio of up to three (3) registered pharmacy technicians to one (1) pharmacist (3:1). The 3:1 ratio only applies to pharmacists and technicians engaged in sterile compounding, and does not affect the technician ratios for other activities not involving sterile compounding in areas of the pharmacy physically separated from the area in which sterile compounding activities take place.

(5) Six to One (6:1) Ratio: Any pharmacy or any pharmacist may allow a supervision ratio of up to six (6) registered pharmacy technicians to one (1) pharmacist (6:1), as long as the pharmacist or registered pharmacy technicians are not engaged in sterile compounding.

(6) Eight to One (8:1) Ratio:

(a) Non-dispensing pharmacies. Any pharmacy which does not dispense medicinal drugs, and the pharmacist(s) employed by such pharmacy, may allow a supervision ratio of up to eight (8) registered pharmacy technicians to one (1) pharmacist (8:1), as long as the pharmacist or registered pharmacy technicians are not engaged in sterile compounding.

(b) Dispensing pharmacies. A pharmacy which dispenses medicinal drugs may utilize an eight to one (8:1) ratio in any physically separate area of the pharmacy from which medicinal drugs are not dispensed. A "physically separate area" is a part of the pharmacy which is separated by a permanent wall or other barrier which restricts access between the two areas.

(7) The determination of the appropriate pharmacist-technician supervision ratio shall be made by the Prescription Department Manager or Consultant Pharmacist of Record. No other person, permittee, or licensee shall interfere with the exercise of the Prescription Department Manager or Consultant Pharmacist of Record's independent professional judgment in setting the pharmacist to technician ratio(s).

*Rulemaking Authority 465.005, 456.069(1), 465.014, 465.017, 465.022 FS. Law Implemented 465.014, 465.022 FS. History—New 2-14-77, Amended 3-31-81, Formerly 21S-4.02, Amended 8-31-87, Formerly 21S-4.002, Amended 9-9-92, Formerly 21S-27.410, 61F10-27.410, Amended 1-30-96, Formerly 59X-27.410, Amended 2-23-98, 10-15-01, 1-1-10, 1-7-15, 7-6-15, 5-8-18, 1-16-19.*

**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.

*Rulemaking Authority 465.005, 465.014 FS. Law Implemented 465.014 FS. History—New 8-31-87, Formerly 21S-4.0025, Amended 7-30-91, Formerly 21S-27.420, 61F10-27.420, 59X-27.420, Amended 2-23-98, 1-1-10, 8-26-12, 2-5-15, 7-6-15, 2-2-20.*

#### **64B16-27.430 Responsibilities of the Pharmacist.**

*Rulemaking Authority 465.005 FS. Law Implemented 465.014 FS. History—New 2-14-77, Formerly 21S-4.03, Amended 9-1-87, Formerly 21S-4.003, 21S-27.430, 61F10-27.430, 59X-27.430, Amended 1-1-10, Repealed 10-8-15.*

#### **64B16-27.440 Policies and Procedures.**

*Rulemaking Authority 465.005 FS. Law Implemented 465.014 FS. History—New 2-14-77, Formerly 21S-4.04, 21S-4.004, Amended 9-9-92, Formerly 21S-27.440, 61F10-27.440, 59X-27.440, Amended 1-1-10, Repealed 10-8-15.*

#### **64B16-27.450 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. Pursuant to Rules 64B16-28.820, 64B16-28.830, and 64B16-28.901, F.A.C., applications for permits for a Special Parenteral and Enteral, Special Closed System, or Nuclear pharmacy require the supervising licensed pharmacist be designated as the prescription department manager. Finally, applications for a Special Sterile Compounding Permit require the supervising licensed pharmacist or consultant pharmacist be designated as either the prescription department manager or the consultant pharmacist of record, as applicable to the underlying permit type. Initial designation is accomplished as part of the application process using the appropriate application form incorporated in Rule 64B16-28.100, F.A.C., or as part of the application for an Internet Pharmacy Permit, utilizing Form DH-MQA 1220, Special Pharmacy Permit Application and Information, 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, a Special Parenteral and Enteral pharmacy, a Special Closed System pharmacy, a Nuclear pharmacy, or a Special Sterile Compounding permittee, 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, 01/18, Prescription Department Manager (PDM) Designation and Privacy Statement Acknowledgement, which is hereby incorporated by reference and which can be obtained from <http://www.flrules.org/Gateway/reference.asp?No=Ref-09439>, 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>. In addition, an outgoing prescription department manager may choose to notify the Board they will no longer serve as prescription department manager using this form.

(c) Submission of Fingerprints. In addition to submission of Form DOH/MQA/PH10, the newly designated prescription department manager shall comply with the fingerprinting requirements of Sections 456.0135 and



465.022, F.S. Electronic fingerprint information ("EFI") that has been submitted to the Florida Agency for Health Care Administration may be accessible by the Florida Department of Health for a period of sixty (60) months. If the Department is able to access EFI from AHCA, applicants will not be required to resubmit EFI for additional or new applications submitted during this time period. After sixty (60) months, new electronic fingerprint information must be submitted as part of all applications.

(2) Responsibilities of Prescription Department Managers. 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.

(3) All community, internet, Special Parenteral and Enteral, Special Closed System, Nuclear and, if applicable, Special Sterile Compounding pharmacy permittees shall continuously maintain a designated prescription department manager at all times the pharmacy is open and in operation.

(4) Pursuant to Section 465.022(11)(c), F.S., a registered pharmacist may not serve as prescription department manager at more than one pharmacy location unless otherwise approved by the Board.

*Rulemaking Authority 465.005, 465.0155, 465.022(1), (10) FS. Law Implemented 456.0135, 465.018(2), 465.0197(1), (3)(b), 465.022(2), (3), (10), (11) FS. History—New 3-9-17, Amended 6-5-18.*

#### **64B16-27.500 Negative Drug Formulary.**

The negative drug formulary is composed of medicinal drugs which have been specifically determined by the Board of Pharmacy and the Board of Medicine to demonstrate clinically significant biological or therapeutic inequivalence and which, if substituted, could produce adverse clinical effects, or could otherwise pose a threat to the health and safety of patients receiving such prescription medications. Except where certain dosage forms are included on the negative drug formulary as a class, all medicinal drugs are listed by their official United States Pharmacopoeia Non-Proprietary (generic) name. The generic name of a drug shall be applicable to and include all brand-name equivalents of such drug for which a prescriber may write a prescription. Substitution by a dispensing pharmacist on a prescription written for any brand name equivalent of a generic named drug product listed on the negative formulary or for a drug within the class of certain dosage forms as listed, is strictly prohibited. In cases where the prescription is written for a drug listed on the negative drug formulary but a brand name equivalent is not specified by the prescriber, the drug dispensed must be one obtained from a manufacturer or distributor holding an approved new drug application or abbreviated new drug application issued by the Food and Drug Administration, United States Department of Health and Welfare permitting that manufacturer or distributor to market those medicinal drugs or when the former is non-applicable, those manufacturers or distributors supplying such medicinal drugs must show compliance with other applicable Federal Food and Drug Administration marketing requirements. The following are included on the negative drug formulary:

- (1) Digitoxin.
- (2) Conjugated Estrogen.
- (3) Dicumarol.
- (4) Chlorpromazine (Solid Oral Dosage Forms).
- (5) Theophylline (Controlled Release).
- (6) Pancrelipase (Oral Dosage Forms).

*Rulemaking Authority 465.005, 465.025(6) FS., Chapter 2001-146, Laws of Florida. Law Implemented 465.025(6) FS., Chapter 2001-146, Laws of Florida. History—New 12-14-76, Amended 3-17-77, 7-2-79, 4-9-81, 9-14-82, 9-26-84, Formerly 21S-5.01, Amended 3-30-89, 7-1-90, Formerly 21S-5.001, Amended 12-25-90, 10-1-92, Formerly 21S-27.500, Amended 2-21-94, Formerly 61F10-27.500, 59X-27.500, Amended 12-4-01, 3-18-10.*

#### **64B16-27.510 Identification of Manufacturer.**

*Rulemaking Authority 465.005 FS. Law Implemented 465.025 FS. History—New 3-16-77, Formerly 21S-5.02, 21S-5.002, 21S-27.510, 61F10-27.510, 59X-27.510, Repealed 10-8-15.*

**64B16-27.520 Positive Drug Formulary.**

A positive formulary of generic and brand name drug products is required of each community pharmacy pursuant to Section 465.025(5), F.S. Those medicinal drugs on the positive formulary shall be obtained from manufacturers or distributors holding an approved new drug application or abbreviated new drug application issued by the Food and Drug Administration, U.S. Department of Health, Education and Welfare permitting that manufacturer or distributor to market those medicinal drugs or when the former is non-applicable, those manufacturers or distributors supplying those medicinal drugs must show compliance with other applicable Federal Food and Drug Administration marketing requirements.

*Rulemaking Authority 465.005 FS. Law Implemented 465.025(6) FS. History—New 12-7-77, Formerly 21S-5.03, 21S-5.003, 21S-27.520, 61F10-27.520, 59X-27.520.*

**64B16-27.530 Duty of Pharmacist to Inform Regarding Drug Substitution.**

Prior to the delivery of the prescription, a pharmacist must inform the person presenting a prescription of any substitution of a generic drug product for a brand name drug product, of any retail price difference between the two, and of the person's right to refuse the substitution. This information must be communicated at a meaningful time such as to allow the person to make an informed choice as to whether to exercise the option to refuse substitution without undue inconvenience to the presenter of the prescription or to the consumer of the drug. This information shall be communicated to the person presenting the prescription in a manner determined to be appropriate by the pharmacist using professional discretion and judgment.

*Rulemaking Authority 465.005 FS. Law Implemented 465.025(3)(a) FS. History—New 11-10-80, Formerly 21S-5.04, 21S-5.004, 21S-27.530, 61F10-27.530, 59X-27.530, Amended 11-18-07.*

**64B16-27.615 Possession and Disposition of Sample Medicinal Drugs.**

(1) Pharmacies may not be in possession of sample medicinal drugs except:

(a) Pharmacies may possess the sample medicinal drugs that are listed within Rule 64B16-27.220, F.A.C., Medicinal Drugs That May be Ordered by Pharmacists.

(b) Institutional pharmacies may possess sample medicinal drugs upon the written request of the prescribing practitioner. Such possession must be in accordance with the provisions of Section 499.028(3)(e)2., F.S.

(c) Those community pharmacies that are pharmacies of health care entities, as defined by Sections 499.003(3) and (14), F.S., may possess sample medicinal drugs upon the written request of the prescribing practitioner. Such possession must be in accordance with the provisions of Section 499.028(3)(e)2., F.S.

(2) Sample packages of medicinal drugs that are found to be unsuitable for dispensing by reason of physical condition or failure to meet requirements of state or federal law shall be returned to the company of origin in accordance with the requirements of Chapter 499, F.S.

*Rulemaking Authority 465.005, 465.022, 499.028 FS. Law Implemented 465.018, 465.019, 465.022, 465.186, 499.028 FS. History—New 11-4-93, Formerly 61F10-27.615, 59X-27.615, Amended 11-18-07.*

**64B16-27.620 Disposition of Complimentary or Sample Medicinal Drugs Which Are Unsuitable for Dispensing.**

*Rulemaking Authority 465.005, 465.022, 499.028 FS. Law Implemented 465.022 FS. History—New 12-26-79, Formerly 21S-15.03, 21S-15.003, 21S-27.620, Amended 11-4-93, Formerly 61F10-27.620, 59X-27.620, Repealed 10-5-09.*

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

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

- (1) Meningococcal B (MenB).
- (2) Zoster Vaccine Recombinant, Adjuvanted.

*Rulemaking Authority 465.005, 465.189 FS. Law Implemented 465.189 FS. History—New 7-14-16, Amended 4-12-18.*

#### **64B16-27.700 Definition of Compounding.**

“Compounding” is the professional act by a pharmacist or other practitioner authorized by law, employing the science or art of any branch of the profession of pharmacy, incorporating ingredients to create a finished product for dispensing to a patient or for administration by a practitioner or the practitioner’s agent; and shall specifically include the professional act of preparing a unique finished product containing any ingredient or device defined by Sections 465.003(7) and (8), F.S. The term also includes the preparation of nuclear pharmaceuticals and diagnostic kits incident to use of such nuclear pharmaceuticals. The term “commercially available products,” as used in this section, means any medicinal product as defined by Sections 465.003(7) and (8), F.S., that are legally distributed in the State of Florida by a drug manufacturer or wholesaler.

(1) Compounding includes:

(a) The preparation of drugs or devices in anticipation of prescriptions based on routine, regularly observed prescribing patterns.

(b) The preparation pursuant to a prescription of drugs or devices which are not commercially available.

(c) The preparation of commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient has been made aware that the compounded product will be prepared by the pharmacist. The reconstitution of commercially available products pursuant to the manufacturer’s guidelines is permissible without notice to the practitioner.

(2) The preparation of drugs or devices for sale or transfer to pharmacies, practitioners, or entities for purposes of dispensing or distribution is not compounding and is not within the practice of the profession of pharmacy, except that the supply of patient specific compounded prescriptions to another pharmacy under the provisions of Section 465.0265, F.S., and Rule 64B16-28.450, F.A.C., is authorized.

(3) Office use compounding, “Office use” means the provision and administration of a compounded drug to a patient by a practitioner in the practitioner’s office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy. A pharmacist may dispense and deliver a quantity of a compounded drug to a practitioner for office use by the practitioner in accordance with this section provided:

(a) The quantity of compounded drug does not exceed the amount a practitioner anticipates may be used in the practitioner’s office before the expiration date of the drug;

(b) The quantity of compounded drug is reasonable considering the intended use of the compounded drug and the nature of the practitioner’s practice;

(c) The quantity of compounded drug for any practitioner and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines and accreditation practices.

(d) The pharmacy and the practitioner enter into a written agreement. The agreement shall specifically provide:

1. That the compounded drug may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity,

2. That the practitioner shall include on the patient’s chart, medication order, or medication administration record the lot number and the beyond-use-date of any compounded drug administered to the patient that was provided by the pharmacy,

3. That the practitioner will provide notification to the patient for the reporting of any adverse reaction or complaint in order to facilitate any recall of batches of compounded drugs.

(e) The pharmacy shall maintain readily retrievable records of all compounded drugs ordered by practitioners for office use. The records must be maintained for a minimum of four (4) years and shall include:

1. The name, address and phone number of the practitioner ordering the compounded drug for office use and the date of the order,
2. The name, strength, and quantity of the compounded drug provided, including the number of containers and quantity in each,
3. The date the drug was compounded,
4. The date the compounded drug was provided to the practitioner,
5. The lot number and beyond use date.

(f) The pharmacy shall affix a label to any compounded drug that is provided for office use. The label shall include:

1. The name, address, and phone number of the compounding pharmacy,
2. The name and strength of the preparation of a list of active ingredients and strengths,
3. The pharmacy's lot number and beyond-use-date,
4. The quantity or amount in the container,
5. The appropriate ancillary instructions such as storage instructions, cautionary statements, or hazardous drug warning labels were appropriate; and,
6. The statement "For Institutional or Office Use Only – Not for Resale," or if the drug is provided to a veterinarian the statement "Compounded Drug."

(g) In the case of compounded products intended for human use, the pharmacy must be in full compliance with 21 U.S.C. §353b, including being registered as an Outsourcing Facility. 21 U.S.C. §353b (eff. Nov. 27, 2013) is hereby adopted and incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-04180>.

*Rulemaking Authority 465.005 FS. Law Implemented 465.003, 465.0155, 465.0265 FS. History–New 10-1-92, Formerly 21S-27.700, 61F10-27.700, 59X-27.700, Amended 11-2-03, 10-7-08, 3-21-13, 6-22-14, 1-28-18.*

#### **64B16-27.797 The Standards of Practice for Compounding Sterile Products.**

The purpose of this section is to assure positive patient outcomes through the provision of standards for 1) pharmaceutical care; 2) the preparation, labeling, and distribution of sterile pharmaceuticals by pharmacies, pursuant to or in anticipation of a prescription drug order; and 3) product quality and characteristics. These standards are intended to apply to all sterile pharmaceuticals, notwithstanding the location of the patient (e.g., home, hospital, nursing home, hospice, doctor's office, or ambulatory infusion center).

(1) Adoption of the United States Pharmacopeia: Beginning on October 1, 2014, all sterile compounding shall be performed in accordance with the minimum practice and quality standards of the following chapters of the United States Pharmacopeia (USP):

- (a) Chapter 797, Pharmaceutical Compounding-Sterile Preparations;
- (b) Chapter 71, Sterility Tests;
- (c) Chapter 85, Bacterial Endotoxins Test;
- (d) Chapter 731, Loss on Drying.

All referenced chapters of the USP, in subsection (1), are specifically referring to the United States Pharmacopeia, 36th revision, Second Supplement, which is hereby incorporated and adopted by reference with the effective chapter dates of December 1, 2013. A subscription to all relevant chapters is available for purchase at [www.uspnf.com](http://www.uspnf.com). The Board has determined that posting the incorporated material on the Internet would constitute a violation of federal copyright law. At the time of adoption, the copyrighted incorporated material will be available for public inspection and examination, but may not be copied, at the Department of Health, 4052 Bald Cypress Way, Tallahassee, Florida 32399-3254, and at the Department of State, Administrative Code and Register Section, Room 701, The Capitol, Tallahassee, Florida 32399-0250.

(2) Minimum Standards: The minimum practice and quality standards of the USP are adopted as the minimum

standards to be followed when sterile products are compounded. However, nothing in this rule shall be construed to prevent the compounding of sterile products in accordance with standards that exceed the USP.

(3) Current Good Manufacturing Practices: The Board deems that this rule is complied with for any sterile products that are compounded in strict accordance with Current Good Manufacturing Practices per 21 U.S.C. §351 (2012), adopted and incorporated herein by reference, available at <https://www.flrules.org/Gateway/reference.asp?No=Ref-04436> and 21 C.F.R. Parts 210 and 211 (2013), adopted and incorporated herein by reference, available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-04437>.

(4) Registered Outsourcing facilities: For any pharmacy registered as an outsourcing facility, the minimum standards of practice for sterile compounding shall be the current good manufacturing practices as adopted in subsection (3).

(5) The board finds that the production of sterile compounded products prepared with a process that includes the lyophilization of the sterile product may not be adequately regulated under the provisions of subsection (1). Sterile compounded products prepared using a process that includes lyophilization shall, in addition to all applicable provisions of USP Chapter 797, be subject to the following additional requirements:

(a) Compounded sterile products prepared for lyophilization shall be maintained in ISO 5 unidirectional laminar flow air throughout sterilization, filling, and transport from the Primary Engineering Control ("PEC") into the lyophilizer. Smoke studies shall be conducted to demonstrate that transport from the PEC to the lyophilizer can be accomplished while maintaining ISO 5 laminar flow air at all times. The smoke study shall be recorded and available for inspection.

(b) The pharmacy shall establish, maintain, and follow policies and procedures for the high-level disinfection of the chamber, piping, and all other areas of the lyophilizer which pose a potential risk of contamination to the product.

(c) The pharmacy shall, initially and after any change to the cleaning process or agents, validate a high-level disinfection process for the lyophilizer. For the purposes of this rule, validation means that the high-level disinfection process shall be proven with validation studies performed with the 5 aerobic bacterial and fungal ATCC organisms referenced in USP Chapter 71. The validation studies must be performed by an external vendor or by an internal laboratory. A pharmacy with an internal laboratory shall be separated from the compounding area and the work area to prevent contamination in the pharmacy. Documentation of validation shall be readily available for inspection.

(d) A policy and procedure for cleaning the lyophilizer prior to high level disinfection to include cleaning agents and schedules shall be established. Documentation of cleaning shall be maintained and readily available for inspection.

(e) The pharmacy shall establish policies and procedures as well as a schedule for the maintenance of the lyophilizer, which shall be, at a minimum, based on the manufacturer's recommendations. As leakage into the vacuum chamber poses a risk of contamination to the product, the maintenance schedule shall include provisions for periodically testing for leaks along with all recommended procedures described by the equipment manufacturer. Documentation of routine maintenance shall be available for inspection.

(f) The pharmacy shall develop standard operating procedures (SOPs) and a quality assurance program to include validation of the filling process, container closure integrity, the frequent monitoring of fill volumes, training and assessment of personnel involved in all aspects of compounding sterile products for lyophilization, identification of overfills and underfills, equipment qualification, formula verification, and evaluation of the finished product for conformance to specifications.

(g) The pharmacy shall establish provisions for sterilizing the inert gas or air used for backfilling during the vacuum release phase. Filters shall be used to sterilize the gas or air and shall undergo manufacturer's recommended integrity testing.

(h) Media fills shall be conducted using maximum batch sizes. The media fills shall demonstrate the filling, transportation to the lyophilizer, loading, and stoppering operations. Media shall not be frozen as part of the media fill as freezing of the media could reduce the ability of the media to support growth.

(i) Personnel preparing sterile compounds for lyophilization shall wear sterile Personal Protective Equipment (PPE) that allows all exposed skin to be covered.

(j) Personnel shall perform Glove Fingertip Sampling with each batch after the fill and transport of the vials. This sampling shall be documented and incorporated into the batch record.

(k) In-process acceptance criteria for each lyophilized product shall be established and may include criteria such as color, moisture limits and visual appearance. A one hundred percent (100%) visual examination of the finished product shall be conducted to determine that the product conforms to the established visual criteria. This examination shall be documented and incorporated in the batch record.

(l) Laboratory testing.

1. Finished product testing shall be conducted on all batches. Procedures for selecting samples from the batch for testing shall be written and followed. Procedures may include location of vials in the lyophilizer (e.g. select from each corner and the middle of each shelf) and position in the fill line (e.g. beginning, middle, and end of fill.)

2. Finished product testing for all batches shall include sterility testing with methods described in USP Chapter 71 unless an alternative method has been validated and shown to be equivalent or better. Diluents for reconstituting the vials for testing shall be preservative free. Lyophilized products released with beyond use dates within USP Chapter 797 guidelines shall, in lieu of sterility testing, conduct viable air, surface, and personnel (gloves and sleeves) sampling for each batch.

3. Endotoxin limits shall be established for every lyophilized product.

4. Endotoxin testing for all lyophilized batches shall be performed in accordance with USP Chapter 85 and confirmed to fall within the set limits. This shall be documented on the batch record.

5. Potency, radiochemical purity or applicable test to assure label claim shall be conducted on every batch and documented in the batch record. In lieu of potency testing, weight-based verification may occur based on formula verification. Weight based verification will be based on ninety to one hundred ten percent (90% – 110%) theoretical yield. Potency testing shall be based on USP monograph if one is available; if not, it shall be based on ninety to one hundred ten percent (90% – 110%) theoretical yield.

6. Initial potency testing shall be established based on worst case scenario.

(6) Clarifications, Variances, or Exceptions to the United States Pharmacopeia:

(a) Although the USP requires the donning of gloves prior to entry into the clean-room, all required donning of gloves can be performed after entry into the clean-room to avoid contamination of the gloves from the door handle or access device leading into the clean-room.

(b) USP Chapter 797 requires that: "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 (see Table 1) environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable." For purpose of said provision, a "low volume of hazardous drugs" is defined as less than 40 doses per month.

(c) USP Chapter 797 provides as follows in the "Facility Design and Environmental Controls" section: "An ISO Class 7 (see Table 1) buffer area and ante-area supplied with HEPA-filtered air shall receive an ACPH of not less than 30. The PEC is a good augmentation to generating air changes in the air supply of an area but cannot be the sole source of HEPA-filtered air. If the area has an ISO Class 5 (see Table 1) recirculating device, a minimum of 15 ACPHs through the area supply HEPA filters is adequate, providing the combined ACPH is not less than 30. More air changes may be required, depending on the number of personnel and processes. HEPA-filtered supply air shall be introduced at the ceiling, and returns should be mounted low on the wall, creating a general top-down dilution of area air with HEPA-filtered make-up air. Ceiling-mounted returns are not recommended." Notwithstanding the quoted provision, pharmacies that meet the standards set forth in the section quotes as of the effective date of this rule are not required to change the location of supply air or return filters or ducts so long as the ISO standards are maintained.

(d) USP Chapter 797 provides in part that the compounding facility's ceiling tiles located in the ante-area, buffer area, and clean room that consist of inlaid panels "shall be impregnated with a polymer to render them impervious and hydrophobic, and they shall be caulked around each perimeter to seal them to the support frame." A pharmacy shall not be required to caulk the inlaid ceiling tiles to the perimeter of the support frame if the following are met:

1. The ceiling tiles are specifically manufactured to be utilized in a facility that must meet and maintain an airborne particulate cleanliness of ISO Class 7 or better.

2. The core of the ceiling tiles are sealed on the front, back, and all edges to render them impervious and hydrophobic, so they can be properly maintained and cleaned as required by this rule.

3. The ceiling tiles are inlaid or installed using a gasket grid sealing system, which is manufactured for use in facilities that must meet and maintain an airborne particulate cleanliness of ISO Class 7 or better. The sealing system must create and maintain a positive seal between the ceiling tiles and the support frame and the seal between the ceiling tiles and support frame shall be secured with retention clips.

*Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.0155, 465.022 FS. History—New 6-18-08, Amended 1-7-10, 10-1-14, 12-18-16, 8-19-19.*

#### **64B16-27.800 Requirement for Patient Records.**

(1) A patient record system shall be maintained by all pharmacies for patients to whom new or refill prescriptions are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a new or refill prescription is presented for dispensing. The pharmacist shall ensure that a reasonable effort is made to obtain, record and maintain the following information:

(a) Full name of the patient for whom the drug is intended;

(b) Address and telephone number of the patient;

(c) Patient's age or date of birth;

(d) Patient's gender;

(e) A list of all new and refill prescriptions obtained by the patient at the pharmacy maintaining the patient record during the four (4) years immediately preceding the most recent entry showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber; and,

(f) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) The pharmacist shall ensure that a reasonable effort is made to obtain from the patient or the patient's agent and shall record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review. The pharmacist shall record any related information indicated by a licensed health care practitioner.

(3) A patient record shall be maintained for a period of not less than four (4) years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

(4) Patient records shall be maintained for prescriptions dispensed subsequent to the effective date of this regulation.

*Rulemaking Authority 465.022, 465.0155 FS. Law Implemented 465.0155, 465.022 FS. History—New 8-18-93, Formerly 21S-27.800, 61F10-27.800, 59X-27.800, Amended 6-15-98, 3-18-15.*

#### **64B16-27.810 Prospective Drug Use Review.**

(1) A pharmacist shall review the patient record and each new and refill prescription presented for dispensing in order to promote therapeutic appropriateness by identifying:

(a) Over-utilization or under-utilization;

- (b) Therapeutic duplication;
- (c) Drug-disease contraindications;
- (d) Drug-drug interactions;
- (e) Incorrect drug dosage or duration of drug treatment;
- (f) Drug-allergy interactions;
- (g) Clinical abuse/misuse.

(2) Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the potential problems which shall, if necessary, include consultation with the prescriber.

*Rulemaking Authority 465.022, 465.0155 FS. Law Implemented 465.0155 FS. History—New 8-18-93, Formerly 21S-27.810, 61F10-27.810, 59X-27.810.*

#### **64B16-27.820 Patient Counseling.**

(1) Upon receipt of a new or refill prescription, the pharmacist shall ensure that a verbal and printed offer to counsel is made to the patient or the patient's agent when present. If the delivery of the drugs to the patient or the patient's agent is not made at the pharmacy the offer shall be in writing and shall provide for toll-free telephone access to the pharmacist. If the patient does not refuse such counseling, the pharmacist, or the pharmacy intern, acting under the direct and immediate personal supervision of a licensed pharmacist, shall review the patient's record and personally discuss matters which will enhance or optimize drug therapy with each patient or agent of such patient. Such discussion shall be in person, whenever practicable, by toll-free telephonic communication, or by an interactive audio and digital image format, and shall include appropriate elements of patient counseling. Such elements may include, in the professional judgment of the pharmacist, the following:

- (a) The name and description of the drug;
- (b) The dosage form, dose, route of administration, and duration of drug therapy;
- (c) Intended use of the drug and expected action (if indicated by the prescribing health care practitioner);
- (d) Special directions and precautions for preparation, administration, and use by the patient;
- (e) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
- (f) Techniques for self-monitoring drug therapy;
- (g) Proper storage;
- (h) Prescription refill information;
- (i) Action to be taken in the event of a missed dose;
- (j) The potential for physical dependence, addiction, misuse, or abuse; and
- (k) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) Patient counseling as described herein, shall not be required for inpatients of a hospital or institution where other licensed health care practitioners are authorized to administer the drug(s).

(3) A pharmacist shall not be required to counsel a patient or a patient's agent when the patient or patient's agent refuses such consultation.

*Rulemaking Authority 465.022, 465.0155 FS. Law Implemented 465.0155 FS. History—New 8-18-93, Formerly 21S-27.820, 61F10-27.820, 59X-27.820, Amended 7-11-18.*

#### **64B16-27.830 Standards of Practice – Drug Therapy Management.**

(1) "Prescriber Care Plan" means an individualized assessment of a patient and orders for specific drugs, laboratory tests, and other pharmaceutical services intended to be dispensed or executed by a pharmacist. The Prescriber Care Plan shall be written by a physician licensed pursuant to Chapter 458, 459, 461, or 466, F.S., or similar statutory provision in another jurisdiction, and may be transmitted by any means of communication. The Prescriber Care Plan shall specify the conditions under which a pharmacist shall order laboratory tests, interpret



laboratory values ordered for a patient, execute drug therapy orders for a patient, and notify the physician.

(2) "Drug Therapy Management" means any act or service by a pharmacist in compliance with orders in a Prescriber Care Plan.

(3) A pharmacist may provide Drug Therapy Management services for a patient, incidental to the dispensing of medicinal drugs or as a part of consulting concerning therapeutic values of medicinal drugs or as part of managing and monitoring the patient's drug therapy. A pharmacist who provides Drug Therapy Management services for a patient shall comply with orders in a Prescriber Care Plan, insofar as they specify:

(a) Drug therapy to be initially dispensed to the patient by the pharmacist, or

(b) Laboratory values or tests to be ordered, monitored and interpreted by the pharmacist, or

(c) The conditions under which the duly licensed practitioner authorizes the execution of subsequent orders concerning the drug therapy for the patient, or

(d) The conditions under which the pharmacist shall contact or notify the physician.

(4) A pharmacist who provides Drug Therapy Management services shall do so only under the auspices of a pharmacy permit that provides the following:

(a) A transferable patient care record that includes:

1. A Prescriber Care Plan that includes a section noted as "orders" from a duly licensed physician for each patient for whom a pharmacist provides Drug Therapy Management services,

2. Progress notes; and,

(b) A pharmaceutical care area that is private, distinct, and partitioned from any area in which activities other than patient care activities occur, and in which the pharmacist and patient may sit down during the provision of Drug Therapy Management services; and,

(c) A continuous quality improvement program that includes standards and procedures to identify, evaluate, and constantly improve Drug Therapy Management services provided by a pharmacist.

*Rulemaking Authority 465.005, 465.0155 FS. Law Implemented 465.003(13), 465.0155, 465.022(1)(b) FS. History—New 4-4-00.*

### **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/ecommm/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 the 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.

*Rulemaking Authority 456.013, 465.005, 465.0155, 465.009, 465.022(12) FS. Law Implemented 456.013, 456.42, 456.43, 465.0155, 465.003, 465.009, 465.016(1)(i), (s), 465.017, 465.022(12), 893.04 FS. History—New 8-29-02, Amended 2-24-03, 11-18-07, 12-24-15, 6-14-18.*

### **64B16-27.850 Standards of Practice for Orthotics and Pedorthics.**

#### (1) Definitions.

(a) "Orthosis" means a medical device used to provide support, correction, or alleviation of neuromuscular or musculoskeletal dysfunction, disease, injury, or deformity, but does not include the following assistive technology devices: upper extremity adaptive equipment used to facilitate the activities of daily living, including specialized utensils, combs, and brushes; finger splints; wheelchair seating and equipment that is an integral part of the wheelchair and not worn by the patient; elastic abdominal supports that do not have metal or plastic reinforcing stays; arch supports; nontherapeutic accommodative inlays and nontherapeutic accommodative footwear, regardless of method of manufacture; unmodified, over-the-counter shoes; prefabricated foot care products; durable medical equipment such as canes, crutches, or walkers; dental appliances; or devices implanted into the body by a physician. For purposes of this subsection, "accommodative" means designed with the primary goal of conforming to the individual's anatomy and "inlay" means any removable material upon which the foot directly rests inside the shoe and which may be an integral design component of the shoe.

(b) "Orthotics" means the practice, pursuant to a licensed physician's written prescription, of evaluating, treatment formulating, measuring, designing, fabricating, assembling, fitting, adjusting, servicing, or providing the initial training necessary to accomplish the fitting of an orthosis or pedorthic device; however, the repair, replacement, adjustment, or servicing of any existing orthosis may be performed without an additional prescription from the patient's physician, unless the original prescription states otherwise. If a patient is under the care of a licensed occupational therapist or physical therapist, the pharmacist must consult with the therapist if the therapist has requested consultation regarding the fitting, design, or fabrication of an orthosis or regarding treatment with an orthosis.

(c) "Pedorthic device" means therapeutic shoes, shoe modifications made for therapeutic purposes, prosthetic fillers of the forefoot, and foot orthoses for use from the ankle and below, but does not include arch supports; nontherapeutic accommodative inlays and nontherapeutic accommodative footwear, regardless of method of manufacture; unmodified, over-the-counter shoes; or prefabricated foot care products. For purposes of this subsection, "accommodative" means designed with the primary goal of conforming to the individual's anatomy and "inlay" means any removable material upon which the foot directly rests inside the shoe and which may be an integral design component of the shoe.

(d) "Pedorthics" means the practice, pursuant to a licensed physician's written prescription, of evaluating, treatment formulating, measuring, designing, fabricating, assembling, fitting, adjusting, servicing, or providing the initial training necessary to accomplish the fitting of a pedorthic device; however, the repair, replacement, adjustment, or servicing of any existing pedorthic device may be performed without an additional prescription from the patient's physician, unless the original prescription states otherwise. If a patient is under the care of a licensed

occupational therapist or physical therapist, the pharmacist must consult with the therapist if the therapist has requested consultation regarding the fitting, design, or fabrication of a pedorthic device or regarding treatment with a pedorthic device.

(2) Pursuant to a licensed physician's written prescription, the pharmacist shall assume the responsibility for assessing the patient, planning the patient's treatment program, and directing the program. No pharmacist shall implement a prescription that, in the pharmacist's judgment, is contraindicated. No change shall be made in the prescription without the authorization of the prescribing physician.

(3) The pharmacist's professional responsibilities include:

(a) Ongoing consultation with the prescribing physician regarding information that will impact the patient's medical and functional outcomes.

(b) Orthotic and/or pedorthic evaluation of the patient.

(c) Identification and documentation of precautions, special problems, or contraindications.

(d) Development of a treatment plan including the short and long terms goals.

(e) Implementation of a treatment plan.

(f) Periodic review and update of the treatment plan, including reassessment of the patient in reference to goals and, when necessary, modification of the treatment plan.

(g) Collaboration with members of the health care team when appropriate.

(h) Advising the patient, in terms which the patient can understand, of the nature and purpose of the services to be rendered and the techniques for use and care of an orthosis or pedorthic device.

(i) Determination of the appropriateness of proper fit and function of any orthosis or pedorthic device.

(4) A pharmacist may delegate duties to nonlicensed supportive personnel if those duties are performed under the supervision of the pharmacist. In such instances the supervising pharmacist is responsible for all acts performed by such persons. It is below the standard of practice and prohibited for a pharmacist to delegate or assign activities, tasks or procedures that fall within the scope of any practice defined in Section 468.812(3), F.S., to support personnel, without providing supervision for the performance of the activities, tasks or procedures.

*Rulemaking Authority 468.812(3) FS. Law Implemented 465.0155, 468.812(3) FS. History—New 5-2-07.*

#### **64B16-27.851 Record-Keeping for Orthotics and Pedorthics.**

(1) The pharmacist or supportive personnel shall prepare and maintain in a timely manner patient records which include, at a minimum, the following:

(a) The patient name, address and telephone number;

(b) The location and dates of all treatment, evaluation or consultation;

(c) The name of the prescribing physician;

(d) All prescriptions pertaining to services provided to the patient;

(e) A treatment or service plan;

(f) Progress notes for each session.

(2) The licensee may charge a fee for the reproduction of records, which shall be no greater than \$ 1.00 per page for the first 25 pages, and \$0.50 per page for every page after 25. In addition, the actual cost of postage may be added. Reasonable costs of reproducing radiographs and such other kinds of records shall be the actual costs. "Actual costs" means the cost of the material and supplies used to duplicate the record and the labor and overhead costs associated with the duplication.

(3) The licensee shall retain the patient record for at least four (4) years from the date of last entry, unless otherwise provided by law.

*Rulemaking Authority 465.1901 FS. Law Implemented 456.057(17), 465.0155, 465.022 FS. History—New 5-2-07, Amended 3-18-15.*

**CHAPTER 64B16-28**  
**GENERAL REQUIREMENTS – PERMITS**

64B16-28.100	Pharmacy Permits – Applications and Permitting
64B16-28.101	Prescription Area Accessible to Inspection
64B16-28.102	Sink and Running Water, Sufficient Space, Refrigeration, Sanitation, Equipment
64B16-28.103	Sufficient Space in Prescription Department (Repealed)
64B16-28.1035	Patient Consultation Area
64B16-28.104	Refrigeration (Repealed)
64B16-28.105	Sanitation (Repealed)
64B16-28.106	Right to Inspect Invoices (Repealed)
64B16-28.107	Pharmacy Equipment (Repealed)
64B16-28.108	All Permits – Labels and Labeling of Medicinal Drugs
64B16-28.1081	Regulation of Daily Operating Hours; Commencement of Operations
64B16-28.10801	All Permits – Delivery of Medicinal Drugs
64B16-28.109	Prescription Department; Padlock; Sign: “Prescription Department Closed”
64B16-28.110	Outdated Pharmaceuticals
64B16-28.111	Storage of Equipment (Repealed)
64B16-28.112	Violations (Repealed)
64B16-28.113	Permits; Single Entity; Single Location
64B16-28.1135	Change of Ownership (Transferred)
64B16-28.114	Prescription Refills (Repealed)
64B16-28.118	Unit Dose and Customized Patient Medication Package Returns
64B16-28.119	Data Processing Systems in Pharmacy (Repealed)
64B16-28.1191	Unclaimed Prescriptions
64B16-28.120	All Permits – Storage of Legend Drugs; Prepackaging
64B16-28.121	Permit Fees (Repealed)
64B16-28.130	Transmission of Prescription Orders (Repealed)
64B16-28.140	Record Maintenance Systems for All Pharmacy Permits
64B16-28.141	Requirements for use of an Automated Pharmacy System by a Community Pharmacy
64B16-28.150	Record Maintenance Systems for Institutional and Animal Shelter Permits (Repealed)
64B16-28.201	Definitions (Repealed)
64B16-28.202	Closing of a Pharmacy; Transfer of Prescription Files
64B16-28.2021	Change of Ownership
64B16-28.203	Transfer of Medicinal Drugs; Change of Ownership; Closing of a Pharmacy
64B16-28.301	Destruction of Controlled Substances – Institutional Class I Pharmacies (Nursing Homes)
64B16-28.303	Destruction of Controlled Substances All Permittees (Excluding Institutional Class I Nursing Homes)
64B16-28.402	Labels and Labeling of Medicinal Drugs – Community Pharmacy Permit (Repealed)
64B16-28.404	Regulation of Daily Operating Hours (Repealed)
64B16-28.450	Centralized Prescription Filling, Delivering and Returning
64B16-28.451	Pharmacy Common Database; Exceptions for Prescription Drug Processing Only Pharmacies
64B16-28.501	Consultant Pharmacist of Record; Initial Designation; Change
64B16-28.502	Class I, Class II and Class III Institutional Permit – Labels and Labeling of Medicinal Drugs for Inpatients of a Nursing Home
64B16-28.503	Transmission of Starter Dose Prescriptions for Patients in Class I or Modified II B Institutional Facilities
64B16-28.602	Institutional Class II and Class III Dispensing

64B16-28.6021	Institutional Class II and Class III Pharmacy – Emergency Department Dispensing
64B16-28.603	Class II and Class III Institutional Pharmacy Operating Hours
64B16-28.604	Class II and Class III Institutional Pharmacy Department Security
64B16-28.605	Class II and Class III Institutional Pharmacies – Automated Distribution and Packaging
64B16-28.606	Remote Medication Order Processing for Class II or Class III Institutional Pharmacies or Special Pharmacy
	Permits Servicing Class I, Class II, Modified Class II, Class III, and Special ALF Permitted Facilities
64B16-28.607	Automated Pharmacy System – Long-Term Care, Hospice, and Prison
64B16-28.608	Automated Filling Systems within a Pharmacy
64B16-28.702	Modified Class II Institutional Pharmacies
64B16-28.750	Class III Institutional Pharmacies
64B16-28.800	Special Pharmacies
64B16-28.802	Special Sterile Compounding Permits for Pharmacies and Outsourcing Facilities
64B16-28.810	Special Pharmacy – Limited Community Permit
64B16-28.820	Sterile Products and Special Parenteral/Enteral Compounding
64B16-28.830	Special – Closed System Pharmacy
64B16-28.840	Special – Non Resident (Mail Service) (Repealed)
64B16-28.850	Special Pharmacy – ESRD
64B16-28.860	Special Pharmacy – Parenteral/Enteral Extended Scope Permit
64B16-28.870	Special-ALF
64B16-28.900	Definitions – Nuclear Pharmacy
64B16-28.901	Nuclear Pharmacy – General Requirements
64B16-28.902	Nuclear Pharmacy – Minimum Requirements
64B16-28.903	Training Qualifications (Repealed)
64B16-28.904	Nuclear Pharmacist – Continuing Education (Repealed)
64B16-28.905	Nonresident Sterile Compounding Permit Inspections; Approved Inspection Entities (Transferred)

### **64B16-28.100 Pharmacy Permits – Applications and Permitting.**

This rule section establishes the application and permitting requirements for pharmacies regulated under Chapter 465, F.S. Any pharmacy establishment shall apply to the board for the appropriate permit on forms indicated in this rule. Applications and forms referenced in this section may be accessed or downloaded from the web at <http://floridaspharmacy.gov/resources/> or may be obtained by contacting the Board the Board of Pharmacy, at 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or (850)488-0595. Inquiries regarding the status of the application or license verification may be obtained at <http://www.FLHealthsource.gov>. The application must be accompanied by the appropriate fee as specified by Rule 64B16-26.1022, F.A.C.

(1) All Permits:

(a) A permit is valid only for the name and, pursuant to Rule 64B16-28.113, F.A.C., physical location (address) to which it is issued. The name in which the permit is issued must be the name in which the company is doing business, i.e., the name that appears on purchase and sales invoices.

1. The name in which a permit is issued may be changed upon notification to the board. To change the name in which a permit is issued the person or establishment must file with the board an original Form DH-MQA 1227 "Pharmacy Permit Name Change Form" effective December 2010, which is incorporated by reference herein, and is available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-02297> or on the web at <http://floridaspharmacy.gov/resources/>.

2. A pharmacy permit holder may request a change of practice location by completing the appropriate section(s) of the application form for the permit type.

3. Pharmacy permits are non-transferrable. However, pursuant to Rule 64B16-28.2021, F.A.C., transfers of ownership interests of business entities holding a permit may be allowed. A pharmacy permit holder shall notify the

Board of changes of ownership interests of business entities by completing the appropriate section(s) of the application form for the permit type.

(b) Each applicant must comply with the fingerprinting requirements in Section 465.022, F.S. Electronic fingerprint information ("EFI") that has been submitted to the Florida Agency for Health Care Administration may be accessible by the Florida Department of Health for a period of sixty (60) months. If the Department is able to access EFI from AHCA, applicants will not be required to resubmit EFI for additional or new applications submitted during this time period. After sixty (60) months, new electronic fingerprint information must be submitted as part of all applications.

(c) Passing an onsite inspection is a prerequisite to issuance of a new permit, whether based on an initial application, change of ownership, or change of address. At the time of the onsite inspection, the board inspector will document the applicant's compliance with all applicable rules and statutes.

(d) Pursuant to subsection 465.022(4), F.S., each applicant must attach to the application the applicant's written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships. The policy and procedure manual shall contain, at a minimum, the following:

1. Provisions to identify and guard against invalid practitioner-patient relationships.
2. Provisions to guard against filling fraudulent prescriptions for controlled substances.
3. Provisions to identify prescriptions that are communicated or transmitted legally.
4. Provisions to identify the characteristics of a forged or altered prescription.

(2) A Community Pharmacy Permit, as authorized by Section 465.018, F.S., is required for every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis. Applicants for a community pharmacy permit must complete an application for a permit using an original Form DH-MQA 1214, "Community Pharmacy Permit Application and Information," Rev 01/18, which is incorporated by reference herein and is available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-09431>. Applicants for a Community Pharmacy Permit must comply with all permitting requirement found in subsection (1) of this rule and designate a prescription department manager as required by Section 465.018, F.S.

(3) An Institutional Pharmacy Permit, as authorized by section 465.019, F.S., is required for any location in any health care institution where medicinal drugs are compounded, dispensed, stored or sold. Applicants for an Institutional Pharmacy permit must complete an application for a permit using an original Form DH-MQA 1215, "Institutional Pharmacy Permit Application and Information," Rev 01/18, which is incorporated by reference herein and is available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-09432>. Applicants for an Institutional Pharmacy Permit must comply with all permitting requirements found in subsection (1) of this rule and designate a consultant pharmacist of record as required by section 465.019, F.S.

(4) A Nuclear Pharmacy Permit, as authorized by Section 465.0193, F.S., is required for every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. Applicants for a Nuclear Pharmacy permit must complete an application for a permit using an original Form DH-MQA 1218, "Nuclear Pharmacy Permit Application and Information," Rev 01/18, which is incorporated by reference herein and is available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-09433>. Applicants for a Nuclear Pharmacy Permit must comply with all permitting requirements found in subsection (1), of this rule and designate a nuclear pharmacist as the prescription department manager as required by subsection 64B16-28.901(1), F.A.C.

(5) A Special Pharmacy Permits as authorized by Section 465.0196, F.S., is required for any location where medicinal drugs are compounded, dispensed, stored, or sold and which is not a community pharmacy, institutional pharmacy, nuclear pharmacy or internet pharmacy. Applicants for a Special-Limited Community, Special – Parenteral and Enteral, Special – Closed System Pharmacy, Special – End Stage Renal Disease (ESRD), Special – Parenteral/Enteral Extended Scope, and Special – Assisted Living Facility (ALF) permits must complete an application for a permit using an original Form DH-MQA 1220, "Special Pharmacy Permit Application and Information," Rev 01/18, which is incorporated by reference herein and is available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-09434>.

(a) Applicants for a Special Pharmacy Permit must comply with all permitting requirement found in subsection (1) of this rule; and designate a prescription department manager or consultant pharmacist of record as required by Section 465.0196, F.S.

(b) The Board recognized the following types of Special Pharmacy permits:

1. A Special Limited Community Permit is required for any Institutional Class II Pharmacy that dispenses medicinal drugs to employees, medical staff, emergency room patients, and other patients on continuation of a course of therapy.

2. A Special Parenteral and Enteral Permit is required for any pharmacy which provides parenteral (IV), enteral, and cytotoxic pharmacy services to outpatients. The applicant must be compliant with the Standard for Compounding Sterile Preparations found in Rule 64B16-27.797, F.A.C. Special – Parenteral and Enteral Pharmacy Permits may stand-alone or be used in conjunction with a Community Pharmacy or Special – Closed System Pharmacy Permit. The permittee must provide 24-hour telephone accessibility.

3. A Special Closed System Pharmacy Permit is required for any pharmacy not open to the public and where prescriptions are individually prepared for dispensing utilizing closed delivery systems, for ultimate consumers in health care institutions including nursing homes, jails, Assisted Living Facilities (ALFs), Intermediate Care Facilities for the Developmentally Delayed (ICF-IID) or other custodial care facilities when defined by AHCA rules which the Board may approve. This permit may not provide medications to in-patients in a hospital.

4. A Special Pharmacy – End Stage Renal Disease (ESRD) Permit is required for any pharmacy which is limited in scope of pharmacy practice to the provision of dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home or specified address.

5. A Special Pharmacy – Parenteral/Enteral Extended Scope Permit is required for any pharmacy which compounds patient specific parenteral/enteral preparations in conjunction with institutional pharmacy permits, as provided in Rule 64B16-28.560, F.A.C.

6. Special – Assisted Living Facility (ALF) Permit is an optional facility license for those Assisted Living Facilities providing a drug delivery system utilizing medicinal drugs provided in unit dose packaging.

(6) An Internet Pharmacy Permit, as authorized by Section 465.0197, F.S., is required for any location not otherwise licensed or issued a permit under this chapter, within or outside this state that uses the Internet to communicate with or obtain information from consumers and uses the information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Applicants for an Internet Pharmacy permit must complete an application for a permit using an original Form DH-MQA 1216, "Internet Pharmacy Permit Application and Information" which is incorporated by reference herein and is available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-09435> Rev 01/18. Applicants for an Internet Pharmacy Permit must comply with all permitting requirements found in subsection (1) of this rule and designate a prescription department manager or consultant pharmacist of record as required by Section 465.0197, F.S.

(7) Special Sterile Compounding Permit: Except those pharmacies which already hold an active stand-alone Special Parenteral/Enteral or Special Parenteral/Enteral Extended Scope Compounding permit, or a Modified Class II-B pharmacy that meets the requirements of subsection 64B16-28.802(6), F.A.C., any pharmacy, including an outsourcing facility, engaged in sterile compounding must obtain a special sterile compounding permit by filing an application on form DH-MQA 1270, "Special Sterile Compounding Permit Application and Information," Rev 01/18, which is incorporated by reference herein and is available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-09436>.

Applicants for a Special Sterile Compounding Permit must comply with all permitting requirements in subsection (1) of this rule and designate a prescription department manager or consultant pharmacist of record.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 456.013, 456.025(3), 456.0635, 465.003, 465.018, 465.019, 465.0193, 465.0196, 465.0197, 465.022 FS. History–New 2-21-13, Amended 9-23-13, 5-31-17, 6-5-18.*

#### **64B16-28.101 Prescription Area Accessible to Inspection.**

(1) The prescription department compounding room or any other place where prescriptions are compounded, filled,



processed, accepted, dispensed, or stored in each pharmacy shall be so situated and located that authorized agents and employees of the Department or other persons authorized by law to enter and inspect, can observe and survey the confines of said department, room or area and can enter into said department, room or area after identifying themselves, for the purpose of inspection at a reasonable hour or when the practice of the profession of pharmacy is being carried on, as defined in Section 465.003, F.S., without having been previously detained or announced. Such inspection may be routinely conducted at any time by authorized agents of the Department to determine whether Chapter 465, F.S., or provisions of these rules have been violated or for other lawful purposes, and need not be in response to a complaint filed with the Department. There shall be a minimum of one (1) inspection per year except as otherwise provided herein or directed by the Board.

(a) A pharmacy shall be inspected twice during the first year of operation.

(b) A pharmacy which has had passing inspections for the most current three years, and no discipline during the most current three years shall be inspected every two years.

(c) A pharmacy which fails to obtain a passing inspection or which is disciplined during the two year inspection cycle will be inspected annually until it achieves passing inspections for the most current three years, and no discipline during the most current three years as set forth in this subsection.

(2) Authorized agents and employees of the Department or other persons authorized by law shall have the right to inspect invoices, shipping tickets, or any other document pertaining to the transfer of drugs or drug preparations, from or to all pharmacies and a reasonable amount of time shall be allowed for said information to be made available.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.017, 465.022 FS. History—New 5-19-72, 11-2-81, Formerly 21S-1.01, 21S-1.001, Amended 7-31-91, Formerly 21S-28.101, 61F10-28.101, 59X-28.101, Amended 5-4-05, 2-2-12.*

#### **64B16-28.102 Sink and Running Water, Sufficient Space, Refrigeration, Sanitation, Equipment.**

There shall be provided for the prescription department of each pharmacy:

(1) An adequate sink in workable condition and running water easily accessible to the prescription counter that shall be available during the hours when the prescription department is normally open for the business related to prescriptions.

(2) Sufficient shelf, drawer or cabinet space for the neat and orderly storage of pharmaceutical stock, prescription containers, prescription labels, the required equipment, and all other items, articles or equipment stored therein and there shall be sufficient walking space and sufficient work counter space within each prescription department of said establishment so as to allow employees or pharmacists employed therein to adequately, safely, and accurately fulfill their duties related to prescriptions.

(3) Adequate facilities for the proper storage of pharmaceuticals which require refrigeration, and such pharmaceuticals shall be stored therein, and in such manner as to preserve their therapeutic activity.

(4) Adequate sanitation to insure the prescription department is operating under clean, sanitary, uncrowded, and healthy conditions.

(5) The following items:

(a) A current pharmacy reference compendium such as the United States Pharmacopoeia/National Formulary, the U.S. Dispensatory, USP DI, (United States Pharmacopoeial Drug Information), the Remington Practice of Pharmacy, Facts and Comparisons or an equivalent thereof sufficient in scope to meet the professional practice needs of that pharmacy, and a current copy of the laws and rules governing the practice of pharmacy in the State of Florida. It shall be acceptable, in lieu of an actual hard copy, to maintain these materials in a readily available electronic data format.

(b) Such other equipment as is necessary to meet the needs of the professional practice of pharmacy.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History—New 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.02, 21S-1.002, 21S-28.102, 61F10-28.102, 59X-28.102, Amended 5-4-05.*

### **64B16-28.103 Sufficient Space in Prescription Department.**

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History–New 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.03, 21S-1.003, 21S-28.103, 61F10-28.103, 59X-28.103, Repealed 5-4-05.*

### **64B16-28.1035 Patient Consultation Area.**

A community pharmacy shall provide a private consultation area so all patients of the pharmacy will be able to obtain counseling without being overheard by others in the prescription dispensing area of the pharmacy. The consultation area must be accessible by the patient from the outside of the prescription dispensing area of the pharmacy without having to traverse a stockroom or the prescription dispensing area. In determining whether the area is suitable, consideration shall be given to the proximity of the counseling area to the check-out or cash register area, the volume of pedestrian traffic in and around the consultation area, and the presence of walls or other barriers between the counseling area and the prescription dispensing area of the pharmacy. The consultation area may consist of designated private counter space. The area shall be designated with a sign bearing "Patient Consultation Area," or words that are substantially similar.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–New 9-20-99, Amended 5-4-05.*

### **64B16-28.104 Refrigeration.**

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History–New 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.04, 21S-1.004, 21S-28.104, 61F10-28.104, 59X-28.104, Repealed 5-4-05.*

### **64B16-28.105 Sanitation.**

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–New 5-19-72, Repromulgated 12-18-74, Amended 1-29-80, Formerly 21S-1.07, 21S-1.007, Amended 7-31-91, Formerly 21S-28.105, 61F10-28.105, 59X-28.105, Repealed 5-4-05.*

### **64B16-28.106 Right to Inspect Invoices.**

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.017 FS. History–New 5-19-72, Repromulgated 12-18-74, Amended 10-10-78, 4-30-85, Formerly 21S-1.008, 21S-28.106, 61F10-28.106, 59X-28.106, Repealed 5-4-05.*

### **64B16-28.107 Pharmacy Equipment.**

*Rulemaking Authority 465.005, 465.022, 465.022(1)(h) FS. Law Implemented 465.022(1)(h) FS. History–New 5-19-72, Repromulgated 12-18-74, Amended 4-8-80, 4-26-84, Formerly 21S-1.10, Amended 4-4-88, Formerly 21S-1.010, Amended 7-31-91, Formerly 21S-28.107, 61F10-28.107, Amended 6-4-97, Formerly 59X-28.107, Amended 2-4-99, Repealed 5-4-05.*

### **64B16-28.108 All Permits – Labels and Labeling of Medicinal Drugs.**

Each container of medicinal drugs dispensed shall have a label or shall be accompanied by labeling.

(1) Definitions.

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

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

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

(c) "Labeling" means a label or other written, printed, or graphic material upon an agent or product or any of its

containers, wrappers, drug carts, or compartments thereof, as well as a medication administration record (MAR) if a medication administration record is an integral part of the unit dose system.

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

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

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

(a) Name and address of the pharmacy.

(b) Date of dispensing.

(c) Serial number.

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

(e) Name of the prescriber.

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

(g) Directions for use.

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

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

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

(a) Brand or generic name.

(b) Strength.

(c) Dosage form.

(d) Name of the manufacturer.

(e) Expiration date.

(f) Lot number:

1. Manufacturer's lot number; or

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

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

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

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

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

(b) The label includes:

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

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

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

4. Patient's name.
5. Name of each prescriber.
6. Directions for use and any cautionary statements required for each medicinal drug.
7. Storage instructions.
8. Name, strength, quantity and physical description of each drug product.
9. A beyond use date that is not more than 60 days from the date of preparation of the customized patient medication package but shall not be later than any appropriate beyond use date for any medicinal drug included in the customized patient medication package.
  - (c) The customized patient medication package can be separated into individual medicinal drug containers, then each container shall identify the medicinal drug product contained.
  - (7) The label affixed to the immediate outer container shield of a radiopharmaceutical shall include:
    - (a) Name and address of the pharmacy.
    - (b) Name of the prescriber.
    - (c) Date of the original dispensing.
    - (d) The standard radiation symbol.
    - (e) The words "Caution Radioactive Material."
    - (f) Name of the procedure.
    - (g) Prescription order number.
    - (h) Radionuclide and chemical form.
    - (i) Amount of radioactivity and the calibration date and time.
    - (j) Expiration date and time.
    - (k) If a liquid, the volume.
    - (l) If a solid, the number of items or weight.
    - (m) If a gas, the number of ampules or vials.
    - (n) Molybdenum 99 content to the United States Pharmacopeia (UPS) limits.
    - (o) Name of the patient or the words "Physician's Use Only."
  - (8) The label affixed to the immediate inner container of a radiopharmaceutical to be distributed shall include:
    - (a) The standard radiation symbol.
    - (b) The words "Caution Radioactive Material."
    - (c) Radionuclide and chemical form.
    - (d) Name of the procedure.
    - (e) Prescription order number of the radiopharmaceutical.
    - (f) Name of the pharmacy.
  - (9) The labeling on a carton or package containing a medicinal drug or product dispensed from an Extended Scope Renal Dialysis (ESRD) pharmacy shall include:
    - (a) "Use as Directed" statement.
    - (b) The name and address of the person to whom the products will be delivered.
    - (c) Name of the prescriber.
    - (d) Name and address of the ESRD pharmacy location from which the products were shipped.
    - (e) Prescription number.
    - (f) Any special instructions regarding delivery dates or locations.
    - (g) Beyond use date or, if the medicinal drug or product is dispensed in an unopened sealed package, the manufacturer's expiration date.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1), 465.0255 FS. History—Amended 5-19-72, Repromulgated 12-18-74, Amended 10-10-78, 9-18-84, 1-20-85, Formerly 21S-1.13, Amended 10-2-88, Formerly 21S-1.013, Amended 7-31-91, 10-1-92, 4-19-93, 7-12-93, Formerly 21S-28.108, 61F10-28.108, 59X-28.108, Amended 3-31-05, 4-22-13.*

**64B16-28.1081 Regulation of Daily Operating Hours; Commencement of Operations.**

(1) Any person who receives a community pharmacy permit pursuant to Section 465.018, F.S., and commences to operate such an establishment, shall keep the prescription department of the establishment open for a minimum of twenty (20) hours per week.

(a) "Commences to Operate" means the compounding, dispensing, storage, or sale of medicinal drugs or the filling or dispensing of prescriptions.

(b) The Board recognizes that a delay may exist between the time a pharmacy receives a Florida pharmacy permit and commences to operate. Accordingly, upon receipt of a Florida pharmacy permit, a community pharmacy may delay commencement of operations in compliance with the following:

1. Within fourteen (14) days of receipt of the Florida pharmacy permit, the permittee shall notify the Board office, in writing, of the permittee's election to delay commencement of operations and the reason(s) therefore;

2. The permittee shall display a sign in block letters not less than one inch in height at the main entrance of the establishment stating that the pharmacy is not yet open for business and that medicinal drugs may not be dispensed or sold nor prescriptions filled or dispensed;

3. Within two (2) business days of commencement of operations, the permittee shall notify the Board office in writing that the permittee has commenced to operate and the date of commencement.

(c) Any pharmacy permittee that does not commence to operate within six (6) months of the date of receipt of the Florida pharmacy permit shall provide a written statement to the Board office, which shall include the reason(s) the pharmacy has not yet commenced operations, the efforts the pharmacy has made to commence to operate, and the date the pharmacy expects to commence to operate.

(2) At the time a pharmacy commences to operate, a sign in block letters not less than one inch in height stating the hours the prescription department is open each day shall be displayed either at the main entrance of the establishment or at or near the place where prescriptions are dispensed in a prominent place that is in clear and unobstructed view. Any pharmacy that is not open 40 hours a week, must post the days and hours that the pharmacy is open and the information for after-hours access and shall also have a written policy and procedure for transferring a prescription pursuant to Section 465.026, F.S., or receiving an emergency dose pursuant to Section 465.0275, F.S.

*Rulemaking Authority 465.005, 465.022(1) FS. Law Implemented 465.022(1)(b) FS. History—New 4-10-05, Amended 2-1-12, 8-23-16.*

**64B16-28.10801 All Permits – Delivery of Medicinal Drugs.**

(1) Neither a pharmacy nor a pharmacist shall dispense or deliver any adulterated medicinal drugs.

(2) All pharmacies regulated under Chapter 465, F.S., must have and follow policies and procedures to ensure medicinal drugs are not adulterated as defined in Section 499.006, F.S, at the time of receipt by the patient or their agent.

(3) The policies and procedures must include providing instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.

*Rulemaking Authority 465.005, 465.022(1) FS. Law Implemented 465.022(1)(a) FS. History—New 10-29-19.*

**64B16-28.109 Prescription Department; Padlock; Sign: "Prescription Department Closed."**

(1) The prescription department of any community pharmacy permittee shall be considered closed whenever the establishment is open and a pharmacist is not present and on duty. A sign with bold letters not less than two (2) inches in width and height, shall be displayed in a prominent place in the prescription department so that it may easily be read by patrons of that establishment. The sign shall contain the following language: "Prescription Department Closed."

(2) The term "not present and on duty" shall not be construed to prevent a pharmacist from exiting the prescription department for the purpose of consulting or responding to inquiries or providing assistance to patients or customers,

attending to personal hygiene needs, taking a meal break pursuant to Rule 64B16-27.1001, F.A.C., or performing any other function for which the pharmacist is responsible, provided that such activities are conducted in a manner consistent with the pharmacist's responsibility to provide pharmacy services.

(3) At all times when the prescription department is closed, either because of the absence of a pharmacist or for any other reason, it shall be separated from the remainder of the establishment by partition or other means of enclosure, thereby preventing access to the prescription department by persons not licensed in Florida to practice the profession of pharmacy.

(4) The partition or other means of enclosure shall be securely locked or padlocked and only a pharmacist shall have the means to gain access to the prescription department.

(5) Whenever the prescription department of any community pharmacy establishment is closed, no person other than a pharmacist shall enter, be permitted to enter or remain in the prescription department.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History—New 8-20-63, 5-19-72, Repromulgated 12-18-74, Amended 5-6-80, Formerly 21S-1.14, 21S-1.014, Amended 7-31-91, Formerly 21S-28.109, 61F10-28.109, 59X-28.109, Amended 6-15-98, 4-10-05.*

#### **64B16-28.110 Outdated Pharmaceuticals.**

Under no circumstances may prescription drugs, pharmaceuticals or devices which bear upon the container an expiration or beyond use date which has been reached be sold or dispensed to the public. Accordingly, all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs and pharmaceuticals shall be removed or quarantined from active stock.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022, 465.023(1)(c), 499.006(9), 499.0121(5) FS. History—New 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.17, 21S-1.017, 21S-28.110, 61F10-28.110, 59X-28.110, Amended 4-4-19.*

#### **64B16-28.111 Storage of Equipment.**

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History—Promulgated 12-18-74, Formerly 21S-1.19, 21S-1.019, 21S-28.111, 61F10-28.111, 59X-28.111, Repealed 4-10-05.*

#### **64B16-28.112 Violations.**

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History—New 8-20-63, Amended 5-19-72, Promulgated 12-18-74, Formerly 21S-1.23, 21S-1.023, Amended 7-31-91, Formerly 21S-28.112, 61F10-28.112, 59X-28.112, Repealed 4-10-05.*

#### **64B16-28.113 Permits; Single Entity; Single Location.**

A Board of Pharmacy permit shall be issued only to a single entity at a single location. The service provided by the permit shall be consistent with the issued permit. A single location shall be defined as:

(1) A contiguous area under the control of the permit holder. For purposes of this section, a public thoroughfare will be considered to have not broken the area of contiguity; and,

(2) An area not more than one-half mile from the central location of the permit.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(11)(a), 465.018, 465.019, 465.0193, 465.0196 FS. History—New 1-30-96, Formerly 59X-28.113.*

#### **64B16-28.1135 Change of Ownership.**

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(11)(a), 465.018, 465.019, 465.0193, 465.0196, 465.022(7) FS. History—New 4-19-00, Amended 1-2-02, Transferred to 64B16-28.2021.*

#### **64B16-28.114 Prescription Refills.**

*Rulemaking Authority 465.005, 465.016(1), 465.022, 465.022(1)(a), 893.04 FS. Law Implemented 465.022 FS. History—New 12-18-74, Formerly 21S-1.28, 21S-1.028, Amended 7-31-91, Formerly 21S-28.114, 61F10-28.114, 59X-28.114, Amended 2-4-02, 7-1-02, Repealed 10-5-09.*

#### **64B16-28.118 Unit Dose and Customized Patient Medication Package Returns.**

(1) Definitions. As used herein:

(a) A "unit dose system" means a system wherein all individually sealed unit doses are physically connected as a unit. For purpose of this rule, a product in an unopened, sealed, manufacture's container is deemed to be a unit dose package.

(b) A "customized patient medication package" means a system wherein all USP approved multi-dose units are physically connected (also referred to as a "container"). The use of customized patient medication packages must comply with the provisions of subsection 64B16-28.108(5), F.A.C.

(c) A "closed drug delivery system" is a system in which the actual control of the unit dose or customized patient medication package is maintained by the facility rather than by the individual patient.

(d) For purposes of this rule, "facility" shall mean any health care institution operating with a Class I, Class II, Modified Class II, or Special ALF permit.

(2) No pharmacist shall place into the stock of any pharmacy permittee any part of any prescription, compounded or dispensed, which is returned by a patient except under the following conditions:

(a) In a closed drug delivery system in which unit dose or customized patient medication packages are dispensed to in-patients, the unused medication may be returned to the pharmacy for redispensing only if each unit dose or customized patient medication package is individually sealed and if each unit dose or the unit dose system, or the customized patient medication package container or the customized patient medication package unit of which it is clearly a part is labeled with the name of the drug, dosage strength, manufacturer's control number, and expiration date, if any.

(b) In the case of controlled substances, as it is allowed by Federal Law.

(3) All pharmacies utilizing unit dose or customized patient medication packages shall address specific policies and procedures regarding their preparation and use in the pharmacy's Policy and Procedures Manual.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.016(1)(l), 465.019 FS. History—New 11-10-80, Formerly 21S-1.36, 21S-1.036, Amended 7-31-91, Formerly 21S-28.118, 61F10-28.118, 59X-28.118, Amended 9-23-99, 7-1-02, 9-18-17.*

#### **64B16-28.119 Data Processing Systems in Pharmacy.**

*Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.022, 465.026, 893.07 FS. History—New 9-21-83, Formerly 21S-1.38, 21S-1.038, Amended 7-31-91, Formerly 21S-28.119, Amended 3-16-94, Formerly 61F10-28.119, 59X-28.119, Repealed 7-15-99.*

#### **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.

*Rulemaking Authority 465.0255 FS. Law Implemented 465.0255 FS. History—New 4-10-05.*

#### **64B16-28.120 All Permits – Storage of Legend Drugs; Prepackaging.**

(1) All medicinal drugs or drug preparations as defined by Section 465.003(8), F.S., shall be stored:

(a) Within the confines of the prescription department of a community pharmacy permittee as defined in Section 465.018, F.S.

(b) In a Class II Institutional pharmacy as defined by Section 465.019(2)(b), F.S., within the confines of the pharmacy provided, however, that those medicinal drugs established by the consultant pharmacist as supportive to treatment procedures such as medical drugs, surgical, obstetrical, diagnostic, etc., may be permitted to be stored in those areas where such treatment is conducted consistent with proper control procedures as provided by the policy and procedure manual of the pharmacy.

(2) All medicinal drugs or drug preparations as defined in Section 465.003(8), F.S., within Class I Institutional permittees as defined in Section 465.019(2)(a), F.S., and Special ALF Permit Rule 64B16-28.870, F.A.C., shall:

(a) Be administered from individual prescription containers to the individual patient; and,

(b) Be prohibited within the confines of Class I Institutional pharmacies unless obtained upon a proper prescription and properly labeled in accordance with Chapter 499, F.S., and the rules and regulations contained in Chapter 59A-4, F.A.C., incorporated by reference and effective August 1, 2006, pertaining to the licensure of nursing homes and related facilities.

(3) Prepackaging of medication, whether a part of a unit dose system or a part of a multiple dose drug distribution system in an extended care facility or hospital holding a valid Class II Institutional pharmacy permit, must be done in accordance with procedures set up by the consultant pharmacist of record in the policy and procedure manual; and in the case of a pharmacy holding a valid community pharmacy permit must be done in accordance with procedures set up by the prescription department manager.

(4) Medicinal drugs and proprietary preparations as identified above that are stored in treatment areas must be accessible only to licensed staff (pharmacists, nurses, physicians, advanced registered nurse practitioners, physician assistants, respiratory and physical therapist, radiology technicians and registered pharmacy technicians, etc.) in accordance with their license, practice act, or to other personnel specifically authorized by the institution.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 435.019(2), 465.003(7), 465.022 FS. History—New 9-18-84, Formerly 21S-1.44, 21S-1.044, Amended 7-31-91, Formerly 21S-28.120, 61F10-28.120, 59X-28.120, Amended 2-8-07, 8-16-10.*

#### **64B16-28.121 Permit Fees.**

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History—New 7-31-91, Formerly 21S-28.121, 61F10-28.121, 59X-28.121, Amended 10-30-00, Repealed 4-10-05.*

#### **64B16-28.130 Transmission of Prescription Orders.**

*Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.022, 465.026, 893.07 FS. History—New 3-16-94, Formerly 61F10-28.130, 59X-28.130, Repealed 4-10-05.*

#### **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.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(14), 465.022, 465.026, 465.035, 893.07 FS. History—New 3-16-94, Formerly 61F10-28.140, Amended 3-12-97, 6-4-97, Formerly 59X-28.140, Amended 10-*

29-97, 6-15-98, 11-11-98, 10-15-01, 3-24-14.

**64B16-28.141 Requirements for use of an Automated Pharmacy System by a Community Pharmacy.**

(1) Definitions:

(a) "Automated pharmacy system (APS)" means a mechanical system that performs operations or activities, other than compounding or administration, relative to storage, packaging, dispensing, or distribution of medication, and which collects, controls, and maintains all transaction information.

(b) "Establishment" means one general physical location that may extend to one or more contiguous suites, units, floors, or buildings operated and controlled exclusively by entities under common operation and control. Where multiple buildings are under common ownership, operation, and control, an intervening thoroughfare does not affect the contiguous nature of the buildings.

(c) "Pharmacist" means a pharmacist as defined by Section 465.003, FS.

(2) General Requirements. A pharmacy may use an automated pharmacy system provided that:

(a) The automated pharmacy system is located within the prescription department, adjacent to the prescription department, or is located on the establishment of the licensed pharmacy, and the operation of the automated pharmacy system is under the supervision of a pharmacist. An automated pharmacy system that is not located within the prescription department shall be operated as an extension of the licensed pharmacy and the automated pharmacy system shall not require an independent and separate community pharmacy permit. An automated pharmacy system that is not located within the prescription department shall have conspicuously displayed on the automated pharmacy system the name, address, contact information and the permit number of the community pharmacy that is responsible for the operation of the automated pharmacy system.

(b) The pharmacy develops and maintains a policy and procedure manual that includes:

1. The type or name of the system including a serial number or other identifying nomenclature.
2. A method to ensure security of the system to prevent unauthorized access. Such method may include the use of electronic passwords, biometric identification (optic scanning or fingerprint) or other coded identification.
3. A process of filling and stocking the system with drugs; an electronic or hard copy record of medication filled into the system including the product identification, lot number, and expiration date.
4. A method of identifying all the registered pharmacy interns or registered pharmacy technicians involved in the dispensing process.
5. Compliance with a Continuous Quality Improvement Program.
6. A method to ensure that patient confidentiality is maintained.
7. A process to enable the prescription department manager or designee to revoke, add, or change access at any time.

(c) The system ensures that each prescription is dispensed in compliance with the definition of dispense as defined by Section 465.003, F.S., and the practice of the profession of pharmacy. The system shall include a mechanism to ensure that the patient or an authorized agent of the patient has a means to communicate with a pharmacist responsible for dispensing the medical drug product. The means of communication may include in person, electronic, digital, or telephonic.

(d) The system shall maintain a readily retrievable electronic record to identify all pharmacists, pharmacy interns, registered pharmacy technicians, or other personnel involved in the dispensing of a prescription.

(e) The system shall provide the ability to comply with product recalls generated by the manufacturer, distributor, or pharmacy. The system shall have a process in place to isolate affected lot numbers including an intermix of drug product lot numbers.

(3) Additional Requirements for Patient Accessed Automated Pharmacy Systems. A pharmacy may use a patient accessed automated pharmacy system, provided that:

(a) The requirements in subsection (2) above, are met.

(b) Except as provided in paragraph (d) below, the stocking or restocking of a medicinal drug shall only be completed by the following:

1. A pharmacist;
2. A pharmacy intern under the direct and immediate personal supervision of a pharmacist; or
3. A registered pharmacy technician under the direct supervision of a pharmacist.

(c) Access to the Automated Pharmacy System in the absence of a pharmacist for purposes of servicing and maintenance by non-pharmacy licensed personnel shall be permitted provided that the system is capable of tracking individual access and preventing unauthorized access, and the system employs user based access or other technology that will prevent access to areas of the dispensing cabinet where drugs are stored. If the system does not employ such technology, access to the system for servicing and maintenance is permitted only under the direct supervision of a pharmacist.

(d) If the automated pharmacy system uses removable cartridges or containers to store the drug or uses unit of use packages, the stocking or restocking of the cartridges, containers or unit of use packages may occur at a licensed repackaging facility and may be sent to the provider pharmacy to be loaded by personnel designated by the pharmacist if:

1. A pharmacist verifies the cartridge, container or unit of use packages have been properly filled and labeled.
2. The individual cartridge, container or unit of use package is transported to the provider pharmacy in a secure, tamper-evident container.
3. The automated pharmacy system uses a bar code verification, electronic verification, weight verification, radio frequency identification (RFID) or similar process to ensure that the cartridge, container or unit of use package is accurately loaded into the automated pharmacy system.
4. The pharmacist verifying the filling and labeling retains responsibility if the cartridge, container or unit of use package is stocked or restocked incorrectly by the personnel designated to load the cartridges or containers.

(e) The automated pharmacy system must use at least two separate verifications, such as bar code verification, electronic verification, weight verification, radio frequency identification (RFID), visual verification or similar process to ensure that the proper medication is being dispensed from the automated system.

(f) The medication shall bear a patient specific label that complies with Rule 64B16-28.108, F.A.C.

(g) The record of transactions with the patient accessed automated pharmacy system shall be available to authorized agents of the Department of Health. The record of transactions shall include:

1. Name of the patient.
2. Name, strength, and dosage form of the drug product dispensed.
3. Quantity of drug dispensed.
4. Date and time of dispensing.
5. Name of provider pharmacy.
6. Prescription number.
7. Name of prescribing practitioner.
8. Identity of the pharmacist who approved the prescription or order.
9. Identity of the person to whom the drug was released.

(4) The pharmacist responsible for filling, verifying, loading or supervising the automated pharmacy system shall be responsible for her or his individual action.

(5) A prescription dispensed pursuant to the requirements of this rule shall be deemed to have been certified by the pharmacist.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.018, 465.022 FS. History—New 11-29-04, Amended 12-30-07, 1-1-10, 7-5-18.*

#### **64B16-28.150 Record Maintenance Systems for Institutional and Animal Shelter Permits.**

*Rulemaking Authority 465.005, 465.0155, 465.022, 828.055 FS. Law Implemented 465.022, 465.019, 465.026, 893.07, 828.055 FS. History—New 4-12-95, Formerly 59X-28.150, Repealed 5-3-05.*

### **64B16-28.201 Definitions.**

*Rulemaking Authority 465.005, 465.022, 465.022(1)(g) FS. Law Implemented 465.022(1)(g) FS. History—New 12-26-79, Amended 4-28-83, 4-30-85, Formerly 21S-16.01, 21S-16.001, Amended 7-31-91, Formerly 21S-28.201, 61F10-28.201, 59X-28.201, Repealed 4-5-05.*

### **64B16-28.202 Closing of a Pharmacy; Transfer of Prescription Files.**

(1) The term "prescription files" as used herein shall mean the drug dispensing records of a pharmacy which shall include all orders for drugs or medicinal supplies as defined by Section 465.003(7), F.S., inclusive of dispensing records for medicinal drugs listed within the provisions of Section 893.03, F.S., issued by a duly licensed practitioner, which serve to transfer possession of medicinal drugs from the pharmacy to the ultimate consumer.

(2) The term "closing of a pharmacy" as used herein shall mean the cessation or termination of professional and business activities within a pharmacy for which a permit has been issued under Chapter 465, F.S.

(3) Prior to closure of a pharmacy the permittee shall notify the Board of Pharmacy in writing as to the effective date of closure, and shall:

(a) Return the pharmacy permit to the Board of Pharmacy office or arrange with the local Bureau of Investigative Services of the Department to have the pharmacy permit returned to the Board of Pharmacy;

(b) Advise the Board of Pharmacy which permittee is to receive the prescription files.

(4) On the date of closure of a pharmacy the former permittee shall:

(a) Physically deliver the prescription files to a pharmacy operating within reasonable proximity of the pharmacy being closed and within the same locality. This delivery of prescription files may occur prior to the return of the pharmacy permit to the Board of Pharmacy office; and,

(b) Affix a prominent sign to the front entrance of the pharmacy advising the public of the new location of the former permittee's prescription files or otherwise provide a means by which to advise the public of the new location of their prescription files.

(5) After the closing of a pharmacy as defined herein, the custody of the prescription files of the pharmacy shall be transferred to the new permittee, unless the former permittee and the new permittee inform the Board in writing that custody of the prescription files have been or are to be transferred to a pharmacy other than the new permittee.

(6) A pharmacy receiving custody of prescription files from another pharmacy shall maintain the delivered prescriptions in separate files so as to prevent intermingling with the transferee pharmacy's prescription files.

*Rulemaking Authority 465.022(1)(g) FS. Law Implemented 465.022(1)(g) FS. History—New 12-26-79, Formerly 21S-16.02, 21S-16.002, Amended 7-31-91, Formerly 21S-28.202, 61F10-28.202, 59X-28.202, Amended 4-5-05.*

### **64B16-28.2021 Change of Ownership.**

(1) A pharmacy permit is not transferable. If upon the sale of an existing pharmacy, there is any change in the identity of the natural person, partnership, or business entity which holds the permit, a new application must be filed and a new permit obtained. For purposes of this rule, the test for determining change of identity shall be whether the person or entity's Federal Employer Identification Number (FEIN) remains the same following the sale.

(2) Permits held by business entities with no change in identity. In those cases where the permit is held by a business entity (e.g. a corporation, limited liability company, limited partnership, etc.) which entity continues to hold the permit without change in identity, the transfer of the ownership interests of said business entity to another person or business entity does not constitute a change of ownership (requiring application for and issuance of a new pharmacy permit). Upon transfer of the ownership interests in the business entity, the following steps shall be taken:

(a) Within fifteen (15) days of closing the transfer, the permittee shall notify the Board office of the transfer of ownership interests; and,

(b) As specified in Section 465.022(3), F.S., all persons, members, partners, officers, directors, and agents having an ownership or other financial interest of greater than five percent (5%), and all persons who directly or indirectly

manage, oversee, or control the operation of the business entity, must file with the board a set of fingerprints as specified in paragraph 64B16-28.100(1)(c), F.A.C.

(3) If a criminal history check identifies any person listed in paragraph (2)(b) above, as meeting any of the provisions of Section 465.022(5) or (6), F.S., the Board staff shall refer the matter to the Department for investigation and possible prosecution as provided in Section 465.023, F.S.

(4) A change in ownership (and issuance of a new permit number) requires that new records be started and old records closed. The process for closing a pharmacy, including the transfer of prescription files and medicinal drugs, as outlined in Rules 64B16-28.202 and 64B16-28.203, F.A.C., must be followed for the old permit. If the old permit has controlled substances, the new permit must record an "opening inventory" for DEA purposes. Both the new permit and the old permit must keep appropriate records for four (4) years for the transfer of legend drugs and controlled substances.

(5) A change in the company or person who leases the building where the permit is housed or a change in the management company which contracts with the owner of the permit for the operation of the permit does not constitute a change in ownership.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(11)(a), 465.018, 465.019, 465.0193, 465.0196, 465.022, 465.023 FS. History—New 4-19-00, Amended 1-2-02, Formerly 64B16-28.1135, Amended 4-5-05, 7-14-14, 7-14-16.*

#### **64B16-28.203 Transfer of Medicinal Drugs; Change of Ownership; Closing of a Pharmacy.**

Ownership of medicinal drugs, including those medicinal drugs within the provisions of Section 893.03, F.S., may be transferred to a new owner upon the change of ownership of a pharmacy, as defined in Rule 64B16-28.202, F.A.C., or upon the closing of a pharmacy, as defined in Rule 64B16-28.202, F.A.C. The transferee entity acquiring ownership shall be authorized to prescribe, dispense or distribute such drugs. The transferor pharmacy shall provide the Florida Board of Pharmacy with the following information:

(1) The name, address, pharmacy permit number and D.E.A. registration number of the transferor pharmacy.

(2) The name, address, permit number, D.E.A. registration number (if available), and authorized business activity of the transferee entity.

(3) The date on which the transfer will occur.

(4) A complete inventory of all medicinal drugs within the provisions of Section 893.03, F.S., as of the date of transfer. If the medicinal drug is listed in Schedule II, the transferor shall make an exact count or measure of the contents. If the medicinal drugs are listed in Schedule III, IV, or V, the transferor shall make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules, in which case an exact count of the contents shall be made. This inventory shall serve as the final inventory of the permittee transferor and the transfer inventory of the transferee entity. The transferor and transferee shall each retain a copy of the inventory in their records and shall provide the Board of Pharmacy with a copy of such inventory. Transfer of any controlled substance in Schedule II shall require the use of order form, D.E.A. form number 222.

(5) Unless the permittee-transferor is informed by the Board of Pharmacy or the regional D.E.A. Administrator prior to the date on which the transfer was stated to occur, that the transfer may not occur, the permittee-transferor may proceed with the transfer.

(6) On the date of transfer of the medicinal drugs, all records required to be kept by the permittee-transferor of the transferred drugs which are listed in Section 893.03, F.S., shall be transferred to the permittee-transferor. Responsibility for the accuracy of records prior to the date of transfer remains with the permittee-transferor, but responsibility for custody and maintenance shall be upon the permittee-transferee. It is the responsibility of the permittee-transferor to return all unused Schedule II order forms (D.E.A. form no. 222) to the regional D.E.A. office.

*Rulemaking Authority 465.005, 465.022(1)(g) FS. Law Implemented 465.022(1)(g) FS. History—New 12-26-79, Formerly 21S-16.03, 21S-16.003, 21S-28.203, 61F10-28.203, 59X-28.203, Amended 4-5-05.*

**64B16-28.301 Destruction of Controlled Substances – Institutional Class I Pharmacies (Nursing Homes).**

(1) Controlled substances that have been dispensed and not used by the patient shall not be returned to the pharmacy and shall be securely stored by the nursing home until destroyed.

(2) For each controlled substance destroyed, documentation must be completed showing the name and quantity of the drug, strength and dosage form, patient's name, prescription number and name of the institution. Destruction of the controlled substance shall be witnessed by at least two (2) of the following individuals:

(a) Consultant pharmacist;

(b) Director of nursing;

(c) Facility administrator;

(d) A licensed physician, mid-level practitioner, nurse, or another pharmacist employed by or under contract or written agreement with the facility; or

(e) A sworn law enforcement officer.

Those individuals witnessing the destruction of the controlled substance shall sign the completed documentation.

(3) The consultant pharmacist shall be responsible for the creation and implementation of policies and procedures to ensure that controlled substances are disposed of in accordance with applicable state and federal laws and rules. Furthermore, the consultant pharmacist shall review all controlled substance destruction documentation monthly to ensure compliance with this rule and federal and state law.

(4) The consultant pharmacist shall ensure that non-controlled substances are returned to the provider pharmacy in compliance with Rule 64B16-28.118, F.A.C.

*Rulemaking Authority 465.005, 465.022(12) FS. Law Implemented 465.022(12), 465.019, 893.07(1), (3), (5) FS. History—New 4-21-87, Formerly 21S-19.001, Amended 7-31-91, Formerly 21S-28.301, 61F10-28.301, Amended 1-30-96, Formerly 59X-28.301, Amended 7-21-09, 2-10-14, 11-5-17.*

**64B16-28.303 Destruction of Controlled Substances All Permittees (Excluding Institutional Class I Nursing Homes).**

(1) Controlled substances that cannot be retained as usable shall be securely stored in the pharmacy/prescription department of the permittee pharmacy until destroyed.

(2) Permittees are required to complete a United States Drug Enforcement Administration (D.E.A.) Form DEA-41 "Registrants Inventory of Drugs Surrendered" (effective 8/31/2014), herein incorporated by reference, available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-03998> or

[http://www.deadiversion.usdoj.gov/21cfr\\_reports/surrend/](http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/). This form, at the time of destruction, shall be witnessed and signed by the prescription department manager or the consultant pharmacist of record and D.E.A. agent, or a Department inspector. This method of destruction requires that a copy of the completed and witnessed Form DEA 41 be mailed to the D.E.A. office in his/her area within one (1) business day after the destruction.

(3) Another method of destruction shall be conducted by at least two persons: One will be the prescription department manager or the consultant pharmacist of record. The other will be one of the following: medical director or his/her physician designee, director of nursing or his/her licensed nurse designee, or a sworn law enforcement officer. These persons shall serve as the witnesses for the Form DEA-41 and the destruction. This method of destruction requires that a copy of the completed and witnessed Form DEA-41 be mailed to the D.E.A. office in the permittee's area within one (1) business day after destruction.

(4) In lieu of destruction on the premises as outlined in subsections (2) and (3) above, controlled substances may also be shipped to reverse distributors for destruction in conformity with federal guidelines.

(5) For patient specific controlled substance prescriptions in a Modified Institutional Class II B pharmacy, the destruction method in subsection 64B16-28.301(2), F.A.C., must be followed.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022, 465.018 FS. History—New 4-21-87, Formerly 21S-19.003, Amended 7-31-91, Formerly 21S-28.303, 61F10-28.303, Amended 1-30-96, Formerly 59X-*

28.303, Amended 2-5-07, 10-27-09, 2-1-12, 4-20-14.

**64B16-28.402 Labels and Labeling of Medicinal Drugs – Community Pharmacy Permit.**

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1), 465.0255 FS. History–New 7-3-91, Formerly 21S-28.402, Amended 12-27-93, Formerly 61F10-28.402, 59X-28.402, Amended 9-17-97, Repealed 5-11-05.*

**64B16-28.404 Regulation of Daily Operating Hours.**

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–New 8-20-65, Amended 5-19-72, Repromulgated 12-18-74, Amended 5-6-80, 3-31-81, Formerly 21S-1.24, Amended 7-14-88, Formerly 21S-1.024, Amended 7-31-91, 3-15-92, Formerly 21S-28.404, 61F10-28.404, Amended 9-21-94, Formerly 59X-28.404, 59X-28.404, Repealed 2-28-07.*

**64B16-28.404 Regulation of Daily Operating Hours (Repealed).**

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–New 8-20-65, Amended 5-19-72, Repromulgated 12-18-74, Amended 5-6-80, 3-31-81, Formerly 21S-1.24, Amended 7-14-88, Formerly 21S-1.024, Amended 7-31-91, 3-15-92, Formerly 21S-28.404, 61F10-28.404, Amended 9-21-94, Formerly 59X-28.404, 59X-28.404, Repealed 2-28-07.*

**64B16-28.450 Centralized Prescription Filling, Delivering and Returning.**

(1) As used herein:

(a) The term “originating pharmacy” means a pharmacy wherein the prescription which will be filled by the central fill pharmacy is initially presented; and,

(b) The term “central fill pharmacy” means a pharmacy which performs centralized prescription filling, delivering, and returning for one or more originating pharmacies.

(2) Pharmacies acting as the central fill pharmacy must:

(a) Be authorized to dispense medications under the provisions of Chapter 465, F.S., and the rules promulgated thereto; and,

(b) Have the same owner as the originating pharmacy or have a written contract specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which the pharmacies will comply with federal and state laws, rules, and regulations.

(3) All central fill and originating pharmacies engaged in centralized prescription filling shall create and keep current a Policy and Procedure Manual which shall:

(a) Be maintained at the locations of the central fill and originating pharmacies;

(b) Include the information required by subsections 465.0265(2)(a)-(f), F.S.;

(c) Designate the types of medications that may and may not be filled by the central fill pharmacy;

(d) Set forth procedures for communicating orders from the originating pharmacy to the central fill pharmacy;

(e) Set forth procedures for securely transporting the filled prescriptions from the central fill pharmacy to the originating pharmacy; and,

(f) Designate the specific services provided and the duties and responsibilities of the central fill and originating pharmacies.

(4) The central fill and originating pharmacy shall each be identified on the prescription container label. The originating pharmacy shall be identified with pharmacy name and address. The central fill pharmacy may be identified by a code available at the originating pharmacy. Prescription and labeling requirements for pharmacies participating in central prescription filling, delivering and returning:

(a) Prescriptions may be transmitted electronically from an originating pharmacy to a central fill pharmacy including via facsimile. The originating pharmacy transmitting the prescription information must:



1. Electronically record in the pharmacy record keeping system or document on the face of the original prescription that the prescription has been filled at a central fill pharmacy. If a controlled substance, write the word "central fill" on the face of the original prescription and record the name, address, and DEA registration number of the originating pharmacy to which the prescription has been transmitted and the name of the originating pharmacy's pharmacist transmitting the prescription, and the date of transmittal,
2. Ensure all the information required to be on a prescription pursuant to sections 456.0392 and 893.04, F.S., is transmitted to the central fill pharmacy either on the face of the prescription or in the electronic transmission of information,
3. Indicate in the information transmitted the number of refills already dispensed and the number of refills remaining,
4. Maintain the original prescription for a period of four (4) years from the date the prescription was last filled,
5. Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier) and the name of the originating pharmacy's employee accepting delivery.

(b) The central fill pharmacy receiving the transmitted prescription must:

1. Keep a copy of the prescription if sent via facsimile, or an electronic record of all the information transmitted by the originating pharmacy, including the name, address, and DEA registration number, if a controlled substance, of the originating pharmacy transmitting the prescription,
2. Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, and dates of filling or refilling of the prescription,
3. Keep a record of the date the filled prescription was delivered to the originating pharmacy and the method of delivery (private, common or contract carrier),
4. A central fill pharmacy's pharmacist filling a written or emergency oral prescription for a controlled substance listed in Schedule II shall affix to the package a label showing the date of filling, the originating pharmacy's name and address, a unique identifier (e.g., the central fill pharmacy's DEA registration number) indicating the prescription was filled at the central fill pharmacy, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription or required by law.

(5) Delivery of medications. All deliveries of medications from the central fill pharmacy to the originating pharmacy or to the ultimate consumer must be made in a timely manner.

(a) A community central fill pharmacy may deliver medications for an originating pharmacy to the ultimate consumer or the consumer's agent under the following additional conditions:

1. The pharmacies are under the same ownership or have a written contract specifying the services to be provided by each pharmacy, including delivery services to the ultimate consumer or the consumer's agent.
2. The pharmacies shall have a pharmacist available 40 hours a week, either in person or via two-way communication technology, such as a telephone, to provide patient counseling.
3. The pharmacies shall include a toll-free number that allows the patient to reach a pharmacist for the purposes of patient counseling.
4. The central fill pharmacy shall only deliver via carrier to the ultimate consumer or the consumer's agent those medications which could have been delivered via carrier by the originating pharmacy.
5. The central fill pharmacy shall not deliver to the ultimate consumer or consumer's agent substances listed as controlled substances under Chapter 893, F.S.

(b) The delivery of a filled prescription by a community central fill pharmacy to the ultimate consumer or the consumer's agent pursuant to a contract with an originating pharmacy shall not be considered dispensing within the definition set forth in subsection 465.003(6), F.S.

(c) A Class II institutional central fill pharmacy may only deliver medications to the originating pharmacy.

(6) Each pharmacist that performs a specific function within the processing of a central fill prescription shall be responsible for any errors or omissions committed by that pharmacist during the performance of that specific function.

(7) A community pharmacy which acts as the central fill pharmacy and which notifies the Board that its pharmacy practice is limited only to such practice shall be exempt from the following rules:

- (a) Rule 64B16-28.1035, F.A.C., Patient Consultation Area;
- (b) The signage requirement of subsection 64B16-28.109(1), F.A.C.; and,
- (c) Rule 64B16-28.1081, F.A.C., Regulation of Daily Operating Hours.

*Rulemaking Authority 465.005, 465.0155, 465.0265 FS. Law Implemented 465.003(16), 465.019, 465.022, 465.0265 FS. History—New 9-23-03, Amended 7-27-04, 4-28-08, 2-5-14, 8-27-15, 3-15-16.*

#### **64B16-28.451 Pharmacy Common Database; Exceptions for Prescription Drug Processing Only Pharmacies.**

(1) A pharmacy licensed under this chapter may perform prescription drug processing for other pharmacies, provided that all pharmacies are under common ownership, utilize a common database, and are properly licensed, permitted or registered in this state or another state. Nothing in this subsection shall prohibit a pharmacist employee of said pharmacies who is licensed in Florida or in another state from remotely accessing the pharmacy's electronic database from outside the pharmacy in order to process prescriptions, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

(2) Prescription drug processing shall include the following:

- (a) Receiving, interpreting, or clarifying a prescription;
- (b) Entering prescription data into the pharmacy's record;
- (c) Verifying or validating a prescription;
- (d) Performing prospective drug review as defined by the Board;
- (e) Obtaining refill and substitution authorizations;
- (f) Interpreting or acting on clinical data;
- (g) Performing therapeutic interventions;
- (h) Providing drug information concerning a patient's prescription; and,
- (i) Providing patient counseling.

(3) Each pharmacist that performs a specific function within the prescription drug processing process via use of a common database shall be responsible for any errors or omissions committed by that pharmacist during the performance of that specific function.

(4) Each pharmacy performing prescription drug processing pursuant to this section must maintain a policy and procedure manual, which shall be made available to the Board or its agent upon request. The policy and procedures manual shall include the following information:

- (a) A description for how each pharmacy will comply with federal and state laws, rules and regulations;
- (b) The procedure for maintaining appropriate records to identify the pharmacies and pharmacists responsible for the prescription drug processing and dispensing of the prescription;
- (c) The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information; and,
- (d) The procedure to be used by the pharmacy in implementing and operating a quality assurance program designed to objectively and systematically monitor, evaluate, and improve the quality and appropriateness of patient care.

(5) The prescription drug processing of a prescription by one pharmacy for another pursuant to this section shall not be construed as the transferring of a prescription as set forth in Section 465.026, F.S.

(6) In addition to all record requirements of Rule 64B16-28.140, F.A.C., all pharmacies participating in prescription drug processing, shall maintain appropriate records which identify, by prescription, the name(s), initials, or identification code(s) of each pharmacist or registered pharmacy technician who performs a processing function for a prescription. Such records shall be maintained:

- (a) Separately by each pharmacy and pharmacist, or
- (b) In a common electronic file, as long as the records are maintained in such a manner that the data processing system can produce a printout which lists the functions performed by each pharmacy, pharmacist, registered

pharmacy intern and registered pharmacy technician.

(7) Prescription drug processing only pharmacies. A pharmacy permittee which solely performs prescription drug processing for other pharmacies pursuant to this rule, and at which medicinal drugs are not compounded, dispensed, stored or sold, nor are prescriptions filled or dispensed, and which notifies the Board that its pharmacy practice is limited solely to prescription drug processing shall be exempt from the following rules:

- (a) Rule 64B16-28.102, F.A.C., Sink and Running Water, Sufficient Space, Refrigeration, Sanitation, Equipment;
- (b) Rule 64B16-28.1035, F.A.C., Patient Consultation Area;
- (c) Rule 64B16-28.1081, F.A.C., Regulation of Daily Operating Hours; and,
- (d) Subsection 64B16-28.109(1), F.A.C., relating to signage.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0266 FS. History—New 3-24-08, Amended 1-1-10, 7-14-16.*

### **64B16-28.501 Consultant Pharmacist of Record; Initial Designation; Change.**

(1) Designation as Consultant Pharmacist of Record.

(a) Initial Designation. Pursuant to Sections 465.019 and 465.022, F.S., a permit for an Institutional pharmacy may not be issued unless a licensed pharmacist is designated as the consultant pharmacist of record. In addition, pursuant to Rule 64B16-28.870, F.A.C., an application for a Special Assisted Living Facility pharmacy permit requires the supervising licensed pharmacist be designated as the consultant pharmacist of record. Finally, applications for Special Sterile Compounding Permits associated with an Institutional pharmacy require the pharmacist-in-charge be designated as the consultant pharmacist of record. Initial designation is accomplished as part of the application process using the appropriate application form incorporated in Rule 64B16-28.100, F.A.C.

(b) Change of Consultant Pharmacist of Record.

No later than ten (10) days after a change of designated consultant pharmacist for an Institutional, or Special Assisted Living Facility pharmacy, or a Special Sterile Compounding Permittee, both the pharmacy permittee and the newly designated consultant pharmacist of record shall notify the Board of the change and the identity of the newly designated consultant pharmacist. Notification shall be accomplished by completing Form DH-MQA 1184 (01/18), Consultant Pharmacist of Record (COR) Designation and Privacy Statement Acknowledgement, which is hereby incorporated by reference and which can be obtained from <http://www.flrules.org/Gateway/reference.asp?No=Ref-09437> or the Board's website at [http://floridaspharmacy.gov/Applications/app\\_change-consultant-pharmacist.pdf](http://floridaspharmacy.gov/Applications/app_change-consultant-pharmacist.pdf). In addition, an outgoing consultant pharmacist of record may choose to notify the Board they will no longer serve as consultant pharmacist of record using this form.

(c) Submission of Fingerprints. In addition to submission of Form DH-MQA 1184, the newly designated consultant pharmacist shall comply with the fingerprinting requirements of Sections 456.0135 and 465.022, F.S. Electronic fingerprint information ("EFI") that has been submitted to the Florida Agency for Health Care Administration may be accessible by the Florida Department of Health for a period of sixty (60) months. If the Department is able to access EFI from AHCA, applicants will not be required to resubmit EFI for additional or new applications submitted during this time period. After sixty (60) months, new electronic fingerprint information must be submitted as part of all applications.

(2) Continuous Designation. All Institutional, Special Assisted Living Facility, and, if applicable, Special Sterile Compounding Pharmacy permittees shall continuously maintain a designated consultant pharmacist of record at all times the pharmacy is open and in operation.

(3) Drug Regimen Reviews. The consultant pharmacist of record for a Class I, Class II, Modified Class II, or Class III Institutional permit shall conduct Drug Regimen Reviews as required by Federal or State law, inspect the facility and prepare a written report to be filed at the permitted facility at least monthly. In addition, the consultant pharmacist of record must monitor the facility system for providing medication administration records and physician order sheets to ensure that the most current record of medications is available for the monthly drug regimen review. The consultant pharmacist of record may utilize additional consultant pharmacists to assist in this review and in the

monthly facility inspection.

(4) Remote Access. A consultant pharmacist licensed in Florida may remotely access a facility or pharmacy's electronic database from outside the facility or pharmacy to conduct any services additional or supplemental to regular drug regimen reviews, subject to the pharmacy or facility establishing policies and procedures to ensure the security and privacy of confidential patient records, including compliance with applicable Federal HIPAA regulations.

*Rulemaking Authority 465.005, 465.0125, 465.022 FS. Law Implemented 465.0125, 465.019, 465.022, 465.0266 FS. History–New 7-18-94, Formerly 61F10-28.501, 59X-28.501, Amended 1-2-02, 12-30-07, 11-5-17, 6-5-18, 9-27-18.*

**64B16-28.502 Class I, Class II, and Class III Institutional Permit – Labels and Labeling of Medicinal Drugs for Inpatients of a Nursing Home.**

(1) The label affixed to a container used in conventional dispensing to a Class I, Class II or Class III Institutional permit which, within the scope of its practice, services only the inpatients of a nursing home as defined by subsection 400.021(5), F.S., shall contain at least the following information:

- (a) The name of and address of the pharmacy;
- (b) The name of the prescriber;
- (c) The name of the patient;
- (d) The date of the original filling or the refill date;
- (e) The prescription number or other prescription identification adequate to readily identify the prescription;
- (f) The directions for use;
- (g) The name of the medicinal drug dispensed (except where the health care practitioner prescribing the drug specifically denotes that the name is to be withheld);
- (h) The quantity of the drug in the container.

(2) The label affixed to a container used in dispensing substances listed in any of the schedules appearing in Chapter 893, F.S., in regard to conventional dispensing shall contain at least the following information:

- (a) All of the information required by subsection (1) of this rule;
- (b) The number of the prescription as recorded in the prescription files of the pharmacy in which it is filled; and,
- (c) A clear, concise warning that it is a crime to transfer the controlled substance to any person other than the patient for whom prescribed.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–New 7-31-91, Amended 10-1-92, Formerly 21S-28.502, 61F10-28.502, 59X-28.502, Amended 8-16-10, 9-27-18.*

**64B16-28.503 Transmission of Starter Dose Prescriptions for Patients in Class I or Modified II B Institutional Facilities.**

(1) Definitions.

- (a) "Vendor pharmacy" means a community pharmacy or special closed system pharmacy which has a contract to dispense a medicinal drug to a patient in a facility holding a Class I Institutional Permit or Modified II B Permit.
- (b) "Starter dose pharmacy" means a pharmacy that dispenses a medicinal drug pursuant to a starter dose prescription for a patient in a facility served by the vendor pharmacy.
- (c) "Starter dose prescription" means a prescription transmitted by a vendor pharmacy to a starter dose pharmacy for the purpose of initiating drug therapy for a patient in a facility served by the vendor pharmacy. The term "starter dose prescription" does not include prescriptions for controlled substances.

(2) A vendor pharmacy may transmit a starter dose prescription, excluding a prescription for a controlled substance, to a starter dose pharmacy if the vendor pharmacy:

- (a) Has written authorization from the facility to utilize a starter dose pharmacy.
- (b) Has written authorization from a prescribing practitioner, directly or via facility agreement, to act as the

practitioner's agent for the purpose of transmitting a starter dose prescription.

(c) Possess a valid prescription from the prescribing practitioner prior to transmitting the starter dose prescription.

(d) Maintains a record of each starter dose prescription.

(e) Maintains a policy and procedure manual that references starter dose prescriptions.

(3) A starter dose pharmacy may dispense a medicinal drug, excluding a controlled substance, pursuant to a starter dose prescription for a patient in a facility that holds a Class I Institutional Permit or Modified II B Permit if the starter dose pharmacy maintains a record of each starter dose prescription and maintains a policy and procedure manual that references starter dose prescriptions.

(4) A record of each starter dose prescription shall be readily retrievable and maintained for four (4) years.

*Rulemaking Authority 465.005, 465.019(4), 465.022 FS. Law Implemented 465.019, 465.022(12) FS. History—New 11-29-04, Amended 7-14-14, 7-19-17.*

#### **64B16-28.602 Institutional Class II and Class III Dispensing.**

(1) Pharmaceutical preparations which are administered to patients of a hospital by the personnel of such institution shall only be taken from the original container, or from a container which has been prepared by a Florida licensed pharmacist. Only single doses of such preparations shall be removed from the container, and then only after the preparation has been prescribed for a specific patient, and the order has been duly recorded upon the records of the institution. This requirement shall not apply to nor be construed as preventing the administration of treatment in bona fide emergency cases, or further as prohibiting any person who is a duly licensed physician from dispensing medicinal drugs as defined in Chapter 465, F.S. A single dose of medicinal drugs based upon a valid physician's drug order may also be obtained and administered under the supervision of the nurse in charge consistent with good institutional practice procedures as established by the consultant pharmacist of record and written in the policy and procedure manual which shall be available within the pharmacy.

(2) A Class II or Class III Institutional pharmacy may contract with a Special Parenteral/Enteral Extended Scope pharmacy for the pharmacy services provided for by Rule 64B16-28.860, F.A.C.

(a) Special Parenteral/Enteral Extended Scope pharmacies and institutional pharmacy permits shall create and comply with Policy and Procedure Manuals that delineate duties and responsibilities of each entity, including the following provisions:

1. The institutional pharmacy permit shall maintain records appropriate to ensure the provision of proper patient care.

2. The institutional pharmacy permit designee shall inspect and log in all medicinal drugs provided by the Special Parenteral/Enteral Extended Scope pharmacy.

3. A pharmacist for the institutional pharmacy shall provide drug utilization review and shall review each prescription order prior to transmission to the Special Parenteral/Enteral Extended Scope pharmacy.

(b) Such Policy and Procedure manuals shall be made available to the Board or Department upon request.

(c) Prior to contracting for such services the institutional pharmacy shall ensure that the Special Parenteral/Enteral Extended Scope pharmacy is licensed under the provisions of Rule 64B16-28.860, F.A.C.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.019(2)(b), 465.0196, 465.022(1) FS. History—Amended 5-19-72, Repromulgated 12-18-74, Amended 10-10-78, Formerly 21S-1.11, 21S-1.011, Amended 7-31-91, Formerly 21S-28.602, 61F10-28.602, Amended 9-4-96, Formerly 59X-28.602, Amended 8-16-10, 9-27-18.*

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

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

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

- (a) Patient name and address.
- (b) Drug and strength prescribed/dispensed.
- (c) Quantity prescribed/dispensed.
- (d) Directions for use.
- (e) Prescriber/dispenser.
- (f) Prescriber DEA registration, if applicable.
- (g) Reason community pharmacy services were not readily accessible.
- (3) Labeling of the prescription container must meet the requirements of Section 465.0276, F.S.
- (4) Quantity dispensed must not exceed a 24-hour supply or the minimal dispensable quantity, whichever is greater.

*Rulemaking Authority 465.005, 465.019(4), 465.022 FS. Law Implemented 465.019(2)(b), (4), 465.0196, 465.022(1) FS. History—New 9-20-99, Amended 8-16-10, 9-27-18.*

**64B16-28.603 Class II and Class III Institutional Pharmacy Operating Hours.**

Any person who receives a Class II or Class III Institutional permit pursuant to Section 465.019, F.S., and commences to operate such a pharmacy shall, for the benefit of the institutions’ patients’ health and welfare, keep the pharmacy of the establishment open for a sufficient number of daily operating hours required to provide adequate and quality pharmaceutical services to the patients of said institution.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History—New 7-31-91, Formerly 21S-28.603, 61F10-28.603, 59X-28.603, Amended 9-27-18.*

**64B16-28.604 Class II and Class III Institutional Pharmacy Department Security.**

The pharmacy department shall be considered closed whenever a Florida licensed pharmacist is not present and on duty. At all times when the pharmacy department is closed, either because of the absence of a Florida licensed pharmacist or for any other reason, it shall be secured to prevent access. When the pharmacy department is closed, no person other than a Florida licensed pharmacist shall enter, except as authorized by paragraph 465.019(2)(b), F.S., and Rule 64B16-28.602, F.A.C.

*Rulemaking Authority 465.005, 465.022(1), 465.019 FS. Law Implemented 465.019, 465.022(1) FS. History—New 9-21-94, Formerly 59X-28.604.*

**64B16-28.605 Class II and Class III Institutional Pharmacies – Automated Distribution and Packaging.**

- (1) Definitions.
  - (a) “Automated medication system” means a robotic, mechanical or computerized device that is not used for medication compounding and is designed to:
    1. Distribute medications in a licensed health care facility; or
    2. Package medications for final distribution by a pharmacist.
  - (b) “Centralized automated medication system” means an automated medication system located in a pharmacy department from which medication is distributed or packaged for final distribution by a pharmacist.
  - (c) “Decentralized automated medication system” means an automated medication system that is located outside of a pharmacy department but within the same institution.
  - (d) “Distribute” or “Distribution” means the process of providing a drug to an individual authorized to administer medications and licensed as a health care provider in the state of Florida pursuant to an order issued by an authorized prescriber.
  - (e) “Medication” means a medicinal drug or proprietary preparation.
  - (f) “Override medication” means a single dose of medication that may be removed from a decentralized automated medication system prior to pharmacist review because a practitioner licensed pursuant to Chapter 458, 459 or 466, F.S., determined that the clinical status of the patient would be significantly compromised by delay.

(g) "Low risk override medication" is a medication determined by a practitioner licensed pursuant to Chapter 458, 459 or 466, F.S., to have a low risk of drug allergy, drug interaction, dosing error, or adverse patient outcome, and may be removed from a decentralized automated medication system independent of a pharmacist's review of the medication order or clinical status of the patient.

(h) "Physician controlled medication" is medication distributed in an environment where a practitioner controls the order, preparation and administration of the medication.

(2) General Requirements for the Use of Automated Medication Systems.

(a) The consultant pharmacist of record shall be responsible for:

1. Maintaining a record of each transaction or operation.
2. Controlling access to the system.
3. Maintaining policies and procedures for:
  - a. Operation of the automated medication system.
  - b. Training personnel who use the automated medication system.
  - c. Maintaining patient services whenever the automated medication system is not operating; and,
  - d. Defining a procedure for a pharmacist to grant or deny access to the medication in the system.
4. Security of the system.
5. Assuring that a patient receives the pharmacy services necessary for good pharmaceutical care in a timely manner.
6. Assuring that the system maintains the integrity of the information in the system and protects patient confidentiality.
7. Establishing a comprehensive Quality Assurance program.
8. Establishing a procedure for stocking or restocking the automated medication system; and,
9. Ensuring compliance with all requirements for packaging and labeling.

(b) A pharmacist shall perform prospective drug use review and approve each medication order prior to administration of a medication except an override medication, a low risk override medication or a physician controlled medication.

(c) A pharmacist shall perform retrospective drug use review for an override medication.

(3) Multidisciplinary Committee for Decentralized Automated Medication Systems.

(a) The consultant pharmacist of record shall convene or identify a multidisciplinary committee, which is charged with oversight of the decentralized automated medication system.

(b) The Multidisciplinary Committee shall:

1. Include at least one pharmacist,
2. Establish the criteria and process for determining which medication qualifies as an override medication or a low risk override medication in a decentralized automated medication system,
3. Develop policies and procedures regarding the decentralized automated medication system; and,
4. Have its decisions reviewed and approved by the consultant pharmacist of record.

(4) Stocking or Restocking of a Decentralized Automated Medication System.

(a) Medications in a decentralized Automated Medication System shall be stocked or restocked by a pharmacist, registered pharmacy intern, or by a registered pharmacy technician supervised by a pharmacist.

(b) The stocking or restocking of a decentralized automated medication system shall follow one of the following procedures to assure correct medication selection:

1. A pharmacist shall conduct a daily audit of medications placed or to be placed into an automated medication system that includes random sampling.
2. A bar code verification, electronic verification, or similar verification process shall be utilized to assure correct selection of medication placed or to be placed into an automated medication system. The utilization of a bar code, electronic, or similar verification technology shall require an initial quality assurance validation followed by a monthly quality assurance review by a pharmacist.

(5) Centralized Automated Medication Systems. A pharmacist utilizing a centralized medication system may

distribute patient specific medications within the licensed health care facility without checking each individual medication selected or packaged by the system, if:

- (a) The initial medication order has been reviewed and approved by a pharmacist; and,
- (b) The medication is distributed for subsequent administration by a health care professional permitted by Florida law to administer medication; and,

(c) A bar code verification, electronic verification, or similar verification process shall be utilized to assure correct selection of medication placed or to be placed into an automated medication system. The utilization of a bar code, electronic verification, or similar verification technology shall require an initial quality assurance validation, followed by monthly quality assurance review by a pharmacist.

(6) Quality Assurance Program. The consultant pharmacist of record shall be responsible for establishing a quality assurance program for the automated medication system. The program shall provide for:

- (a) Review of override and low risk override medication utilization;
- (b) Investigation of a medication error related to the automated medication system;
- (c) Review of a discrepancy or transaction reports and identify patterns of inappropriate use or access;
- (d) Review of the operation of the system;
- (e) Integration of the automated medication system quality assurance program with the overall continuous quality improvement of the pharmacy as defined in Rule 64B16-27.300, F.A.C.; and,
- (f) Assurance that individuals working with the automated medication system receive appropriate training on the operation of the system and procedures for maintaining pharmacy services when the system is not in operation.

(7) Record Keeping.

(a) The consultant pharmacist of record shall maintain records related to the automated medication system in a readily retrievable manner.

(b) The following records shall be maintained for at least 60 days:

1. Daily audits of stocking or restocking, if applicable;
2. Daily audits for the output of centralized automated medication system, if applicable; and,
3. Transaction records for all non-controlled medications or devices distributed by the automated medication system.

(c) The following records shall be maintained for at least four (4) years:

1. Any report or analysis generated as part of the quality assurance program,
2. A report or database related to access to the system or any change in the access to the system or to medication in the system; and,
3. Transaction records from the automated medication system for all controlled substances dispensed or distributed.

(8) Compliance. The consultant pharmacist of record shall assure compliance with all requirements of Chapter 465, F.S., and the rules of Division 64B16, F.A.C.

(9) Security. A decentralized automated medication system that contains controlled substances shall prohibit simultaneous access to multiple drug entities, drug strengths, or dosage forms of controlled substances, unless otherwise contained in labeled patient-specific form.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.019, 465.022, 465.0235, 465.026 FS. History—New 4-22-07, Amended 1-1-10, 7-14-14.*

**64B16-28.606 Remote Medication Order Processing for Class II or Class III Institutional Pharmacies or Special Pharmacy Permits Servicing Class I, Class II, Modified Class II, Class III, and Special ALF Permitted Facilities.**

(1) Definitions.

(a) "Remote Medication Order Processing" includes any of the following activities performed for a Class II or Class III Institutional Pharmacy or for Special Pharmacy Permits servicing Class I, Class II, Modified Class II, Class III, and Special ALF permitted facilities from a remote location:

1. Receiving, interpreting, or clarifying medication orders;



2. Entering or transferring medication order data;
3. Performing prospective drug use review;
4. Obtaining substitution authorizations;
5. Interpreting and acting on clinical data;
6. Performing therapeutic interventions;
7. Providing drug information;
8. Authorizing the release of a medication for administration.

(b) "Medication" means a medicinal drug or proprietary preparation.

(c) "Prospective drug use review" means an evaluation of medication orders and patient medication records for:

1. Over-utilization or under-utilization of medication;
2. Therapeutic duplication of medication;
3. Drug-disease contraindications;
4. Drug interactions;
5. Incorrect drug dosage or duration of drug treatment;
6. Clinical abuse or misuse of medication.

(2) General requirements.

(a) All pharmacists participating in remote medication order processing shall be Florida licensed pharmacists.

(b) A Class II or Class III Institutional pharmacy or Special Pharmacy servicing Class I, Class II, Modified Class II, Class III, and Special ALF permitted facilities may utilize remote medication order processing if the pharmacist performing the remote medication order processing has access to sufficient patient information necessary for prospective drug use review and approval of medication orders.

(c) A pharmacist shall perform the final check of a medication order.

(d) If the pharmacist performing remote medication order processing is not an employee of the pharmacy, the Class II or Class III, Institutional pharmacy or Special Pharmacy servicing Class I, Class II, Modified Class II, Class III, and Special ALF permitted facilities must have a written agreement or contract with the pharmacist or entity employing the pharmacist. The written agreement or contract shall:

1. Outline the services to be provided;
2. Delineate the responsibilities of each party including compliance with federal and state laws and regulations governing the practice of pharmacy as well as state and federal medical privacy requirements including compliance with applicable Federal HIPAA regulations;
3. Require that the parties adopt a policies and procedures manual;
4. Provide that the parties have access to or share a common electronic file such that the pharmacist performing remote medication order processing has sufficient patient information necessary for prospective drug use review and approval of medication orders.

(3) Policy and Procedures. A policy and procedures manual shall:

- (a) Be accessible to each party involved in remote medication order processing;
- (b) Be available for inspection by the Board or an authorized agent of the Department;
- (c) Outline the responsibilities of each party involved in remote medication order processing;
- (d) Include a current list of the name, address, telephone number, and license number of each pharmacist involved in remote medication order processing;
- (e) Include policies and procedures for:
  1. Ensuring the security and privacy of confidential patient records, including compliance with applicable Federal HIPAA regulations;
  2. Ensuring that a pharmacist performing prospective drug use review has access to appropriate drug information resources;
  3. Ensuring that medical and nursing staff understand how to contact a pharmacist;
  4. Maintaining records to identify the name, initials, or identification code of each person who performs a processing function for a medication order;

5. Complying with federal and state laws and regulations;
6. Operating or participating in a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems;
7. Reviewing the written policies and procedures and documenting the review every year.

(4) Records.

(a) A Class II or Class III Institutional Pharmacy or Special Pharmacy Permits servicing Class I, Class II, Modified Class II, Class III, and Special ALF permitted facilities involved in remote medication order processing shall maintain a record that identifies the name, initials, or identification code of each person who performed a processing function for every medication order. The record shall be available by medication order or by patient name.

(b) The record may be maintained in a common electronic file if the record is maintained in such a manner that the data processing system can produce a printout which identifies every person who performed a processing function for a medication order.

(c) The record shall be readily retrievable for at least the past four (4) years.

(d) The record shall be available for inspection by the Board or an authorized agent of the Department.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.019, 465.022, 465.026, 465.0266 FS. History—New 11-29-04, Amended 7-14-14, 7-19-17, 9-27-18.*

**64B16-28.607 Automated Pharmacy System – Long Term Care, Hospice, and Prison.**

(1) Definitions.

(a) "Automated pharmacy system" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and delivery of a medicinal drug, and which collects, controls, and maintains a record of each transaction.

(b) "Provider pharmacy" means a pharmacy that provides pharmacy services by using an automated pharmacy system at a remote site.

(c) "Remote site" means a long term care facility or hospice licensed under chapter 400, F.S., or a state correctional institution operated under Chapter 944, F.S., that is not located at the same location as the provider pharmacy, at which pharmacy services are provided using an automated pharmacy system.

(d) "Controlled substance" means a substance listed in Chapter 893, F.S., or 21 C.F.R. Part 1308.

(2) Provider Pharmacy Requirements.

(a) A provider pharmacy may provide pharmacy services to a long term care facility or hospice licensed under Chapter 400 or 429, F.S., or a state correctional institution operated under Chapter 944, F.S., through the use of an automated pharmacy system.

(b) An automated pharmacy system shall only be used to provide pharmacy services to an inpatient or a resident of the remote site.

(c) Supervision of the automated pharmacy system shall be the responsibility of a Florida pharmacist employed by the provider pharmacy.

(d) Every medicinal drug stored in the automated pharmacy system shall be owned by the provider pharmacy.

(e) An automated pharmacy system shall be under the supervision of a pharmacist employed by the provider pharmacy. The pharmacist need not be physically present at the remote site if the system is supervised electronically.

(f) A provider pharmacy shall have policies and procedures to ensure adequate security.

(3) Prescription Department Manager Requirements.

(a) The prescription department manager shall ensure that the automated pharmacy system complies with Chapter 893, F.S., and 21 C.F.R., relating to the regulation of controlled substances, for each automated pharmacy system that contains a controlled substance.

(b) The prescription department manager shall ensure that the use of an automated pharmacy system does not compromise patient confidentiality.

(c) The prescription department manager or a designee shall:

1. Authorize or deny access to the data from an automated pharmacy system or to a drug stored inside the automated pharmacy system.
2. Document the training of each person who has access to the data from an automated pharmacy system or to a drug stored inside the automated pharmacy system.

(4) Automated Pharmacy System Requirements.

(a) A medicinal drug stored in bulk or unit-of-use in an automated pharmacy system is part of the inventory of the provider pharmacy and is not part of the inventory of any other pharmacy permit for the facility.

(b) A medicinal drug may be removed from an automated pharmacy system for administration to a patient only after a prescription or order has been received and approved by a pharmacist at the provider pharmacy. This provision does not apply to a medication designated as an emergency medication if the automated pharmacy system is also used as an emergency medication kit in compliance with Section 400.142, F.S., and Rule 59A-4.112, F.A.C.

(c) A pharmacist at the provider pharmacy shall control all operations of the automated pharmacy system and approve release of the initial dose of a prescription or order. A subsequent dose from an approved prescription or order may be released without additional approval of a pharmacist. However, any change made in a prescription or order shall require a new approval by a pharmacist to release the drug.

(d) A pharmacist at the provider pharmacy shall comply with the patient record requirements in Rule 64B16-27.800, F.A.C., and prospective drug use review requirements in Rule 64B16-27.810, F.A.C., for every medicinal drug delivered through an automated pharmacy system.

(e) If the facility where pharmacy services are being provided maintains a medication administration record that includes directions for use of the medication, a unit dose medication may be utilized if the provider pharmacy or the automated pharmacy system identifies and records the dispensing pharmacy, the prescription or order number, the name of the patient, and the name of the prescribing practitioner for each medicinal drug delivered.

(f) Stocking or Restocking of an Automated Pharmacy System.

1. The stocking or restocking of a medicinal drug in an automated pharmacy system at the remote site shall be completed by a pharmacist or other licensed personnel, except as provided in subparagraph 2., below, of this subsection.

2. If the automated pharmacy system uses removable cartridges or containers to store the drug, the stocking or restocking of the cartridges or containers may occur at the provider pharmacy and be sent to the remote site to be loaded by personnel designated by the pharmacist if:

a. A pharmacist verifies the cartridge or container has been properly filled and labeled.

b. The individual cartridge or container is transported to the remote site in a secure, tamper-evident container.

c. The automated pharmacy system uses bar code verification, electronic verification, or similar process to assure that the cartridge or container is accurately loaded into the automated pharmacy system.

(g) A medicinal drug that has been removed from the automated pharmacy system shall not be replaced into the system unless a pharmacist has examined the medication, the packaging, and the labeling and determined that reuse of the medication is appropriate.

(h) Medication to be returned to the provider pharmacy's stock shall meet the requirements of Rule 64B16-28.118, F.A.C.

(5) Security Requirements.

(a) If a provider pharmacy intends to store a controlled substance in an automated pharmacy system:

1. It shall maintain a separate DEA registration for each remote site at which a controlled substance is stored, unless the automated pharmacy system is solely used as an emergency kit pursuant to Rule 59A-4.112, F.A.C.

2. It may utilize one DEA registration to include multiple automated pharmacy systems located at a single address.

(b) A provider pharmacy shall only store a medicinal drug at a remote site within an automated pharmacy system which is locked by a mechanism that prevents access to a drug or to data by unauthorized personnel.

(c) Access to the drugs shall be limited to a pharmacist or a registered pharmacy technician employed by the

provider pharmacy or licensed personnel in the facility or institution who are authorized to administer medication.  
(d) An automated pharmacy system that contains a controlled substance shall prohibit simultaneous access to multiple drug entities, drug strengths, or dosage forms of controlled substances.

(6) Emergency medication. If an automated pharmacy system is utilized for both a medication ordered for a specific patient and an emergency medication for which the review of a pharmacist is not required:

(a) The emergency medication shall be stored separately from other patient medications.

(b) The record shall identify the storage location from which the medication was released.

(c) The record shall include the name of the medication, the patient, the prescriber, the person who accessed the automated pharmacy system, and the date and time of the release.

(7) Record Keeping Requirements.

(a) The record of transactions with the automated pharmacy system shall be maintained in a readily retrievable manner.

(b) The record shall be available to an authorized agent of the Department of Health or the Board of Pharmacy.

(c) The record shall include:

1. Name or identification of the patient or resident.

2. Name, strength and dosage form of the drug product released.

3. Quantity of drug released.

4. Date and time of each release of a drug.

5. Name of provider pharmacy.

6. Prescription number or order number.

7. Name of prescribing practitioner.

8. Identity of the pharmacist who approved the prescription or order.

9. Identity of the person to whom the drug was released.

(d) A record of every transaction with the automated pharmacy system shall be maintained for four (4) years.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.019, 465.022, 465.0235 FS. History—New 4-22-07, Amended 1-1-10, 7-14-14, 10-29-19.*

#### **64B16-28.608 Automated Filling Systems within a Pharmacy.**

(1) Definitions. The following definitions shall be applicable for purposes of this rule:

(a) "Automated filling system" means an automated system used within a pharmacy to assist in filling a prescription drug order by selecting, labeling, filling, or sealing medication for dispensing. An "automated filling system" shall not include automated devices used solely to count medication, vacuum tube drug delivery systems, or systems governed by Rule 64B16-28.606 or 64B16-28.607, F.A.C.

(b) "Electronic verification process" means an electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process or system that accurately verifies medication has been properly prepared for dispensing by an automated filling system.

(c) "Manufacturer Unit of Use Package" means a drug dispensed in the manufacturer's original and sealed packaging, or in the original and sealed packaging of a repackager.

(d) "Repackager" means a repackager registered with the United States Food and Drug Administration (FDA), as defined by subsection 499.003(50), F.S.

(e) "Prepacked" means any drug that has been removed from the original packaging of the manufacturer or an FDA Repackager and is placed in a container for use in an automated filling system, as referenced by subsection 499.003(42), F.S.

(f) "System drug identifier database" means the database or other system which positively identifies the drug to be dispensed by the automated filling system.

(2) The system drug identifier database shall be maintained by a pharmacist and shall not be delegated.

(3) Medication Stocking. Automated filling systems (hereinafter "system") may be stocked or restocked by a pharmacist, pharmacy intern, or registered pharmacy technician under the supervision of a pharmacist, as each are

defined by subsection 64B16-27.1001(7), F.A.C.

(4) Verification. Except as provided herein, a licensed pharmacist must verify the accuracy of the final contents of any medication filled or packaged by a system, and any label affixed thereto, prior to dispensing, as defined by subsection 64B16-27.1001(3), F.A.C.

(5) The pharmacist verification requirements of subsection (4), shall be deemed satisfied if:

(a) The pharmacy establishes and follows a policy and procedure manual that complies with subsection (6), of this rule;

(b) The system is fully automated from the time the medication is stocked into the machine until a completed, labeled and sealed prescription is produced by the system that is ready for dispensing to the patient. No manual intervention with the medication may occur after the medication is stocked into the system. For purposes of this section, manual intervention shall not include preparing a finished prescription for mailing, delivery, or storage;

(c) A pharmacist must perform a prospective drug review and verify the accuracy of the prescription information used by or entered into the system for a specific patient prior to initiation of the automatic fill process. The name, initials or identification codes(s) of the verifying pharmacist shall be recorded in the pharmacy's records and maintained for four (4) years after dispensing, or longer if required by applicable law;

(d) All medication Prepacked by the pharmacy must be verified by a pharmacist pursuant to subsection 64B16-27.1001(3), F.A.C.

(e) A pharmacist verifies the correct medication, either the Manufacturer Unit of Use Package, Repacked, or Prepacked container, was properly filled and stocked in the system. Alternatively, an electronic verification process may be used to verify a Manufacturer Unit of Use Package, repackaged, or prepacked containers;

(f) The medication to be dispensed is selected, filled, labeled, or sealed in the prescription container by the system or dispensed by the system in a Manufacturer's Unit of Use Package, repacked, or prepacked container;

(g) An electronic verification process is used to verify the proper prescription label has been affixed to the correct medication, prepackaged medication or Manufacturer Unit of Use Package for the correct patient; and,

(h) An audit trail is maintained for the prescription from the beginning of the system to the dispensing from the system, and maintain for four (4) years.

(6) The pharmacist verification requirements of subsection (4), shall be deemed satisfied for a system that is not fully automated when all or part of the system is used for Manufacturer Unit of Use Packages if:

(a) The system utilizes an Electronic Verification Process to verify that the correct drug matches the correct prescription label;

(b) The Electronic Verification Process activities are undertaken by a pharmacist, pharmacy intern, or registered pharmacy technician under the supervision of a pharmacist, as each are defined by subsection 64B16-27.1001(7), F.A.C., and consistent with Section 64B16-27.4001, F.A.C.; and,

(c) An audit trail is maintained for the prescription from the beginning of the system to the dispensing from the system, and maintained for four (4) years.

(7) Policies and Procedures. Pharmacies verifying prescriptions pursuant to subsection (5) or (6) of this rule, shall establish and follow written policies and procedures to ensure the proper, safe, and secure functioning of the system. Policies and procedures shall be reviewed annually by the prescription department manager or consultant pharmacist of record and shall be maintained in the pharmacy's records for a minimum of four (4) years. The required annual review shall be documented in the pharmacy's records and made available upon request. At a minimum, the pharmacy shall establish and follow policies and procedures for:

(a) Maintaining the system and any accompanying electronic verification process in good working order;

(b) Ensuring the integrity of the system drug identifier database and identification of persons responsible for database entries;

(c) Ensuring accurate filling, stocking, and verification of the system, as applicable;

(d) Ensuring sanitary operations of the system and preventing cross-contamination of cells, cartridges, containers, cassettes, or packages;

(e) Testing the accuracy of the system and any accompanying electronic verification process. At a minimum, the

system and electronic verification process shall be tested before the first use of the system or restarting the system and upon any modification to the system or electronic verification process that changes or alters the filling or electronic verification process;

(f) Training persons authorized to access, stock, restock, or utilize the system in equipment use and operations, as applicable;

(g) Conducting routine and preventive maintenance and, if applicable, calibration;

(h) Removing expired, adulterated, misbranded or recalled drugs;

(i) Preventing unauthorized access to the system, including assigning, discontinuing or changing security access;

(j) Identifying and recording persons responsible for stocking, and filling the system;

(k) Ensuring compliance with state and federal law, including, all applicable labeling, storage, and security requirements;

(l) Maintaining an ongoing quality assurance program that monitors performance of the system and any electronic verification process to ensure proper and accurate functioning, including tracking and documenting of automated filling system errors that are not corrected prior to dispensing to the patient. Such documentation shall be maintained for four (4) years and produced to the Board upon request.

(8) Recordkeeping. Except as otherwise provided herein, records required by this rule shall be maintained in the pharmacy's records electronically or in writing for a minimum of four (4) years, or longer if required under applicable law. If the verification requirements of paragraph (5)(d) of this rule, are completed by a pharmacist, the name, initials or identification code(s) of the verifying pharmacist shall be recorded in the pharmacy's records and maintained for four (4) years after dispensing. Records shall be made available for inspection and produced to the Board or the Board's authorized designee upon request.

*Rulemaking Authority 465.005, 465.0155, 465.022(1) FS. Law Implemented 465.003(17), 465.0155, 465.022(1) FS. History—New 3-24-14, Amended 11-5-17.*

#### **64B16-28.702 Modified Class II Institutional Pharmacies.**

(1) Modified Class II Institutional Pharmacies are those Institutional Pharmacies which provide specialized pharmacy services restricted in scope of practice and designed to provide certain health care pharmacy services that are not generally obtainable from other pharmacy permittees. These specialized institutional pharmacy practices are generally identifiable with short-term or primary care treatment modalities in entities such as primary alcoholism treatment centers, free-standing emergency rooms, rapid in/out surgical centers, certain county health programs, and correctional institutions. Medicinal drugs may not be administered, except to patients of the institution for use on the premises of the institution, in any facility which has been issued a Modified Class II Institutional Pharmacy Permit. All medicinal drugs as defined by subsection 465.003(7), F.S., which are stocked in these pharmacies are only to be administered on premises as defined by subsection 465.003(1), F.S., to inpatients on an inpatient or in-program basis. In-program patients are defined as those patients who have met program admission criteria required by the institution.

(2) Modified Class II Institutional Pharmacies are categorized according to the type of specialized pharmaceutical delivery system utilized and the following criteria (Categories are designated as Type "A," Type "B," and Type "C"):

(a) The type of the medicinal drug delivery system utilized at the facility, either a patient-specific or bulk drug system, and, the quantity of the medicinal drug formulary at the facility.

(b) Type "A" Modified Class II Institutional Pharmacies provide pharmacy services in a facility which has a formulary of not more than 15 medicinal drugs, excluding those medicinal drugs contained in an emergency box, and in which the medicinal drugs are stored in bulk and in which the consultant pharmacist shall provide on-site consultations not less than once every month, unless otherwise directed by the Board after review of the policy and procedure manual.

(c) Type "B" Modified Class II Institutional Pharmacies provide pharmacy services in a facility in which medicinal drugs are stored in the facility in patient specific form and in bulk form and which has an expanded drug formulary, and in which the consultant pharmacist shall provide on-site consultations not less than once per month, unless

otherwise directed by the Board after review of the policy and procedure manual.

(d) Type "C" Modified Class II Institutional Pharmacies provide pharmacy services in a facility in which medicinal drugs are stored in the facility in patient specific form and which has an expanded drug formulary, and in which the consultant pharmacist shall provide onsite consultations not less than once per month, unless otherwise directed by the Board after review of the policy and procedure manual.

(3) All Modified Class II Institutional Pharmacies shall be under the control and supervision of a certified consultant pharmacist.

(4) The consultant pharmacist of record for the Modified Class II Institutional Pharmacy shall be responsible for establishing a written protocol and a policy and procedure manual for the implementation of a drug delivery system to be utilized and the requirements of this rule.

(5) A copy of the permittee's policy and procedure manual as provided herein shall accompany the permit application. The original policy and procedure manual shall be kept within the Modified Class II Institutional Pharmacy and shall be available for inspection by the Department of Health.

(6) Drugs as defined in subsection 465.003(7), F.S., stocked in Modified Class II Institutional Pharmacies, Type "A," and Type "B," as provided herein, shall be those drugs generally utilized in the treatment modalities encompassed within the health care scope of the particular institutional care entity. The protocol and the policy and procedure manual for Type "A," and Type "B," Modified Class II Institutional Pharmacies shall contain definitive information as to drugs and strengths thereof to be stocked.

(a) The policy and procedure manual of facilities which are issued Type A Modified Class II Institutional Permits shall provide the following:

1. Definitive information as to drugs and strengths to be stored.
2. The establishment of a Pharmacy Services Committee which shall meet at least annually.
3. Provisions for the handling of the emergency box including the utilization of separate logs for recordkeeping.
4. Provisions for the secure ordering, storage and recordkeeping of all medicinal drugs at the facility.
5. Provisions for the utilization of proof-of-use forms for all medicinal drugs within the facility.
6. A diagram of the facility and the security and storage of the medicinal drugs.
7. Provisions for maintaining the records of consultations for not less than four (4) years at the facility which shall be stored onsite and available for inspection by the Department of Health.

(b) The policy and procedure manual of facilities which are issued Type B Modified Class II Institutional Permits shall provide the following:

1. The establishment of a Pharmacy Services Committee which shall meet at least annually.
2. Provisions for the handling of the emergency box including the utilization of separate logs for recordkeeping.
3. Provisions for the secure ordering, storage and recordkeeping of all medicinal drugs at the facility.
4. Provisions for the utilization of a perpetual inventory system for all controlled substances.
5. Provisions for the utilization of an inventory system for injectables and other medicinal drugs as required by the Pharmacy Services Committee.
6. A diagram of the facility and the security and storage of the medicinal drugs.
7. Provisions for maintaining the records of consultations for not less than four (4) years at the facility which shall be stored on-site and available for inspection by the Department of Health.

(c) The policy and procedure manual of facilities which are issued Type C Modified Class II Institutional Permit shall provide the following:

1. The establishment of a Pharmacy Services Committee which shall meet at least annually.
2. Provisions for the handling of the emergency box including the utilization of separate logs for recordkeeping.
3. Provisions for the secure ordering, storage and recordkeeping of all medicinal drugs at the facility.
4. Provisions for the utilization of a Medication Administration Record (MAR) for all medicinal drugs administered to patients of the facility.
5. A diagram of the facility and the security and storage of the medicinal drugs.
6. Provisions for maintaining the records of consultations for not less than four (4) years at the facility which shall

be stored on-site and available for inspection by the Department of Health.

(7) Controlled drugs as defined in chapter 893, F.S., stocked as provided herein within a Type "A" Modified Class II Institutional Pharmacy shall be stocked in unit size not to exceed 100 dosage units unless an exception thereto is granted by the Board of Pharmacy. Proof of use record sheets showing patient's name, date of administration, initials of person administering drug, and other pertinent control requirements are required for both controlled and noncontrolled substance medicinal drugs in Type "A" Modified Class II Institutional Pharmacies.

(8) A Modified Class II institutional pharmacy may contract with a Special Parenteral/Enteral Extended Scope pharmacy for the pharmacy services provided for by Rule 64B16-28.860, F.A.C.

(a) Special Parenteral/Enteral Extended Scope pharmacies and institutional pharmacy permits shall create and comply with Policy and Procedure Manuals that delineate duties and responsibilities of each entity including the following provisions:

1. The institutional pharmacy permit shall maintain records appropriate to ensure the provision of proper patient care.

2. The institutional pharmacy permit designee shall inspect and log in all medicinal drugs provided by the Special Parenteral/Enteral Extended Scope pharmacy.

(b) Such Policy and Procedure manuals shall be made available to the Board or Department upon request.

(c) Prior to contracting for such services the institutional pharmacy shall ensure that the Special Parenteral/Enteral Extended Scope pharmacy is licensed under the provisions of Rule 64B16-28.860, F.A.C.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.019(2)(c), 465.022 FS. History—New 4-22-82, Amended 11-5-85, Formerly 21S-1.37, Amended 4-16-86, Formerly 21S-1.037, Amended 7-31-91, Formerly 21S-28.702, 61F10-28.702, Amended 9-4-96, Formerly 59X-28.702, Amended 10-15-01, 7-14-14, 3-15-16.*

#### **64B16-28.750 Class III Institutional Pharmacies.**

(1)(a) Class III Institutional Pharmacies are those Institutional Pharmacies authorized by Section 465.019(2)(d), F.S. All Class III Institutional Pharmacies must be affiliated with a hospital. An Institutional Pharmacy may hold only a Class III Institutional Pharmacy Permit, or may hold a Class III Institutional Permit in conjunction with other permits authorized by Florida statute or administrative rule.

(b) A Class III Institutional Permit may be issued to existing Class II or Modified Class II Institutional Pharmacy Permittees or as an initial permit to new pharmacy facilities meeting the statute's requirements or Central Distribution Facilities under common control with a hospital.

(2) Change of Association for Existing Permittees. Institutional Pharmacies affiliated with a hospital currently holding Class II or Modified Class II Institutional Pharmacy Permits may request the facility be associated as a Class III Institutional Pharmacy Permit by completing Form DH5033-MQA, 08/2018, "Change of Permit Association – Class III Pharmacy," which is incorporated by reference and is available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-09949>. Upon approval of the request, the existing Class II or Modified Class II permit will be re-associated as a Class III Institutional Pharmacy Permit, with no change of permit number. Because pharmacy permits are non-transferrable, this option is not available if there is any change in the ownership or identity of the business entity holding the existing Class II or Modified Class II Institutional Pharmacy Permit.

(3)(a) New Class III Permits. Applicants for a new Class III Institutional Pharmacy permit must complete an application for a permit using an original Form DH5032-MQA, 08/2018, "Class III Institutional Pharmacy Permit Application and Information," which is incorporated by reference herein and is available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-09948>. Applicants for an Institutional Pharmacy Permit must designate a consultant pharmacist of record as required by Section 465.019, F.S. and Rule 64B16-28.501, F.A.C.

(b) A copy of the permittee's policy and procedure manual as provided herein shall accompany the permit application. The original policy and procedure manual shall be kept within the Class III Institutional Pharmacy and shall be available for inspection by the Department of Health or authorized representative of the Board.



(5)(a) The policy and procedure manual of facilities which are issued or re-associated as a Class III Institutional Permit shall, at a minimum, include the following:

1. The process for designation of the consultant pharmacist responsible for pharmaceutical services, including maintenance of drug records required by law and drug handling procedures.
2. Safe practices for the preparation, dispensing, prepackaging, distribution, and transportation of medicinal drugs and prepackaged drug products.
3. Provisions for maintaining records to monitor the movement, dispensing, distribution, and transportation of medicinal drugs and prepackaged drug products.
4. Provisions for maintaining records of pharmacy staff responsible for each step in the preparation, dispensing, prepackaging, transportation, and distribution of medicinal drugs and prepackaged drug products.
5. Identification of medicinal drugs and prepackaged drug products that may not be safely distributed among Class III Institutional Pharmacies and health care establishment permittees.
6. If an Institutional Formulary system is to be adopted and used, the policies and procedures for the development and approval of the system.
7. The establishment of a Pharmacy Services Committee which shall meet at least annually.
8. Provisions for the secure ordering, storage and recordkeeping of all medicinal drugs at the facility.
9. Provisions for the utilization of a perpetual inventory system for all controlled substances.
10. Provisions to ensure prepackaged drug products are not adulterated and are free of contamination or cross-contamination.
11. Provisions to ensure medicinal drugs and prepackaged drug products are transported according to manufacturer's recommended guidelines for storage and transportation, including exposure to light, heat, etc.
12. Provisions regarding compliance with all state and Federal laws, regulations, and rules regarding controlled substances, including ordering, inventory and anti-diversion mechanisms.
13. Provisions regarding the labeling of medicinal drugs and prepackaged drug products, including, if applicable, labels related to transfers between Class III pharmacies, transportation requirements, or safe handling/hazardous precautions.

(b) The Class III Institutional Pharmacy's policies and procedures shall be based upon authoritative literature, studies, and materials generally accepted and commonly relied upon by the Pharmacy and pharmaceutical professions, which must be identified in the policies and procedures.

(c) In addition to the policies and procedures manual, the Class III Institutional Pharmacy shall create and maintain documentation of: the hospital with which the permittee is affiliated; all other Class III Institutional Pharmacy Permits under common control with the permittee; all health care clinic establishments under common control with the permittee; and the way/manner in which the permittee and other entities are under common control. Such documentation shall be maintained by the permittee and shall be available for review by a Department Inspector or authorized agent of the Board.

(d) Pursuant to Section 465.022(4), F.S., each applicant must attach to the application the applicant's written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships. The policy and procedure manual shall contain, at a minimum, the following:

1. Provisions to identify and guard against invalid practitioner-patient relationships.
2. Provisions to guard against filling fraudulent prescriptions for controlled substances.
3. Provisions to identify prescriptions that are communicated or transmitted legally.
4. Provisions to identify the characteristics of a forged or altered prescription.

(6) As required by paragraph 64B16-28.100(1)(c), F.A.C., prior to issuance of a Class III Institutional Pharmacy Permit, the applicant must pass an on-site inspection. For applicants who currently hold Institutional Class II or Modified Class II permits, the on-site inspection required for issuance of the Class III permit shall be coordinated, to the extent practicable, with any other inspections required or recently conducted, and in no event, shall reset or disrupt the permittee's existing inspection schedule.

(7) Each applicant must comply with the fingerprinting requirements of Section 465.022, F.S., unless the applicant qualifies for the statutory exception for corporations having more than \$100 million of business taxable assets in Florida. Electronic fingerprint information ("EFI") that has been submitted to the Florida Agency for Health Care Administration may be accessible by the Florida Department of Health for a period of sixty (60) months. If the Department is able to access EFI from AHCA, applicants will not be required to resubmit EFI for additional or new applications submitted during this time period. After sixty (60) months, new electronic fingerprint information must be submitted as part of all applications, unless the applicant is a corporation having more than \$100 million of business taxable assets in Florida.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 456.0635, 465.019(2)(d), 465.022 FS. History—New 10-10-18.*

#### **64B16-28.800 Special Pharmacies.**

(1) Special pharmacies are pharmacies providing miscellaneous specialized pharmacy service functions. The Board of Pharmacy, by this rule, provides for the establishment of the following special pharmacy permits:

- (a) Special-Limited Community.
- (b) Special-Parenteral and Enteral.
- (c) Special-Closed System Pharmacy.
- (d) Special-End Stage Renal Disease.
- (e) Special-Parenteral/Enteral Extended Scope.
- (f) Special-ALF.
- (g) Special Sterile Compounding.

(2) An applicant for any special pharmacy permit shall provide the Board of Pharmacy with a Policy and Procedure Manual which sets for a detailed description of the type of pharmacy services to be provided within the special pharmacy practice. The Policy and Procedures Manual shall contain detailed provisions for compliance with the provision of Section 465.0196, F.S., and other applicable requirements contained in the chapter.

(3) The Policy and Procedure Manual shall be prepared, maintained, and will be reviewed and is subject to approval by the Board of Pharmacy or its designee prior to the issuance of the permit and the initiation of the operation of the permittee. The policy and procedure manual is reviewed to determine if the operation of the facility will be in compliance with Chapters 465 and 893, F.S., and Division 64B16, F.A.C. The Policy and Procedure Manual shall be made available upon request of the Board or its agents. The applicant who requests a special permit shall be subject to inspection prior to the issuance of the permit.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0196, 456.022 FS. History—New 2-21-84, Formerly 21S-1.39, 21S-1.039, Amended 7-31-91, 10-14-91, Formerly 21S-28.800, 61F10-28.800, Amended 3-10-96, 6-4-97, Formerly 59X-28.800, Amended 11-11-98, 10-15-01, 7-2-13, 4-26-17.*

#### **64B16-28.802 Special Sterile Compounding Permits for Pharmacies and Outsourcing Facilities.**

(1) A Special Sterile Compounding Permit (SSCP) is required before any pharmacy may engage in the preparation of compounded sterile products. For purposes of this rule, an outsourcing facility shall be deemed a pharmacy.

(2) An SSCP shall be issued by the department as an additional permit with a separate permit number that differs from the permit number of the pharmacy obtaining the SSCP.

(3) All sterile compounding shall be done in strict compliance with the standards set forth in Rules 64B16-27.700 and 64B16-27.797, F.A.C.

(4) An outsourcing facility shall comply with current good manufacturing practices as adopted and incorporated in Rule 64B16-27.797, F.A.C.

(a) If a pharmacy is not registered as an outsourcing facility at the time the pharmacy applies for an SSCP, the applicant shall amend the application within 7 business days if the pharmacy becomes a registered outsourcing facility before the SSCP is issued.

(b) If a pharmacy is issued an SSCP and later becomes registered as an outsourcing facility, the pharmacy will not be required to obtain a new or additional SSCP. However, the pharmacy shall comply with current good manufacturing practices to be eligible to retain the issued SSCP and the pharmacy shall notify the department in writing within 7 business days of becoming a registered outsourcing facility.

(c) An outsourcing facility that does not engage in patient specific sterile compounding and dispensing pursuant to such prescription shall only be required to obtain the SSCP. However, if the outsourcing facility engages in patient-specific sterile compounding, in addition to the SSCP, the outsourcing facility shall be required to obtain a pharmacy permit specific to the type of patient dispensing that the pharmacy will be engaged in (i.e., community pharmacy permit or institutional pharmacy permit).

(5) The SSCP is not required for a Special Parenteral/Enteral or Special Parenteral/Enteral Extended Scope pharmacy if that pharmacy holds no other pharmacy permit and is not registered as an outsourcing facility.

(6) The SSCP is not required for a Type B Modified Class II Institutional Pharmacy under the following conditions:

(a) The pharmacy only compounds low-risk level compounded sterile preparations; and,

(b) The pharmacy only compounds those low-risk level compounded sterile preparations for immediate use pursuant to the provisions the United States Pharmacopeia adopted and incorporated in Rule 64B16-27.797, F.A.C.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0196 FS. History—New 6-18-13, Amended 10-20-13, 5-8-16, 12-18-16, 11-5-17.*

#### **64B16-28.810 Special Pharmacy – Limited Community Permit.**

A Special-Limited Community Permit shall be obtained by a Class II or Class III Institutional Pharmacy that dispenses medicinal drugs, including controlled substances to:

(1) Employees, medical staff and their dependents for their personal use;

(2) Patients of the hospital who are under a continuation of a course of therapy not to exceed a three (3) day supply;

(3) Patients obtaining medical services in the facility's emergency room and, whenever it is otherwise appropriate, as indicated in the applicant's policy and procedure manual; and,

(4) Discharged patients of the hospital who are under a continuation of a course of therapy using multi-dose medicinal drugs if the following requirements are met:

(a) The label affixed to a container used in dispensing multi-dose medicinal drugs contains at least the following information:

1. The name of and contact information of the pharmacy.

2. The name of the prescriber.

3. The name of the patient.

4. The date of the original filling and any applicable expiration date.

5. The prescription number or other prescription identification adequate to readily identify the prescription.

6. The directions for use.

7. The name, strength, and size of the medicinal drug dispensed; and,

8. The quantity of the drug in the container.

(b) The patient is deemed competent to handle and administer the multi-dose medicinal drug.

(c) A specific order is written by the patient's physician to authorize that the multi-dose medicinal drug is appropriate to dispense upon discharge.

(d) Before the hospital dispenses a multi-dose medicinal drug as specified in subsection (4) of this rule, the hospital shall establish protocols to ensure the following:

1. Infection control during transport and handling of multi-dose medicinal drug containers that have been in contact with a patient.

2. Patient or caregiver education on administration of the multi-dose medicinal drug if necessary on an individual basis.

(e) A "multi-dose medicinal drug" as used in this rule means, but is not limited to, commercially available multi-

dose packages such as inhalers, ocular products, insulin vials or pens, otic products, bulk antibiotic suspensions, topical agents, and methylprednisolone dose packets dispensed to inpatients, provided in containers that may exceed a three (3) day supply, and are intended to be continued by the patient on an outpatient basis but not to be re-filled by the hospital. Controlled substances are not considered multi-dose medicinal drugs as defined in this rule.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0196 FS. History—New 7-31-91, Formerly 21S-28.810, 61F10-28.810, 59X-28.810, Amended 7-17-05, 2-10-14, 9-27-18.*

#### **64B16-28.820 Sterile Products and Special Parenteral/Enteral Compounding.**

##### (1) Sterile Products and Parenteral/Enteral Compounding.

(a) A sterile products and parenteral/enteral compounding pharmacy is a type of special pharmacy as provided by Section 465.0196, F.S., which is limited in scope of pharmacy practice to render sterile products and parenteral/enteral compounding functions. This pharmacy practice facilitates the utilization of certain institutional therapeutic measures by patients in the home environment or by patients in an institutional environment where such pharmacy service is unavailable. Pharmacy services, sterile products and parenteral/enteral products provided by a special sterile products and parenteral/enteral compounding pharmacy pursuant to prescription as defined by Section 465.003(13), F.S., shall be limited to the compounding and/or dispensing of:

1. Sterile preparations for parenteral therapy, parenteral nutrition; and/or
2. Sterile preparations for jejunostomy feeding and sterile irrigation solutions; and/or
3. Sterile preparations of cytotoxic or antineoplastic agents; and/or
4. Sterile products (i.e., injectables, eye drops, etc.).

(b) Prior to engaging in a sterile products and parenteral/enteral compounding pharmacy practice an entity shall obtain a special sterile products and parenteral/enteral compounding pharmacy permit as provided herein.

(2) Pharmacy Environment. The compounding and dispensing of sterile products and parenteral/enteral prescription preparations within a special sterile products and parenteral/enteral compounding pharmacy shall be accomplished in a pharmacy environment subject to the pharmacy permit laws of this state and in accordance with those requirements for the safe handling of drugs. The environment for this practice shall be set apart, and designed, and equipped to facilitate controlled aseptic conditions. Aseptic techniques shall prevail in this practice to minimize the possibility of microbial contamination.

##### (3) General Requirements.

(a) A special sterile products and parenteral/enteral compounding pharmacy shall be under the control and supervision of a licensed pharmacist, who shall be designated prescription department manager on the application for a special sterile products and parenteral/enteral compounding pharmacy. The prescription department manager or other licensed qualified pharmacist as provided herein shall be present on duty during all hours of operation of said pharmacy. Changes in prescription department manager shall be reported to the Board of Pharmacy office within 10 days by the permit holder and prescription department manager of record. A prescription department manager of a special sterile products and parenteral/enteral compounding pharmacy shall not be designated prescription department manager of record of more than one special sterile products and parenteral/enteral compounding pharmacy, unless otherwise approved by the Board. The Board will consider the proximity of the facility as well as the administrative workload created by the two permits, in determining whether or not it will approve the designation of someone as a prescription department manager of more than one special sterile products and parenteral/enteral compounding pharmacy.

(b) A special sterile products and parenteral/enteral compounding pharmacy shall provide special handling and packaging of compounded parenteral and enteral preparations when delivering from the pharmacy to the patient or institution as required to maintain stability of the preparations. All such preparations shall include the time and/or date of expiration on the label. Delivery from the pharmacy to the patient shall be made within a reasonable time. A special sterile products and parenteral/enteral compounding pharmacy shall provide telephone accessibility to its pharmacist(s) for its patients at all hours.

(c) A patient profile shall be maintained for each patient. The profile must contain available medical information consistent with prevailing pharmacy standards which shall be confidential.

(d) A Policy and Procedure Manual shall be prepared and maintained at each special sterile products and parenteral/enteral compounding pharmacy, and be available for inspection by authorized agents of the Board of Pharmacy and the Department. The Policy and Procedure Manual shall set forth in detail the objectives and operational guidelines of the permittee. The Policy and Procedure Manual shall include a Quality Assurance Program which monitors personnel qualifications, training and performance, equipment facilities, and random production sampling consistent with recommended standards for compounding and dispensing intravenous admixtures as set forth by the Joint Commission on Accreditation of Health Organizations, the National Coordinating Committee and Large Volume Parenteral, and as provided by the Florida Board of Pharmacy.

(e) Compounding shall be conducted within an annually certified laminar air flow (LAF) hood, except in the existence of a Class 100 certified compounding environment, or certified mobile isolation chamber, in which case compounding may be conducted without the use of a certified laminar air flow hood. All cytotoxins must be compounded in a certified vertical laminar air flow hood or certified mobile isolation chamber. The use of a Type A or Type B LAF hood used shall be dependent upon the volume of work anticipated. All certifications shall be performed following manufacturer specification.

(f) Protective garb: gloves, face and eye, and gowns should be provided and used.

(g) Proper aseptic procedures must be used at all times to prevent bacterial contamination of the product as well as chemical contamination of the operator.

(h) All unused cytotoxic agents and material must be disposed of properly in accordance with accepted professional standards and applicable law.

(4) An applicant for a special sterile products and parenteral/enteral compounding pharmacy permit shall provide the Board of Pharmacy with the following:

(a) Completed Board of Pharmacy permit application form (Form DPR/PH/107/9-88).

(b) Copy of Policy and Procedure Manual.

(c) Permit fee as provided in Rule 64B16-28.121, F.A.C.

(5) Minimum Requirements for Space, Equipment, Supplies and Publications.

(a) To ensure compliance with the general requirements as set forth, the following minimum requirements for space, equipment, supplies and publications shall be met by a pharmacy which operates under the special permit of a sterile products and parenteral/enteral compounding pharmacy. These requirements are in addition to the minimum requirements for space and equipment required of other types of pharmacies when applicable. The minimum permit requirements are set forth as follows:

(b) Space:

1. The area for preparing sterile prescriptions as provided for by this rule referred to as the sterile admixture room shall be set apart from general work and storage areas. The room shall be adequately air conditioned or shall be under positive pressure.

2. The sterile admixture room shall provide space for a minimum of one laminar flow hood. Additionally, the space shall be of adequate size to accommodate other equipment as provided herein and sufficient space to allow pharmacists and other employees working therein to adequately, safely, and accurately fulfill their duties related to prescriptions.

(c) Equipment:

1. Laminar Air Flow Hood(s):

a. Horizontal; and/or

b. Vertical.

2. Refrigerator/freezer convenient to the clean room.

3. Sink and wash area convenient to the clean room.

4. Appropriate waste containers for:

a. Used needles and syringes.

b. All cytotoxic waste including apparel.

(d) Supplies:

1. Gloves, masks and gowns.
2. Needles and syringes of various standard sizes.
3. Disinfectant cleaning agents.
4. Clean towels.
5. Handwashing materials with bactericidal properties.
6. Vacuum containers and various transfer sets.
7. "Spill kits" for cytotoxic agent spills.

(e) Current References:

1. Chapter 465, F.S.
2. Chapter 499, F.S.
3. Chapter 893, F.S.
4. Division 64B16, F.A.C., Rules of the Florida Board of Pharmacy.
5. United States Pharmacopeia and National Formulary, or Remington Pharmaceutical Sciences, or the United States Dispensatory (along with the latest supplements), or an equivalent thereof sufficient in scope to meet the professional practice needs of the pharmacy, and a current authoritative therapeutic reference.
6. Handbook of Injectable Drugs by American Society of Hospital Pharmacists.
7. "Practice Guidelines For Personnel Dealing With Cytotoxic Drugs."

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.018, 456.0196 FS. History–New 4-26-84, Formerly 21S-1.40, Amended 7-27-86, Formerly 21S-1.040, Amended 7-31-91, 10-14-91, Formerly 21S-28.820, 61F10-28.820, Amended 3-11-96, 6-4-97, Formerly 59X-28.820, Amended 7-1-02, 1-29-03, 6-4-14.*

#### **64B16-28.830 Special – Closed System Pharmacy.**

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

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

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

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

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

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

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0196, 465.022 FS. History–New 7-31-91, Amended 10-1-92, Formerly 21S-28.830, 61F10-28.830, 59X-28.830, Amended 1-1-10, 5-8-18.*

#### **64B16-28.840 Special – Non Resident (Mail Service).**

*Rulemaking Authority 465.005, 465.022, 465.0156 FS. Law Implemented 465.0156 FS. History—New 10-14-91, Formerly 21S-28.840, 61F10-28.840, 59X-28.840, Amended 10-27-09, Repealed 4-26-17.*

**64B16-28.850 Special Pharmacy – ESRD.**

(1) An ESRD Pharmacy is a type of special pharmacy as provided by Section 465.0196, F.S., which is limited in scope of pharmacy practice to the provision of dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home or specified address. Pharmacy services and dialysis supplies and products provided by an ESRD pharmacy shall be limited to the distribution and delivery of legend drugs included in schedule subsection (3), below; or legend devices included in schedule subsection (4), below; which are ordered by a physician for administration or delivery to a person with chronic kidney failure for self-administration at the person's home or specified address. All dialysis supplies and products provided by an ESRD pharmacy shall be prepackaged and shall be covered by an approved NDA or 510 (k) application issued by the Federal Food and Drug Administration.

(2) Prior to engaging in an ESRD pharmacy practice an entity shall obtain a special ESRD pharmacy permit as provided herein.

(3) Schedule of legend drugs:

- (a) Saline Solutions.
- (b) Porcine Heparin.
- (c) Beef Heparin.
- (d) Dextrose Solutions.
- (e) Doxercalciferol.
- (f) Epoetin Alfa.
- (g) NAACL INJ 50 MEQ/20 ML.
- (h) Levocarnitine.
- (i) Lidocaine.
- (j) Vitamin Preparations (dialysate use only).
- (k) Paricalcitol.
- (l) Peritoneal Dialysate Solutions.
- (m) Protamine Sulfate.
- (n) Potassium 20 MEQ/10ML (dialysate use only).
- (o) Sodium Ferric Gluconate Complex or equivalent.
- (p) Sterile Water for Irrigation.

(4) The schedule of legend devices includes:

- (a) Hemodialyzers.
- (b) Hemodialysis solutions.
- (c) Bloodlines and Associated Connectology.
- (d) Peritoneal Dialysis Tubing and Connectology.

(5) The provision of legend drugs and devices included in the schedule necessary to perform dialysis to a person with chronic kidney failure for self-administration at the person's home or specified address shall be under the professional supervision of an appropriate practitioner licensed under Florida law. The consultant pharmacist shall assure that the following occurs:

(a) The ESRD pharmacy receives a prescription from the prescribing practitioner directing the pharmacist to dispense and deliver to a person with chronic kidney failure (or such person's designee) any legend drugs and/or devices included in the formulary necessary for the self-administration of dialysis at such person's home or specified address.

(b) That no dispensing shall occur unless the person with chronic kidney failure has been trained in the proper use and administration of such products. Further, the consulting pharmacist shall ensure that the ESRD pharmacy has received records confirming the completion of such training.

(c) After the delivery of such products by the ESRD pharmacy, the ESRD pharmacy shall upon request therefor, make available to the prescribing practitioner documentation describing, in sufficient detail, the types and quantities of products dispensed and delivered by the ESRD pharmacy. The ESRD pharmacy shall also, upon request, make available to the prescribing practitioner documentation confirming shipment of such products and receipt thereof by the person with chronic kidney failure.

(6) The licensed ESRD pharmacy shall comply with all applicable state and federal regulatory requirements and shall maintain in effect all applicable permits and licenses required to dispense and deliver legend drugs and/or devices included in the formulary described in this Section.

(7) The ESRD pharmacy shall deliver products to a person with chronic kidney failure only upon receipt of a valid prescription from a prescribing practitioner specifying or including:

(a) Documentation that the intended recipient of the products has been trained in home dialysis therapy and will require such products;

(b) The duration of prescribing practitioner's order; and,

(c) The name and product code of each product prescribed and the quantity prescribed.

(d) The prescription may indicate the person with chronic kidney failure shall have the right to request refills of legend drugs, devices or both, included in the schedule and described in the order for a period of one year.

(8) The ESRD pharmacy shall assemble the products to be delivered pursuant to the prescribing practitioner's prescription. In assembling such products for delivery, the ESRD pharmacy shall take steps necessary to assure the following:

(a) The code numbers and quantities of the products assembled match the code numbers identified in the prescribing practitioner's prescription;

(b) With respect to any dated products, a minimum of three (3) full months of shelf-life remain; and,

(c) All cartons and other packaging are properly labeled as noted below:

1. "Use as Directed" statement;

2. The name and address of the person to whom the products will be delivered;

3. The name of the prescribing practitioner;

4. The name and address of the ESRD pharmacy location from which the products were shipped;

5. The prescription number identifying the shipment to the order created by the prescribing practitioner; and,

6. Any special instructions regarding delivery dates or locations.

7. The date after which the drug(s) and/or device(s) must be discarded. Notwithstanding any other rule, the ESRD pharmacy may use, in lieu of a discard after date, the manufacturer's expiration date when such is displayed in an unopened sealed package.

(d) All cartons and related packaging shall be visually inspected to confirm compliance with the specifications in paragraph (8)(c). Compliance with the requirements set forth in paragraph (8)(c), shall be conducted by the consulting pharmacist or independently by not less than two employees of the ESRD pharmacy trained in the performance of the foregoing activities, each of whom shall acknowledge in writing their completion of such activities with respect to each group of products assembled for delivery.

(9) The ESRD pharmacy permit holder shall assure through visual inspection and comparison of records that products assembled for delivery to persons with chronic kidney failure are consistent with the prescribing practitioner's order therefor.

(10) The products ordered by the prescribing practitioner under this Rule shall be delivered by either the ESRD pharmacy or a carrier authorized by the ESRD pharmacy.

(11) Upon delivery of the products by the ESRD pharmacy or its carrier to the person identified on the prescribing practitioner's order, the ESRD pharmacy or its carrier shall confirm receipt by the patient or the patient's designee that the number of units delivered equals the number of units identified on the appropriate documentation. Compliance with the foregoing requirements set forth above shall be conducted by an employee or agent of the ESRD pharmacy trained in the performance of such activities, who shall acknowledge in writing the delivery of the products and the completion of such activities with respect to each delivery.



- (12) In addition to the foregoing operation requirements, an ESRD pharmacy shall comply with the following:
- (a) The ESRD pharmacy license shall be displayed at each ESRD pharmacy location.
  - (b) The Board of Pharmacy shall be notified in writing of the Consulting Pharmacist responsible, at the time of application for the permit, for supervising the ESRD pharmacy operations and within 10 days, if the Consultant Pharmacist of record changes.
  - (c) The ESRD pharmacy's hours of business shall be posted. The ESRD pharmacy shall be open such hours as are necessary to safely and effectively dispense and deliver supplies to those persons designated by the applicable prescribing practitioner. An ESRD pharmacy shall provide twenty-four hour emergency and on-call service.
  - (d) The ESRD pharmacy shall have sufficient space and storage capabilities as are necessary to carry out its operation.
  - (e) All legend drugs and/or legend devices included in the formulary subject to this rule shall be properly identified.
  - (f) The ESRD pharmacy shall maintain a current copy of the Florida pharmacy laws and rules.
  - (g) The ESRD pharmacy shall comply with patient counseling requirements of Rules 64B16-27.800-.810 and 64B16-27.820, F.A.C.
- (13) ESRD Pharmacy Application Requirements. An applicant for an ESRD pharmacy permit shall provide the Board of Pharmacy with a Policy and Procedure Manual setting forth in detail the operational guidelines of the applicant. The Policy and Procedure Manual shall include a Quality Assurance Program which monitors personnel qualifications, training and performance.
- (14) An ESRD pharmacy shall be under the control and supervision of licensed Consultant Pharmacist licensed under Section 465.0125, F.S. The Consulting Pharmacist shall be responsible for the drug/device delivery system.
- (15) The Consultant Pharmacist of record for the ESRD Pharmacy shall be responsible for establishing a written protocol and Policy and Procedure Manual for the implementation of a delivery system to be utilized in compliance with the requirements of this rule.
- (16) The Consultant Pharmacist shall inspect the permitted ESRD pharmacy on a monthly basis.
- (17) A copy of the ESRD pharmacy's Policy and Procedure Manual as provided above shall accompany the permit application, shall be kept within the ESRD Pharmacy, and shall be available for inspection by the Department of Health. Changes in the Policy and Procedure Manual shall be approved by the Consulting Pharmacist.

*Rulemaking Authority 465.005, 465.0125 FS. Law Implemented 465.0196, 465.022 FS. History—New 10-2-94, Formerly 59X-28.850, Amended 9-20-99, 7-17-05, 6-24-08.*

#### **64B16-28.860 Special Pharmacy – Parenteral/Enteral Extended Scope Permit.**

- (1)(a) A Special Parenteral/Enteral Extended Scope permit, as authorized by Section 465.0196, F.S., is required for pharmacies to compound patient specific enteral/parenteral preparations in conjunction with institutional pharmacy permits, provided requirements set forth herein are satisfied. Prior to engaging in a parenteral/enteral compounding pharmacy practice as described in this section, an entity shall obtain a Special Parenteral/Enteral Extended Scope pharmacy permit.
- (b) Special Parenteral/Enteral Extended Scope pharmacies and institutional pharmacy permits shall create and comply with Policy and Procedure Manuals that delineate duties and responsibilities of each entity, including the following provisions:
1. When dispensing patient specific prescriptions provided by an institutional pharmacy permit, the Special Parenteral/Enteral Extended Scope pharmacy shall confirm accuracy of the prescription and dosage.
  2. The institutional pharmacy permit shall maintain records appropriate to ensure the provision of proper patient care.
  3. The institutional pharmacy permit designee shall inspect and log in all medicinal drugs provided by the Special Parenteral/Enteral Extended Scope pharmacy.
  4. A pharmacist for the Class II institutional pharmacy shall provide drug utilization review and shall review each prescription order prior to transmission to the Special Parenteral/Enteral Extended Scope pharmacy.
  5. The Policy and Procedure Manual for a Special Parenteral/Enteral Extended Scope pharmacy shall also meet the

policy and procedure manual requirements of paragraph 64B16-28.820(3)(d), F.A.C.

(c) Such Policy and Procedure manuals shall be made available to the Board or Department upon request.

(2) Facilities obtaining this permit may also provide services described in paragraph 64B16-28.820(1)(a), F.A.C., without obtaining an additional permit. Pharmacy services and parenteral/enteral products provided by a Special Parenteral/Enteral Extended Scope pharmacy shall be limited to the compounding and/or dispensing of sterile:

(a) Preparations for parental therapy, parenteral nutrition; and/or

(b) Preparations for enteral feeding and sterile irrigation solutions; and/or

(c) Preparations of cytotoxic or antineoplastic agents.

(3) Facilities operating under this permit may provide all necessary supplies and delivery systems so that the medicinal drugs listed herein may be properly administered.

(4) Pharmacy Environment. The compounding and dispensing of sterile parenteral/enteral prescription preparations within a Special Parenteral/Enteral Extended Scope pharmacy shall be accomplished in a pharmacy environment subject to the pharmacy permit laws contained in Chapter 465, F.S., and in accordance with those requirements for the safe handling of drugs. Special Parenteral/Enteral Extended Scope permittees shall comply with the requirements contained in subsections 64B16-28.820(3) through (4), F.A.C., and the following:

(a) Shall include an active and ongoing end product testing program to ensure stability, sterility, and quantitative integrity of finished prescriptions.

(b) Shall insure each compounding process undergoes an initial and thereafter annual sterility validation utilizing media fill to ensure the integrity and validity of the compounding process.

(5) Records.

(a) Special Parenteral/Enteral Extended Scope pharmacies shall comply with the record maintenance requirements as contained in Rule 64B16-28.140, F.A.C.

(b) Special Parenteral/Enteral Extended Scope pharmacies dispensing medicinal products to patients under the provisions of paragraph 64B16-28.820(1)(a), F.A.C., or to patients of Modified Class II institutional pharmacies under the provisions of Rule 64B16-28.860, F.A.C., shall comply with the records, utilization review, and patient counseling requirements of Rules 64B16-27.800, 64B16-27.810 and 64B16-27.820, F.A.C.

(c) Special Parenteral/Enteral Extended Scope pharmacies dispensing medicinal products to patients of Class II institutional pharmacies under the provisions of Rule 64B16-28.860, F.A.C., shall be exempt from the records, utilization review, and patient counseling requirements of Rules 64B16-27.800, 64B16-27.810 and 64B16-27.820, F.A.C.

(d) Compounding records shall be organized in such a manner as to include: lot number traceability of components used during compounding, documentation of any equipment used during compounding, documentation of staff performing compounding, and records recording ultimate dispensing of the compounded product.

*Rulemaking Authority 465.005 FS. Law Implemented 465.0196, 465.022 FS. History—New 9-4-96, Formerly 59X-28.860, Amended 7-17-05.*

#### **64B16-28.870 Special-ALF.**

(1) The Special-ALF permit is an optional facility license for those Assisted Living Facilities providing a drug delivery system utilizing medicinal drugs provided in unit dose packaging.

(2) Medicinal Drugs.

(a) Medicinal drugs may not be dispensed on the premises.

(b) All medicinal drugs must be maintained in individual prescription containers for the individual patient.

(c) Medicinal drugs dispensed to the residents of a Special-ALF permit shall meet the labeling requirements of Rules 64B16-28.502 and 64B16-28.108, F.A.C.

(d) Medicinal drugs may not be dispensed on the premises. Medicinal drugs dispensed to patients of Special-ALF permits may be returned to the dispensing pharmacy's stock under the provisions of Rule 64B16-28.118, F.A.C. Dispensed controlled substances that have been discontinued shall be disposed of under the provisions of Rule 64B16-28.301, F.A.C.

(3) Consultant Pharmacist of Record.

(a) Each facility holding a Special-ALF permit shall designate a consultant pharmacist of record to ensure compliance with the laws and rules governing the permit. The Board office shall be notified in writing within ten (10) days of any change in the consultant pharmacist of record.

(b) The consultant pharmacist of record shall be responsible for the preparation of the Policy and Procedure Manual required by subsection 64B16-28.800(2), F.A.C. Policy and Procedure Manuals must provide for the appropriate storage conditions and security of the medicinal drugs stored at the facility.

(c) The consultant pharmacist of record shall inspect the facility and prepare a written report to be filed at the permitted facility at least monthly.

(d) The consultant pharmacist of record shall conduct Drug Regimen Reviews as required by Federal or State law, inspect the facility, and prepare a written report to be filed at the permitted facility at least monthly. In addition, the consultant pharmacist of record must monitor the facility's system for maintaining medication administration records and physician order sheets to ensure that the most current record of medications is available for the monthly drug regimen review. The consultant pharmacist of record may utilize additional consultant pharmacists to assist in this review and ~~or~~ in the monthly facility inspection.

(e) A consultant pharmacist licensed in Florida may remotely access a facility or pharmacy's electronic database from outside the facility or pharmacy to conduct supplemental drug regimen review services, subject to the pharmacy or facility establishing policies and procedures to ensure the security and privacy of confidential patient records, including compliance with applicable Federal HIPAA regulations.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(11)(a), 465.016(1)(l), 465.0196 FS. History—New 2-23-98, Amended 7-19-17.*

**64B16-28.900 Definitions – Nuclear Pharmacy.**

(1) A "nuclear pharmacy" is a pharmacy which provides radiopharmaceutical services.

(2) A "nuclear pharmacist" is a pharmacist who has met the training qualifications as described in Rule 64B16-26.303, F.A.C., and has been licensed by the Board of Pharmacy.

(3) A "radiopharmaceutical service" shall include, but shall not be limited to, the procurement, storage, preparation, labeling, quality assurance testing, distribution, record keeping and disposal of radiopharmaceuticals.

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

(5) "Radiopharmaceutical quality assurance" includes, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals, and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history and the keeping of proper records.

(6) "Authentication of product history" includes, but is not limited to, identifying the purchasing source, the ultimate fate, and intermediate handling of any component of a radiopharmaceutical or other drug.

*Rulemaking Authority 465.005 FS. Law Implemented 465.003(14), 465.022(1)(e) FS. History—New 1-7-76, Formerly 21S-3.01, Amended 4-4-88, Formerly 21S-3.001, Amended 7-31-91, 4-15-92, 10-1-92, Formerly 21S-28.900, 61F10-28.900, 59X-28.900, Amended 4-5-05.*

**64B16-28.901 Nuclear Pharmacy – General Requirements.**

The process employed by any permit holder in this state concerning the handling of radioactive materials must involve appropriate procedures for the purchase, receipt, storage, manipulation, compounding, distribution and

disposal of radioactive materials. In order to insure the public health and safety in this respect, a nuclear pharmacy in this state shall meet the following general requirements:

(1) Each nuclear pharmacy shall designate a nuclear pharmacist as the prescription department manager who shall be responsible for compliance with all laws and regulations, both state and federal pertaining to radiopharmaceuticals and radiopharmaceutical services. A nuclear pharmacist must personally supervise the operation of only one nuclear pharmacy during all times when radiopharmaceutical services are being performed.

(2) The nuclear pharmacy area shall be secured from access by unauthorized personnel.

(3) Each nuclear pharmacy shall maintain accurate records of the acquisition, inventory, distribution, and disposal of all radiopharmaceuticals.

(4) All nuclear pharmacies shall provide a secured radioactive storage and decay area.

(5) Nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies for the procurement, secure storage, inventory, preparation, distribution and disposal of radiopharmaceuticals and other drugs.

(6) Radiopharmaceuticals are to be distributed only upon a prescription order from an authorized licensed medical practitioner or through the practitioner's agent.

(7) A nuclear pharmacist may transfer radioactive materials in accordance with all applicable laws and regulations.

(8) A nuclear pharmacist upon receiving an oral prescription order for a radiopharmaceutical shall immediately have the prescription order reduced to writing. The pharmacist may delegate this duty to a registered pharmacy technician only as authorized by Rule 64B16-27.410, F.A.C. The prescription order shall contain at least the following:

(a) The name of the user or his agent;

(b) The date of distribution and the time of calibration of the radiopharmaceutical;

(c) The name of the procedure;

(d) The name of the radiopharmaceutical;

(e) The dose or quantity of the radiopharmaceutical;

(f) Any specific instructions; and,

(g) The initials of the person who received the prescription order.

(h) The patient's name must be obtained and recorded prior to dispensing, if the prescription order is for a therapeutic or blood product radiopharmaceutical.

(9) The immediate outer container shield of a radiopharmaceutical to be dispensed shall be labeled with:

(a) The name of and address of the pharmacy;

(b) The name of the prescriber;

(c) The date of the original filling;

(d) The standard radiation symbol;

(e) The words "Caution Radioactive Material";

(f) The name of the procedure;

(g) The prescription order number of the radiopharmaceutical;

(h) The radionuclide and chemical form;

(i) The amount of radioactivity and the calibration date and time;

(j) The expiration date and time;

(k) The volume if a liquid;

(l) The number of items or weight, if a solid;

(m) The number of ampules or vials, if a gas;

(n) Molybdenum 99 content to USP limits, applies only to Tc 99m products; and,

(o) The name of the patient for therapeutic or blood-product radiopharmaceuticals or the words "Physician's Use Only" for diagnostic radiopharmaceuticals. If the prescription order is for a therapeutic or blood-product radiopharmaceutical, the patient's name must be obtained and recorded prior to dispensing. The requirements of this subsection shall be met when the name of the patient is readily retrievable from the physician upon demand.

- (p) The initials of the pharmacist who dispensed the medication.
- (10) The immediate inner container label of a radiopharmaceutical to be distributed shall be labeled with:
  - (a) The standard radiation symbol;
  - (b) The words "Caution Radioactive Material";
  - (c) The radionuclide;
  - (d) The chemical form;
  - (e) The prescription order number of the radiopharmaceutical.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(11)(a)3., 465.003(14), (15), 465.0126, 465.014 FS. History—New 1-7-76, Formerly 21S-3.03, Amended 12-11-86, 4-4-88, Formerly 21S-3.003, 21S-28.901, 61F10-28.901, Amended 2-26-95, Formerly 59X-28.901, Amended 4-5-05, 1-1-10, 12-31-13.*

#### **64B16-28.902 Nuclear Pharmacy – Minimum Requirements.**

In order to insure compliance with the general safety requirements as previously set forth above, the following minimum requirements shall be met by a nuclear pharmacy. These requirements are in addition to the general requirements for space and equipment for other types of pharmacies, the requirements of the Department of Health for the control of radiation hazards, and the applicable requirements of the Federal Food and Drug Administration. Such minimum permit requirements are set forth as follows:

(1) Space:

- (a) The area for the storage, compounding, distribution and disposal of radiopharmaceuticals shall be adequate to completely separate such radioactive pharmaceuticals from pharmacy areas which contain non-radioactive medicinal drugs;
- (b) The Hot lab, storage area, and compounding and dispensing area shall be a minimum of 150 square feet.

(2) Equipment:

- (a) Fume hood with appropriate air sampling equipment;
- (b) Shielded radiation containment drawing station;
- (c) Dose calibrator;
- (d) Well scintillation counters;
- (e) Area rate meters;
- (f) Geiger-Mueller (GM) Survey meters;
- (g) Refrigerator;
- (h) Microscope;
- (i) Syringe shields; and,
- (j) Personnel radiation detection devices.

(3) Supplies:

- (a) Syringes and vials required to perform practice;
- (b) Disposable gloves and protective lab coats;
- (c) Appropriate supplies to ensure sterile practices for I.V. solutions;
- (d) Appropriate supplies to perform thin layer chromatography;
- (e) Lead transport shields for syringes and vials. No person shall utilize reusable unit dose transport containers for radioactive doses without either an effective process to decontaminate the transport container of blood and other biohazardous substances or an effective mechanism to avoid contamination of the transport container. No person shall re-use a unit dose transport container that remains contaminated with blood or other biohazardous substances. Any unit dose transport container that is returned with the tamper-evident seal broken and the unit dose syringe included shall be considered to be contaminated.
- (f) D.O.T. Type 7A approved transport containers and other labels and supplies for shipping radioactive materials.

(4) Current references:

- (a) Chapter 465, F.S.;
- (b) Chapter 404, F.S.;

- (c) Chapter 893, F.S.;
- (d) Chapters 64B16-26 and 64B16-28, F.A.C., Rules of the Florida Board of Pharmacy;
- (e) Chapter 64E-5, F.A.C., Rules of the Department of Health;
- (f) Title 10 C.F.R., Code of Federal Regulations, FDA Regulations;
- (g) Title 49 C.F.R., Code of Federal Regulations, Department of Transportation Regulations;
- (h) United States Pharmacopeia/National Formulary;
- (i) USP-DI.

It shall be acceptable, in lieu of an actual hard copy, to maintain these materials in a readily available electronic data format.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0193, 465.022(1) FS. History–New 1-7-76, Formerly 21S-3.04, Amended 12-11-86, 4-4-88, Formerly 21S-3.004, Amended 7-31-91, Formerly 21S-28.902, 61F10-28.902, Amended 2-26-95, Formerly 59X-28.902, Amended 4-26-01, 4-5-05.*

#### **64B16-28.903 Training Qualifications.**

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(14), 465.0126 FS. History–New 4-17-76, Amended 4-8-80, 6-23-83, Formerly 21S-3.05, Amended 8-11-86, 4-4-88, Formerly 21S-3.005, Amended 7-31-91, Formerly 21S-28.903, 61F10-28.903, Amended 6-12-96, Formerly 59X-28.903, Repealed 1-18-05.*

#### **64B16-28.904 Nuclear Pharmacist – Continuing Education.**

*Rulemaking Authority 465.0126, 465.022 FS. Law Implemented 465.009(5), 465.0126 FS. History–New 10-28-91, Formerly 21S-28.904, 61F10-28.904, 59X-28.904, Amended 1-12-03, 10-19-03, Repealed 1-18-05.*

#### **64B16-28.905 Nonresident Sterile Compounding Permit Inspections; Approved Inspection Entities.**

*Rulemaking Authority 465.0158 FS. Law Implemented 465.0158 FS. History–New 12-24-15, Transferred to 64B16-32.015.*

**CHAPTER 64B16-29  
ANIMAL CONTROL SHELTER PERMITS**

64B16-29.001	Definition
64B16-29.002	General Requirements
64B16-29.003	Drug Requirement (Repealed)
64B16-29.004	Records
64B16-29.0041	Record Maintenance Systems for Animal Shelter Permits
64B16-29.005	Storage

**64B16-29.001 Definition.**

An "animal control shelter" is a county or municipal animal control agency or Humane Society registered with the Secretary of State which holds a modified Class II Institutional Pharmacy permit issued by the Department of Health pursuant to certification of compliance with Rule 64B16-29.002, F.A.C., by the Board of Pharmacy. An animal control shelter is issued a pharmacy permit for the sole purpose of obtaining the drugs, sodium pentobarbital and sodium pentobarbital with lidocaine, Tiletamine Hydrochloride, alone or combined with Zolazepam (including Telazol), Xylazine (including Rompun), Ketamine, Acepromazine Maleate (also Acetylpromazine, and including Atravet or Acezine), alone or combined with Etorphine (including Immobilon), and Yohimbine Hydrochloride, alone or combined with Atipamezole (including Antisedan), for euthanization or chemical immobilization of animals within their lawful possession.

*Rulemaking Authority 465.005, 828.055 FS. Law Implemented 828.055 FS. History—New 10-17-79, Formerly 21S-14.01, Amended 4-24-88, Formerly 21S-14.001, 21S-29.001, 61F10-29.001, 59X-29.001, Amended 3-3-13.*

**64B16-29.002 General Requirements.**

(1) Application for an Animal Control Shelter Pharmacy permit shall be made on Board of Pharmacy approved form DOH-MQA/PH/107 "Animal Control Pharmacy Permit Application and Information," effective October 2009, which is incorporated by reference. To obtain an application, 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://www.doh.state.fl.us/mqa/pharmacy>.

(a) The application fee for animal shelters applying for the Modified Class II Institutional permit shall be fifty dollars (\$50.00).

(b) The biennial permit renewal fee for animal shelters holding the Modified Class II Institutional permit shall be fifty dollars (\$50.00).

(2) The applicant shall apply to the Drug Enforcement Administration, United States Department of Justice, by the appropriate DEA form, for Registration as a practitioner, to be designated as "Animal Shelter" on the appropriate DEA form.

(3) The applicant shall be certified by the Board of Pharmacy to the Department as having met the requirements of this rule chapter prior to issuance of a permit. The certification process shall require prior inspection of the facility by authorized persons.

(4) The consultant pharmacist requirement of Section 465.019(5), F.S., is waived as being inapplicable to this special restricted permit.

(5) Authorized employees of the Department shall inspect animal control shelters not less than twice per year to determine compliance with this rule.

(6) Each animal control shelter permittee shall designate an on-site manager of the shelter. The on-site manager and permittee shall notify the Department within ten (10) days of any change in the on-site manager of the shelter.

*Rulemaking Authority 465.005, 828.055 FS. Law Implemented 828.055 FS. History—New 10-17-79, Formerly 21S-*

14.02, Amended 4-24-88, Formerly 21S-14.002, Amended 10-1-92, Formerly 21S-29.002, Amended 7-18-94, Formerly 61F10-29.002, 59X-29.002, Amended 5-11-10.

#### **64B16-29.003 Drug Requirement.**

*Rulemaking Authority 465.005, 828.055 FS. Law Implemented 828.055 FS. History—New 10-17-79, Formerly 21S-14.03, Amended 4-24-88, Formerly 21S-14.003, 21S-29.003, 61F10-29.003, 59X-29.003, Repealed 3-28-12.*

#### **64B16-29.004 Records.**

Animal control shelter permittees shall maintain records of purchases and administration of drugs for euthanization or chemical immobilization for a period of not less than four (4) years. Records of administration shall contain:

- (1) The date of use;
- (2) Identification of the animal;
- (3) The amount of the drug used;
- (4) The signature of the person administering the drug;
- (5) The signature of the on-site manager certifying the accuracy of the administration of sodium pentobarbital and sodium pentobarbital with lidocaine not less than once per month; and,
- (6) The signature of the on-site manager certifying to the accuracy of the records. These records are subject to audit by the Drug Enforcement Administration or authorized employees of the Department to determine adequacy, accuracy and validity of the record keeping.

*Rulemaking Authority 465.005, 828.055 FS. Law Implemented 828.055 FS. History—New 10-17-79, Formerly 21S-14.04, Amended 4-24-88, Formerly 21S-14.004, 21S-29.004, 61F10-29.004, 59X-29.004, Amended 2-7-13.*

#### **64B16-29.0041 Record Maintenance Systems for Animal Shelter Permits.**

- (1) General requirements for records maintained in an electronic system.
  - (a) If a permitted animal shelter's data processing system is not in compliance with the Board's data processing requirements, the facility must maintain a manual recordkeeping system meeting the requirements of Rule 64B16-29.004, F.A.C.
  - (b) Requirements for back-up systems. The facility shall maintain a back-up copy of information stored in the data processing system using disk, tape, or other electronic back-up and up-date this back-up copy on a regular basis, at least monthly, to assure that data is not lost due to system failure.
  - (c) Change or discontinuance of a data processing system.
    1. Records of dispensed and returned medicinal drugs. A permitted animal shelter 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 the same information as required on the audit trail printout as specified in Rule 64B16-29.004, F.A.C.
    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.
  - (d) Loss of data. The shelter manager for permitted animal shelters 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) The permitted animal shelter shall maintain a system(s) which can produce the information required in Rule 64B16-29.004, F.A.C., for the preceding four (4) years. The information required in this paragraph shall be supplied by the permitted animal shelter within seven working days if requested.
    - (3) Failure to maintain records. Failure to provide records set out in this subsection, either on site or within 7



working days for whatever reason, constitutes failure to keep and maintain records.

(4) Data processing system downtime. In the event that a permitted animal shelter which uses a data processing system experiences system downtime, the permitted animal shelter must have an auxiliary procedure which will ensure that all data is retained.

*Rulemaking Authority 465.005, 828.055 FS. Law Implemented 465.019, 828.055 FS. History—New 3-31-05, Amended 7-13-14.*

**64B16-29.005 Storage.**

All controlled substances, medicinal drugs or legend drugs shall be stored in a safe place. At a minimum, this shall require that the drugs be kept in a securely locked cabinet within a locked storage room. Schedule II order forms are to be stored under the same conditions. Records of purchases of all controlled substances, medicinal drugs or legend drugs shall be maintained in a separate file from the records of administration. The records of purchases and administration shall be maintained at the location.

*Rulemaking Authority 465.005, 828.055 FS. Law Implemented 828.055 FS. History—New 10-17-79, Formerly 21S-14.05, Amended 4-24-88, Formerly 21S-14.005, 21S-29.005, 61F10-29.005, 59X-29.005, Amended 6-17-13.*

**CHAPTER 64B16-30  
DISCIPLINARY GUIDELINES**

64B16-30.001	Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances
64B16-30.002	Minor Violations
64B16-30.003	Citations
64B16-30.0035	Mediation

**64B16-30.001 Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances.**

(1) The board sets forth below a range of disciplinary guidelines from which disciplinary penalties will be imposed upon licensees guilty of violating chapters 456, 465, 499, or 893 or section 828.055, F.S. The purpose of the disciplinary guidelines is to give notice to licensees of the range of penalties which will normally be imposed upon violations of particular provisions of chapters 456, 465, 499, 893 or section 828.055, F.S. The term license means any permit, registration, certificate, or license, including a provisional license, issued by the Department. Penalty ranges are shown as minimum and maximum guidelines as well as for first time single count violations and for multiple or repeated violations of the same statutory provision or the rules promulgated thereunder. If an actual range of penalties is not provided, the listed penalty shall be the guideline penalty for the violation(s) unless aggravating or mitigating factors are shown. All penalties at the upper range of the sanctions set forth in the guidelines, e.g., suspension, revocation, etc., include lesser penalties, e.g., fine, continuing education, probation, or reprimand, which may be included in the final penalty at the board’s discretion. Probation may be subject to conditions, including restriction from practice in certain settings, restricting the licensee to working only under designated conditions or in certain settings, requiring continuing or remedial education, or any other restriction found to be necessary for the protection of the public health, safety, and welfare. In addition to any other discipline imposed under these guidelines, the board shall assess costs relating to the investigation and prosecution of the case.

(2) The following disciplinary guidelines shall be followed by the board in imposing disciplinary penalties upon licensees and permittees for violation of the below mentioned statutes and rules. For the purposes of this rule, the descriptions of the violations are abbreviated and the full statute or rule cited should be consulted to determine the prohibited conduct.

VIOLATION	PENALTY RANGE	
	FIRST VIOLATION	SECOND AND SUBSEQUENT VIOLATIONS
(a) Obtaining a license or permit by misrepresentation, fraud, or error. (Section 465.016(1)(a), F.S.); (Section 465.023(1)(a), F.S.)		
1. By negligent misrepresentation on original application or renewal.	\$1,000 fine and 12 hour Laws and Rules course or MPJE and 3-hour ethics course to \$5,000 fine and Revocation.	Revocation.
2. By fraudulent misrepresentation on original application or renewal.	\$10,000 fine for each count and Revocation.	\$10,000 fine for each count and Revocation.
3. By error of the Department or Board on original application or renewal.	Revocation.	Revocation.

(b) Procuring or attempting to procure a license or permit for another person by false representation. (Section 465.016(1)(b), F.S.); (Section 465.023(1)(b), F.S.)	\$10,000 fine for each count and Revocation.	\$10,000 fine for each count and Revocation.
(c) Permitting any unlicensed persons, including owner or operator of pharmacy, to practice pharmacy. (Section 465.016(1)(c), F.S.)	\$2,500 fine and 12-hour Laws & Rules course or Multistate Pharmacy Jurisprudence Exam (MPJE) to \$5,000 fine and one (1) year suspension followed by one (1) year probation.	\$10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
(d) Being unfit or incompetent to practice pharmacy by reason of habitual intoxication, medicinal drug abuse, or physical or mental condition that threatens public safety. (Sections 465.016(1)(d), (m), F.S.)	\$250 fine, indefinite suspension with PRN review and board appearance to Revocation.	One (1) year suspension followed by one (1) year probation, to Revocation.
(e) Violating laws governing the practice of pharmacy. (Section 465.016(1)(e), F.S.); (Section 465.023(1)(c), F.S.)		
1. Chapter 465, F.S.:		
a. Failure to supervise registered pharmacy technician. (Section 465.014, F.S.)	\$250 fine and one (1) year probation and 12-hour Laws and Rules course or MPJE to \$1,000 fine and one (1) year probation.	\$1,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
b. Operating a pharmacy that is not registered. (Section 465.015(1)(a), F.S.)	\$500 fine per month to maximum of \$5,000 (penalty will require permittee to obtain or renew permit or cease practice) to Revocation.	\$10,000 fine, Revocation and referral to State Attorney's Office for criminal prosecution.
c. Operating a pharmacy where an unlicensed, unregistered, or unsupervised person practices pharmacy. (Section 465.015(1)(b), F.S.)	\$5,000 fine and one (1) year probation to one (1) year suspension followed by one (1) year probation.	\$10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
d. Making a false or fraudulent statement to the board. (Section 465.015(2)(a), F.S.)	\$10,000 fine to Revocation.	\$10,000 fine and Revocation.
e. Practicing pharmacy as an inactive licensee. (Section 465.015(2)(b), F.S.)	\$500 fine per month while inactive (maximum \$6,000) to \$10,000 fine and one (1) year suspension.	\$10,000 fine and two (2) years suspension, to Revocation.
f. Selling or dispensing drugs without a prescription.		

(Section 465.015(2)(c), F.S.)		
(I) Non-scheduled legend drugs.	\$1,500 fine to \$5,000 fine and one (1) year probation.	\$5,000 fine and one (1) year probation, to Revocation.
(II) Scheduled (controlled substances) legend drugs.	\$5,000 fine to \$10,000 fine and one (1) year probation.	\$10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
g. Selling samples or complimentary drugs. (Section 465.015(2)(d), F.S.)		
(I) Non-scheduled legend drugs.	\$1,500 fine and (1) year probation to \$5,000 fine and one (1) year suspension.	\$5,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
(II) Scheduled (controlled substances) legend drugs.	\$5,000 fine and one (1) year probation to Revocation.	\$10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
h. Failure to notify the board of, or failure to have, a prescription department manager or a supervising, a responsible, or a consultant pharmacist. (Section 465.018, .019, .0193, .0196, or .0197, F.S. and 465.022(10), (11), F.S.)		
(I) Failure to notify. (Section 465.018, F.S.)	Fine based on length of time prior to notifying board. \$500 per month (maximum \$6,000) to one (1) year probation.	\$7,500 fine and one (1) year suspension to Revocation.
(II) Failure to have prescription department manager or a supervising, a responsible, or a consultant pharmacist of record.	Fine based on length of time practicing without designated pharmacist, \$750 fine per month and one (1) year probation.	\$2,000 fine per month, to Revocation.
i. Failure to comply with substitution of legend drug requirements. (Sections 465.025(2), (3), (4), F.S.)	\$500 fine and 12-hour Laws & Rules course or MPJE to \$2,200 fine and one (1) year probation.	\$2,500 fine, 12-hour Laws & Rules course or MPJE, and one (1) year probation to Revocation.
j. Failure to follow negative formulary requirements. (Section 465.025(6), F.S.); (Rule 64B16-27.500, F.A.C.)	\$1,000 fine and 12-hour Laws & Rules course or MPJE to \$2,500 fine and one (1) year probation.	\$2,500 fine, 12-hour Laws & Rules course or MPJE, and one (1) year probation to Revocation.
k. Failure to follow emergency prescription requirements. (Section 465.0275, F.S.)	\$500 fine to \$2,500 fine and one (1) year probation.	\$2,500 fine and one (1) year probation to \$5,000 fine and one (1) year suspension followed by one (1) year probation.
l. Engage in prohibited rebate scheme. (Section 465.185, F.S.)	\$1,500 fine and 12-hour Laws & Rules course or MPJE to \$5,000 fine and one (1) year probation.	\$5,000 fine, 12-hour Laws & Rules course or MPJE, and one (1) year probation, to Revocation.
m. Failure to comply with pharmacist		

dispensing requirements. (Section 465.186, F.S.)		
(I) Failure to follow procedure, but dispense drug appearing on formulary. (Section 465.186(3), F.S.); (Rule 64B16-27.210, F.A.C.)	\$500 fine to \$1,000 fine and one (1) year probation.	\$1,000 fine and one (1) year probation to suspension of right to dispense.
(II) Dispensing drug not on the formulary. (Section 465.186(2), F.S.); (Rules 64B16-27.220, .230, F.A.C.)	\$1,500 fine and 12-hour Laws & Rules course or MPJE to \$5,000 fine and one (1) year probation.	\$5,000 fine and one (1) year probation to \$10,000 fine and Revocation.
n. Failure to timely report fraudulent obtaining or attempted obtaining of controlled substances from a pharmacy. (Section 465.015(3), F.S.)		
(I) Failure to timely report.	\$500 fine and 12-hour Laws & Rules course or MPJE to one (1) year probation.	\$1,000 fine and one (1) year probation, to Revocation.
(II) Failure to report.	\$1,000 fine and one (1) year probation to one (1) year suspension.	\$5,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
o. Violation of facsimile prescription requirements. (Section 465.035, F.S.)	\$500 fine and 12-hour Laws & Rules course or MPJE to one (1) year probation.	\$1,000 fine and one (1) year probation, to Revocation.
p. Violation of requirements for administration of vaccines and epinephrine auto injection. (Section 465.189, F.S.); (Section 465.009(6)(a), F.S.)		
(I) Failure to enter into a written protocol.	\$2,500 fine and 12-hour Laws & Rules course or MPJE to one (1) year probation.	\$5,000 fine and one (1) year probation, to Revocation.
(II) Failure to maintain proper insurance.	\$500 fine and suspension until insured to one (1) year probation.	\$1,000 fine, suspension until insured, followed by one (1) year probation to Revocation.
(III) Failure to maintain and make available patient records.	\$500 fine to one (1) year probation.	\$1,000 fine and one (1) year probation to Revocation.
(IV) Uncertified administration of vaccine.	\$5,000 fine and one (1) year suspension of immunization certification to one (1) year suspension.	\$7,500 fine and suspension until certified, followed by one (1) year probation, to Revocation.
(V) Failure to submit copy of protocol or written agreement to the board.	\$500 fine to one (1) year probation.	\$1,000 fine and one (1) year probation to Revocation.
q. Failure to request photo or other verification of identity prior to dispensing a controlled substance to a person not known. (Section 465.0155(2), F.S.)	\$500 fine and 12-hour Laws & Rules course or MPJE to one (1) year probation.	\$1,000 fine and one (1) year probation, to Revocation.
r. Failure to inform customers of less expensive drug when cost sharing obligation	\$500 fine and 12-hour Laws & Rules course or MPJE to one (1)	\$1,000 fine to one (1) year suspension of dispensing rights.

to customer exceeds retail price. (Section 465.0244(2), F.S.)	year probation.	
2. Chapter 499, F.S.:		
a. Adulteration or misbranding of a drug. (Sections 499.005(2), (3), F.S.); (Section 499.006, F.S.); (Section 499.007, F.S.)		
(I) Adulteration of a drug. (Section 499.005(2), F.S.); (Section 499.006, F.S.)	\$1,000 fine and 12-hour Laws & Rules course or MPJE to one (1) year probation.	\$5,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
(II) Receipt or delivery of any drug that is adulterated or misbranded. (Section 499.005(3), F.S.)	\$1,000 fine and 12-hour Laws & Rules course or MPJE to one (1) year probation.	\$5,000 fine and one (1) year probation, to Revocation.
(III) Incomplete or inaccurate labeling. (Section 499.007, F.S.); (Rule 64B16-28.108, F.A.C.)	\$250 fine and 12-hour Laws & Rules course or MPJE to one (1) year probation.	\$2,500 fine and one (1) year probation, to Revocation.
(IV) Fraudulent misbranding of legend drugs. (Section 499.007, F.S.)	\$10,000 fine and one (1) year suspension followed by one (1) year probation to two (2) years' suspension.	\$10,000 fine and two (2) years' suspension followed by two (2) years' probation, to Revocation.
b. Failure to obtain a permit or registration, or operating without a valid permit when it is required. (Section 499.005(22), F.S.)	\$500 fine per month to maximum of \$5,000 (penalty will require permittee to renew permit or cease practice) to one (1) year probation.	\$10,000 fine (penalty will require permittee to renew permit or cease practice), to Revocation.
c. Prescription drug pedigree violations. (Section 499.005(28), F.S.); (Section 499.0051, F.S.)	\$500 fine and 12-hour Laws & Rules course or MPJE to one (1) year probation.	\$5,000 fine and one (1) year probation, to Revocation.
d. Recordkeeping requirement. (Section 499.0121, F.S.); (Sections 499.005(18), (19), F.S.)	\$500 fine and 12-hour Laws & Rules course or MPJE to one (1) year probation.	\$5,000 fine and one (1) year probation, to Revocation.
e. Storage of drugs. (Section 499.0121, F.S.)	\$500 fine and 12-hour Laws & Rules course or MPJE to one (1) year probation.	\$5,000 fine and one (1) year probation, to Revocation.
3. Chapter 893, F.S. (Controlled Substances):		
a. Filling a written or oral prescription for controlled substances that does not meet the requirements of Chapter 893, F.S. (Sections 893.04(1)(a), (b), (c), F.S.)	\$1,500 fine and 12-hour Laws & Rules course or MPJE to one (1) year probation.	\$5,000 fine and one (1) year probation, to Revocation.
b. Failing to retain prescription records for two (2) years. (Section 893.04(1)(d), F.S.)	\$1,000 fine and 12-hour Laws & Rules course or MPJE to one (1) year probation.	\$5,000 fine and one (1) year probation, to Revocation.
c. Failing to appropriately label. (Section 893.04(1)(e), F.S.)	\$250 fine and 12-hour Laws & Rules course or MPJE to one (1) year probation.	\$2,500 fine and (1) year probation, to Revocation.

d. Dispensing a Schedule II drug inappropriately with a non-written prescription. (Section 893.04(1)(f), F.S.)	\$5,000 fine and one (1) year probation to one (1) year suspension.	\$10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
e. Inappropriate refilling of Schedule III, IV, or V drugs. (Section 893.04(1)(g), F.S.); (Section 893.04(2)(e), F.S.)	\$1,750 fine and one (1) year probation to one (1) year suspension.	\$5,000 fine and one (1) year suspension, to Revocation.
f. Receiving controlled substances without an appropriate order form. (Section 893.06(1), F.S.)	\$2,500 fine to one (1) year probation.	\$5,000 fine and one (1) year probation, to Revocation.
g. Possession of controlled substances outside the regular course of business, occupation, profession, employment, or duty. (Section 893.06(2), F.S.)	\$2,500 fine and one (1) year probation to one (1) year suspension.	\$5,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
h. Failure to take a biennial inventory. (Sections 893.07(1)(a), (2), (3), (4), (5), F.S.)	\$1,000 fine and 12-hour Laws & Rules course or MPJE to one (1) year probation.	\$2,500 fine and one (1) year probation, to Revocation.
i. Failure to maintain a complete and accurate record of controlled substances. (Sections 893.07(1)(b), (2), (3), (4), (5), F.S.)	\$1,000 fine, 12-hour Laws & Rules course or MPJE to one (1) year probation.	\$5,000 fine and two (2) years' probation, to Revocation.
j. Dispensing Schedule V controlled substances in other than good faith. (Section 893.08(3)(b), F.S.)	\$5,000 fine and one (1) year probation to one (1) year suspension.	\$10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
k. Inappropriate selling of Schedule V controlled substance. (Section 893.08(3)(c), F.S.)	\$1,500 fine and one (1) year probation to one (1) year suspension.	\$5,000 fine and one (1) year suspension, to Revocation.
l. Unlawful possession of controlled substance. (Section 893.13, F.S.)	\$5,000 fine and two (2) years' probation to one (1) year suspension.	\$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
m. Failure to report information regarding dispensed controlled substances to the Prescription Drug Monitoring Program Controlled Substance Dispensing Information Electronic System. (Section 893.055(3), F.S.)	\$250 fine and 12-hour Laws & Rules course or MPJE to one (1) year probation.	\$5,000 fine and one (1) year probation, to Revocation.
n. Failure to consult the Prescription Drug Monitoring Program Controlled Substance Dispensing Information Electronic System prior to dispensing a controlled substance. (Section 893.055(8), F.S.)	\$250 fine and 12-hour Laws & Rules course or MPJE to one (1) year probation.	\$5,000 fine and one (1) year probation, to Revocation.
o. Failure to maintain confidentiality of information obtained from the Prescription Drug Monitoring Program Controlled Substance Dispensing Information Electronic System.		

(Section 893.0551(6), F.S.)		
(I) Knowing violation.	\$10,000 fine and one (1) year probation to one (1) year suspension.	\$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
(II) Negligent violation.	Reprimand to \$500 fine and 12-hour Laws & Rules course or MPJE.	One (1) year probation and \$1,000 fine to one (1) year suspension.
4. Violation of Federal Drug Abuse Act 21 U.S.C. 821 et seq. (Manufacture, Distribution, and Dispensing of Controlled Substances.)	\$1,000 fine and one (1) year probation to one (1) year suspension.	\$2,000 fine up to \$10,000 and one (1) year suspension followed by two (2) years' probation, to Revocation.
5. Violation of Food and Drug Act 21 U.S.C. 301 – 392.	\$2,500 fine and one (1) year suspension, to Revocation.	\$7,500 fine and two (2) years' suspension followed by two (2) years' probation, to Revocation.
(f) Criminal conviction related to Pharmacy. (Section 465.016(1)(f), F.S.); (Section 465.023(1)(d), F.S.)		
1. Misdemeanor.	\$1,000 fine to one (1) year probation.	\$5,000 fine and one (1) year probation, to Revocation.
2. Felony.	\$5,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.	\$10,000 fine and two (2) years' suspension followed by three (3) years' probation, to Revocation.
(g) Using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed, except as authorized in Section 465.019(6), F.S. or Section 465.025, F.S. (Section 465.016(1)(g), F.S.); or, compounding, dispensing or distributing legend drugs outside professional practice of pharmacy. (Section 465.016(1)(i), F.S.)	\$250 fine without ingestion or harm, to \$500 with ingestion, and complete approved CE course in the prevention of medication errors of no less than eight (8) hours to one (1) year probation.	\$500 fine without ingestion or harm, to \$1,000 with ingestion, complete approved CE course in the prevention of medication errors of no less than eight (8) hours, and two (2) years' probation, to Revocation.
(h) Filing a false report or failing to file a report required by law. (Section 465.016(1)(j), F.S.)		
1. Knowing violation.	\$10,000 fine and one (1) year probation to one (1) year suspension.	\$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
2. Negligent violation.	Reprimand to \$500 fine and 12-	One (1) year probation and



	hour Laws & Rules course or MPJE.	\$1,000 fine to one (1) year suspension.
(i) Failure to make prescription price information available. (Section 465.016(1)(k), F.S.)	\$250 fine and 12-hour Laws & Rules course or MPJE, to \$1,000 fine and one-year probation.	\$1,000 fine and one (1) year probation to one (1) year suspension.
(j) Improperly placing returned drugs into the stock of a pharmacy. (Section 465.016(1)(l), F.S.)	\$1,500 fine to \$1,000 fine and one-year probation.	\$3,000 fine and one (1) year probation to one (1) year suspension.
(k) Violating a rule or order of the Board or Department. (Section 465.016(1)(n), F.S.)		
1. Rules of Board of Pharmacy.		
a. Rules 64B16-28.101 to 64B16-28.1035, F.A.C. Rule 64B16-27.100, F.A.C. Rule 64B16-28.109, F.A.C. Rule 64B16-27.103, F.A.C. Rule 64B16-27.104, F.A.C. Rule 64B16-26.400, F.A.C. Rule 64B16-26.2032 F.A.C. Rule 64B16-28.1081, F.A.C. Rule 64B16-27.105, F.A.C. Rule 64B16-27.211, F.A.C. Rule 64B16-28.113, F.A.C. Rule 64B16-28.2021, F.A.C. Rule 64B16-28.603, F.A.C.	\$500 fine and 12-hour Laws & Rules course or MPJE, to \$1,000 fine and one-year probation.	One (1) year probation and \$2,000 fine to one (1) year suspension.
b. Sink and running water, sufficient space, refrigeration, sanitation, equipment. (Rule 64B16-28.102, F.A.C.)	Suspension until compliance.	\$2,000 fine to Revocation.
c. Knowingly purchase, sell, possess, or distribute counterfeit drugs. (Section 499.005(8), F.S.)	\$5,000 fine, one (1) year suspension followed by one (1) year probation to Revocation.	\$10,000 fine to Revocation.
d. Failure to remove outdated pharmaceuticals, or dispensing of same. (Rule 64B16-28.110, F.A.C.)	\$500 fine for possession, \$1,000 fine for dispensing to one (1) year probation.	\$2,500 – \$5,000 fine and two (2) years’ probation, to Revocation.
e. Violation of destruction of controlled substances. (Rules 64B16-28.301 and .303 F.A.C.)	\$500 fine and 12-hour Laws & Rules course or MPJE to one (1) year probation.	\$5,000 fine and two (2) years’ probation, to Revocation.
f. Serving as consultant pharmacist without being licensed as a consultant pharmacist. (Rule 64B16-26.300, F.A.C.)	\$500 per month up to \$5,000 fine. (fine based upon the length of time the person is serving as a consultant without being licensed as a consultant pharmacist.)	\$7,500 fine and one (1) year suspension followed by two (2) years’ probation, to Revocation.

g. Violation of requirements for records maintained in a data processing system. (Rule 64B16-28.140, F.A.C.)	\$1,000 fine and 12-hour Laws & Rules course or MPJE plus 8-hours CE course in record keeping to one (1) year probation.	\$5,000 fine and two (2) years' probation, to Revocation.
h. Failure to properly store legend drugs. (Rule 64B16-28.120, F.A.C.)	\$1,000 fine and 12-hour Laws & Rules course or MPJE to one (1) year probation.	\$5,000 fine and one (1) year probation, to Revocation.
i. Practicing nuclear pharmacy without being licensed as a nuclear pharmacist. (Rule 64B16-26.303, F.A.C.)	\$500 per month up to \$5,000 fine. (fine based upon the length of time the person is practicing without being licensed as a nuclear pharmacist.)	\$10,000 fine and one (1) year suspension, to Revocation.
j. Failure to follow technical requirements for nuclear pharmacy. (Rules 64B16-28.901 and .902, F.A.C.)	One (1) year probation and \$1,000 fine, to \$2,500 fine and six (6) months suspension followed by one (1) year probation to one (1) year suspension.	\$5,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
k. Failure to properly transfer prescription files and medicinal drugs when closing pharmacy. (Rules 64B16-28.202 and .203, F.A.C.)	Revocation.	Revocation.
l. Failure to complete the required continuing education during the biennial licensure period. (Rule 64B16-26.103, F.A.C.)		
(I) Failure to complete less than ten (10) hours.	\$500 fine and suspension until completed.	\$1,500 fine and suspension until completed.
(II) Failure to complete ten (10) or more hours.	\$1,000 fine. In addition, licensees shall take two (2) additional hours of continuing education for each of the continuing education deficiencies. Said hours shall not count for continuing education renewal requirements for the next biennium.	\$2,500 fine and suspension until deficiency and penalty units are completed. In addition, licensees shall take two (2) additional hours of continuing education for each of the continuing education deficiencies. Said hours shall not count for continuing education renewal requirements for the next biennium.
m. Failure to retain continuing education records. (Rule 64B16-26.603, F.A.C.)	\$250 fine.	\$1,500 fine and suspension of license until undocumented courses are completed and documentation is submitted to the Department.
n. Failure to practice in accordance with		

established practice standards. (Rules 64B16-27.1001 and .104, F.A.C.)		
(I) Pharmacist.	\$500 to \$1,000 fine and 12-hour Laws & Rules course or MPJE to one (1) year probation.	\$2,500 to \$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
(II) Pharmacy Intern.	\$250 to \$500 fine and 12-hour Laws & Rules course or MPJE.	\$1,000 to \$5,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
(III) Permittee.	\$500 to \$1,000 fine and 12-hour Laws & Rules course or MPJE to one (1) year probation.	\$2,500 to \$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
o. Failure to have or maintain current policies and procedures for automated pharmacy system or central fill pharmacy. (Rules 64B16-28.141 and .450, F.A.C.)	\$500 to \$1000 fine and 12-hour Laws & Rules course or MPJE.	\$2,500 to \$5,000 fine and suspension of license/permit until current policies and procedures are in place, to Revocation.
p. Failure to have or maintain standards for an institutional pharmacy. (Rules 64B16-28.602, .6021, .605, .606, .702, F.A.C.)	\$500 fine and 12-hour Laws & Rules course or MJPE.	\$2,500 to \$5,000 fine and suspension of license until policies and procedures are in place, to Revocation.
q. Failure to have or maintain standards for a special pharmacy. (Rules 64B16-28.800, .810, .820, .840, .850, .860, .870, F.A.C.)	\$500 fine and 12-hour Laws & Rules course or MJPE.	\$2,500 to \$5,000 fine and suspension of license until policies and procedures are in place, to Revocation.
r. Failure to maintain standards for animal control shelters. (Rule Chapter 64B16-29, F.A.C.)	\$500 fine and 12-hour Laws & Rules course or MJPE.	\$2,500 to \$5,000 fine and suspension of license until policies and procedures are in place, to Revocation.
s. Failure to comply with Board's rule on patient counseling. (Rules 64B16-27.800, .810, .820, F.A.C.)	\$250 fine without ingestion or harm, to \$500 with ingestion, and complete approved CE course in the prevention of medication errors of no less than eight (8) hours.	\$500 fine without ingestion or harm, to \$1,000 with ingestion, complete approved CE course in the prevention of medication errors of no less than eight (8) hours, and two (2) years' probation, to Revocation.
t. Standards of practice for compounding CSPs. (Rules 64B16-27.700 and .797, F.A.C.)		
(I) No harm.	\$500 fine, 12-hour Laws & Rules course, and course governing sterile compounds, to \$2,000 fine and one (1) year probation.	\$2,500 to \$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
(II) Harm.	\$2,000 fine, one (1) year probation, and 12-hour Laws &	Revocation.

	Rules course, to Revocation.	
2. Violation of orders of the Board or Department.	\$2,500 fine and one (1) year probation, to suspension until compliance with order.	\$5,000 fine and one (1) year probation, to suspension until compliance with order, to Revocation.
(l) License disciplined by another jurisdiction for an offense that would constitute a violation of this chapter. (Section 465.016(1)(h), F.S.); (Section 465.023(1)(e), F.S.)	Same penalty as imposed in other jurisdiction or as closely as possible to penalties set forth in Florida Statutes.	Same penalty as imposed in other jurisdiction or as closely as possible to penalties set forth in Florida Statutes to \$10,000 fine and Revocation.
(m) Failing to report to the Department any chapter 458 or 459, F.S., licensee violation. (Section 465.016(1)(o), F.S.)	\$500 fine and 12-hour Laws & Rules course or MJPE.	\$1,500 fine and 12-hour Laws & Rules course or MJPE.
(n) Abandoning or allowing permit to become null and void after notice of disciplinary proceedings. (Section 465.018(3), F.S.)	Revocation.	Revocation.
(o) Failing to notify the Board of commencement or cessation of practice due to discipline in another jurisdiction. (Section 465.016(1)(p), F.S.)	\$500 fine and 12-hour Laws & Rules course or MJPE.	\$2,000 fine and two (2) years' probation to Revocation.
(p) Using or releasing patient records improperly. (Section 465.016(1)(q), F.S.)	\$1,000 fine and 12-hour Laws & Rules course or MJPE.	\$2,500 fine and one (1) year probation to Revocation.
(q) Knowingly, or with reason to believe, dispensing based on purported prescription where patient-prescriber relationship is invalid. (Section 465.016(1)(s), F.S.); (Section 465.023(1)(h), F.S.)		
(I) Reason to believe.	\$2,000 fine, 12-hour Laws & Rules course or MJPE, and one (1) year probation to one (1) year suspension.	\$2,500 to \$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
(II) Knowingly.	Revocation.	Revocation.
(r) Committing an error or omission during prescription drug processing. (Section 465.016(1)(t), F.S.)	\$250 fine without ingestion or harm, to \$500 with ingestion, and complete approved CE course in the prevention of medication errors of no less than eight (8) hours.	\$500 fine without ingestion or harm, to \$1,000 with ingestion, complete approved CE course in the prevention of medication errors of no less than eight (8) hours, and two (2) years' probation, to Revocation.
(s) Guilty of a felony involving moral turpitude.	\$1,000 fine and 12-hour Laws & Rules course or MJPE.	\$5,000 fine and one (1) year probation, to Revocation.

(Section 465.023(1)(d), F.S.)		
(t) Guilty of a crime related to health care fraud. (Section 465.023(1)(g), F.S.)	Revocation and a fine of \$10,000, or in the case of application for licensure, denial of license.	Revocation and a fine of \$10,000, or in the case of application for licensure, denial of license.
(u) Violating Section 456.072, F.S. (Section 465.016(1)(r), F.S.)		
1. Making misleading, deceptive, or fraudulent representation in or related to the practice of the licensee's profession. (Section 456.072(1)(a), F.S.)	\$10,000 fine and one (1) year probation to one (1) year suspension.	Revocation, and a fine of \$10,000.
2. Intentionally violating any rule adopted by the Board or the Department. (Section 456.072(1)(b), F.S.)	\$2,500 fine and two (2) years' probation to one (1) year suspension.	\$5,000 to \$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
3. Being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession. (Section 456.072(1)(c), F.S.)		
a. Misdemeanor.	\$1,000 fine to one (1) year probation.	\$2,500 fine and one (1) year probation, to Revocation.
b. Felony.	\$3,000 fine and one (1) year probation to one (1) year suspension.	\$5,000 to \$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
4. Failing to comply with the educational course requirements for human immunodeficiency virus and acquired immune deficiency syndrome, or medical errors. (Section 456.072(1)(e), F.S.) (Rules 64B16-26.103(1)(c), (4)(e), F.A.C.)	\$500 fine and suspension until compliant.	\$1,000 fine and suspension until compliant.
5. Having a license or the authority to practice the regulated profession revoked, suspended, or otherwise acted against, including the denial of licensure, by the licensing authority of any jurisdiction, including its agencies or subdivisions, for a violation that would constitute a violation under Florida law. The licensing authority's acceptance of a relinquishment of licensure, stipulation, consent order, or other settlement, offered in response to or in anticipation of the filing of charges against the license, shall be construed as action	Same penalty as imposed in other jurisdiction or as closely as possible to penalties for similar violation.	Same penalty as imposed in other jurisdiction or as closely as possible to penalties for similar violation, to \$10,000 fine and Revocation.

against the license. (Section 456.072(1)(f), F.S.)		
6. Having been found liable in a civil proceeding for knowingly filing a false report or complaint with the Department against another licensee. (Section 456.072(1)(g), F.S.)	\$3,000 fine.	\$5,000 to \$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
7. Attempting to obtain, obtaining, or renewing a license to practice a profession by bribery, by fraudulent misrepresentation, or through an error of the Department or the Board. (Section 456.072(1)(h), F.S.)	\$10,000 fine and Revocation or denial of license application.	\$10,000 fine and Revocation or denial of license application.
8. Except as provided in section 465.016, F.S., failing to report to the Department any person who the licensee knows is in violation of this part, the chapter regulating the alleged violator, or the rules of the Department or the Board. (Section 456.072(1)(i), F.S.)	\$500 fine and 12-hour Laws & Rules course or MJPE.	\$1,500 fine and 12-hours Laws & Rules or MJPE, to one (1) year suspension or Revocation.
9. Aiding, assisting, procuring, employing, or advising any unlicensed person or entity to practice a profession contrary to this part, the chapter regulating the profession, or the rules of the Department or the Board. (Section 456.072(1)(j), F.S.)	\$2,000 fine and 12-hour Laws & Rules course or MJPE, to one (1) year probation.	\$2,500 to \$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
10. Failing to perform any statutory or legal obligation placed upon a licensee, including failure to repay student loans or perform scholarship service obligations. (Section 456.072(1)(k), F.S.)		
a. Generally.	\$2,000 fine and suspension until compliant.	\$2,500 to \$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
b. Student loans or scholarship service.	The minimum disciplinary action imposed shall be a suspension of the license until new payment terms are agreed upon or the scholarship obligation is resumed, followed by probation for the duration of the student loan or remaining scholarship obligation period, and a fine equal to 10 percent of the defaulted loan amount.	Suspension of the license until new payment terms are agreed upon or the scholarship obligation is resumed, followed by probation for the duration of the student loan or remaining scholarship obligation period, and a fine equal to 10 percent of the defaulted loan amount, to Revocation with a minimum total fine of \$10,000.
11. Making or filing a report which the licensee knows to be false, intentionally or		

negligently failing to file a report or record required by state or federal law, or willfully impeding or obstructing another person to do so. Such reports or records shall include only those that are signed in the capacity of a licensee. (Section 456.072(1)(l), F.S.)		
a. Knowingly filing a false report or willful obstruction.	\$10,000 fine and two (2) years' probation to one (1) year suspension.	\$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
b. Negligently failing to file a report or record.	\$2,500 fine.	\$5,000 fine and one (1) year probation, to Revocation.
12. Making deceptive, untrue, or fraudulent representations in or related to the practice of a profession or employing a trick or a scheme in or related to the practice of a profession. (Section 456.072(1)(m), F.S.)	\$10,000 fine and two (2) years' probation to one (1) year suspension.	\$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
13. Exercising influence on the patient or client for the purpose of financial gain of the licensee or a third party. (Section 456.072(1)(n), F.S.)	\$3,000 fine and two (2) years' probation.	\$5,000 to \$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
14. Practicing or offering to practice beyond the scope permitted by law or accepting and performing professional responsibilities the licensee knows, or has reason to know, the licensee is not competent to perform. (Section 456.072(1)(o), F.S.)	\$2,000 fine and two (2) years' probation to one (1) year suspension.	\$5,000 to \$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
15. Delegating or contracting for the performance of professional responsibilities by a person when the licensee delegating or contracting for performance of such responsibilities knows, or has reason to know, such person is not qualified by training, experience, and authorization when required to perform them. (Section 456.072(1)(p), F.S.)	\$2,000 fine and two (2) years' probation to one (1) year suspension.	\$5,000 to \$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
16. Violating any provision of chapter 456, F.S., the applicable professional practice act, a rule of the Department or the Board, or a lawful order of the Department or the Board, or failing to comply with a lawfully issued subpoena of the Department. (Section 456.072(1)(dd), F.S.); (Section 456.072(1)(q), F.S.)	\$1,000 fine and 12-hour Laws & Rules course or MPJE, to one (1) year probation.	\$5,000 to \$10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
17. Improperly interfering with an investigation or inspection authorized by statute, or with any disciplinary proceeding.	\$2,500 fine and two (2) years' probation.	\$5,000 to \$10,000 fine and one (1) year suspension followed by two (2) years' probation, to

(Section 456.072(1)(r), F.S.)		Revocation.
18. Engaging or attempting to engage in sexual misconduct as defined and prohibited in Section 456.063(1), F.S. (Section 456.072(1)(v), F.S.)	\$10,000 fine and Revocation.	\$10,000 fine and Revocation.
19. Being unable to practice with reasonable skill and safety by reason of illness or use of alcohol, drugs, narcotics, chemicals, or as a result of any mental or physical condition (board has authority to issue order to compel examination). (Section 456.072(1)(z), F.S.)	\$500 fine, suspension until safe to practice with reasonable skill and safety, and appearance before the board.	\$2,500 fine and Revocation.
20. Failing to report to the Board, or the Department if there is no Board, in writing within 30 days after the licensee has been convicted or found guilty of, or entered a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction. (Section 456.072(1)(x), F.S.)	\$1,000 fine.	\$5,000 to \$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
21. Testing positive for any drug, as defined in section 112.0455, F.S., on any confirmed preemployment or employer ordered drug screening when the practitioner does not have a lawful prescription and legitimate medical reason for using such drug. (Section 456.072(1)(aa), F.S.)	\$500 fine, suspension until safe to practice with reasonable skill and safety and appearance before the board.	\$2,500 fine and Revocation.
22. Being terminated from, or failing to successfully complete, an impaired practitioners treatment program. (Section 456.072(1)(hh), F.S.)	Suspension until successful completion or receipt of written confirmation of compliance with ongoing treatment and a fine of up to \$1,000.	Revocation.
23. Being convicted of, or entering a plea of guilty or nolo contendere to, any misdemeanor or felony, regardless of adjudication, under 18 U.S.C. s. 669, ss. 285-287, s. 371, s. 1001, s. 1035, s. 1341, s. 1343, s. 1347, s. 1349, or s. 1518, or 42 U.S.C. ss. 1320a-7b, relating to the Medicaid program. (Section 456.072(1)(ii), F.S.)	Revocation and a fine of \$10,000, or in the case of application for licensure, denial of license.	Revocation and a fine of \$10,000, or in the case of application for licensure, denial of license.
24. Failing to remit the sum owed to the state for overpayment from the Medicaid program pursuant to a final order, judgment, or settlement. (Section 456.072(1)(jj), F.S.)	\$500 to \$5,000 fine and one (1) year probation.	\$2,500 to \$5,000 fine and suspension until amount owed is remitted, followed by two (2) years' probation, to Revocation.
25. Being terminated from the state Medicaid program pursuant to section	\$10,000 fine and one (1) year probation, to one (1) year	\$10,000 fine and two (2) years' suspension followed by two (2)



409.913, F.S., any other state Medicaid program, or the federal Medicare program, as a result of fraud and abuse unless eligibility to participate in the program from which the practitioner was terminated has been restored. (Section 456.072(1)(kk), F.S.)	suspension followed by one (1) year probation.	years' probation, to Revocation.
26. Being convicted of, or entering a plea of guilty or nolo contendere to, any misdemeanor or felony, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud. (Section 456.072(1)(ll), F.S.)	Revocation and a fine of \$10,000, or in the case of application for licensure, denial of license.	Revocation and a fine of \$10,000, or in the case of application for licensure, denial of license.
27. Willfully failing to comply with section 627.64194 or 641.513, F.S., with such frequency as to indicate a general business practice. (Section 456.072(1)(oo), F.S.)	Reprimand and a fine of \$250.	\$500 fine and one (1) year probation, to Revocation.
(v) Violation of section 828.055, F.S. by a permitted county or municipal animal control agency or humane society.		
1. Using drugs for animal euthanasia for an improper use. (Section 828.055(3)(a), F.S.)	Reprimand and a fine of \$250.	\$500 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
2. Failing to take reasonable precautions against misuse, theft, loss, or diversion. (Section 828.055(3)(b), F.S.)	Reprimand and a fine of \$250.	\$500 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
3. Failing to detect or to report a significant loss, theft, or inventory shortage of drugs. (Section 828.055(3)(c), F.S.)	Reprimand, \$500 fine, and one (1) year probation.	\$1,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
4. Failing to follow the rules of the Board regarding proper storage and handling of drugs. (Section 828.055(3)(d), F.S.)	Reprimand and a fine of \$250.	\$500 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
5. Violating any provision of section 828.055, chapter 465, and 499, F.S., or any rule adopted under those chapters. (Section 828.055(3)(e), F.S.)	Reprimand and a fine of \$250.	\$500 fine and one (1) year suspension followed by one (1) year probation, to Revocation.

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

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

1. History of previous violations of the practice act and the rules promulgated thereto.
2. In the case of negligent acts, the magnitude and scope of the damage or potential damage inflicted upon the patient or the general public by the licensee's misfeasance.

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

4. Harm occurred.

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

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

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

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

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

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

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

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

*Rulemaking Authority 456.072, 456.079, 465.005 FS. Law Implemented 456.072, 456.079, 465.016, 465.023 FS. History—New 3-1-87, Amended 5-11-88, Formerly 21S-17.001, 21S-30.001, 61F10-30.001, Amended 6-26-95, 1-30-96, Formerly 59X-30.001, Amended 12-3-97, 11-15-98, 5-3-00, 1-2-02, 11-29-06, 9-26-12, 2-14-13, 2-5-14, 1-10-17, 12-18-18.*

#### **64B16-30.002 Minor Violations.**

(1) The Board sets forth the following guidelines for use by Department investigators when a licensee is in noncompliance of an initial offense of a minor violation. The Board deems the following violations, depending upon severity, to be consistent with section 456.073(3), F.S.

(a) Outdated pharmaceuticals – rule 64B16-28.110, F.A.C.

(b) Failure to meet regulation of daily operating hours – rule 64B16-28.404, F.A.C.

(c) Generic substitution sign not displayed – section 465.025(7), F.S.

(d) Information required on controlled substance prescriptions: practitioner's address, practitioner's DEA registration number, patient's address – section 893.04, F.S.

(e) Failure to have certified by dispensing pharmacists the daily hard-copy printout or daily log – paragraph 64B16-28.140(3)(c) or (e), F.A.C.

(f) Failure to have pharmacy minimally equipped i.e. references, compounding equipment, and a current copy of the laws and rules governing the practice of pharmacy in the State of Florida – rule 64B16-28.107, F.A.C.

(g) Failure to properly identify pharmacy technicians – rule 64B16-27.410, F.A.C.

(h) Results of P&E quality assurance program not documented or available for inspection – paragraph 64B16-28.820(3)(d), F.A.C.

(i) Improper storage of legend drugs – rule 64B16-28.120, F.A.C.

(j) Improper documentation of destruction of controlled substances – rules 64B16-28.301, 64B16-28.303, F.A.C.

(k) Consultant pharmacist's monthly reports not current or available for inspection – rule 64B16-28.501, subsection 64B16-28.702(2), F.A.C.

(l) Controlled substance prescription labels lack transfer crime warning labeling – paragraph 64B16-28.502(2)(c), F.A.C.

(m) Failure to maintain proof of licensure, display licenses/registrations or notices, or to properly identify pharmacy staff – rule 64B16-27.100, F.A.C.

(n) Failure to have a continuously designated Prescription Department Manager or Consultant Pharmacist of Record,

if the gap between designations is less than fifteen (15) business days – rules 64B16-27.450 and 64B16-28.501, F.A.C.

(2) The Department’s investigator may issue a Notice of Deficiencies when the above conditions occur and the requirements of section 456.073(3), F.S., are met. In such cases licensees shall correct the violation and respond to the investigator on forms provided by the Department and with other evidence of compliance as may be necessary, within 30 days, to certify current compliance. Failure to do so shall subject the licensee to further proceedings.

*Rulemaking Authority 456.073(3), 465.005 FS. Law Implemented 456.073(3) FS. History–New 11-12-90, Formerly 21S-17.002, 21S-30.002, 61F10-30.002, 59X-30.002, Amended 12-9-98, 8-26-02, 11-7-17, 7-11-18.*

**64B16-30.003 Citations.**

(1) Pursuant to section 456.077, F.S., the Board sets forth in subsection (3) of this rule, those violations for which there is no substantial threat to the public health, safety and welfare. Next to each violation is the fine to be imposed.

(2) The following violations with accompanying fines may be disposed of by citation:

(a) Practicing pharmacy as an inactive licensee. (Section 465.015(2)(b), F.S.)	Fine based on length of time in practice while inactive; \$200/month or \$5,000 maximum (penalty will require licensee to renew license or cease practice).
(b) Operating a pharmacy with an inactive permit. (Section 465.015(1)(a), F.S.)	\$500 per month to a maximum of \$5000 (penalty will require permittee to renew permit or cease practice).
(c) First time failure to complete the required continuing education during the biennial licensure period. (Section 456.072(3)(a), F.S.)	
Failure to complete less than 10 hours	\$500
Failure to complete 10 or more hours	\$1,000

In addition, licensees shall take two additional hours of continuing education for each of the continuing education deficiencies. Said hours shall not count for continuing education renewal requirements for the next biennium.

(d) Failure to timely pay a fine or costs imposed by a final order.	\$500 per month late to a maximum of \$5,000 (penalty will require permittee or licensee to also pay the original fine and/or costs).
(e) Failure to display any sign, license or permit required by statute or rule.	\$500
(f) Failure to have any reference material required by statute or rule available.	\$500
(g) Failure to notify the board of a change in a prescription department manager or consultant pharmacist. (Rule 64B16-27.450 or 64B16-28.501, F.A.C.)	Fine based on the length of time prior to notifying board. \$200 a month to \$5,000 maximum.
(h) Using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed, except as authorized in section 465.019(6) or 465.025, F.S.; or dispensing a medication with dosage instructions different in any way than prescribed, provided that the medication was not used or	\$250 fine, Completion of an approved CE course in the prevention of medication errors of no less than 8 hours.

ingested. (Section 465.016(1)(g), F.S.)	
(i) Tendering a check payable to the Board of Pharmacy or to the Department of Health that is dishonored by the Institution upon which it is drawn.	\$100 fine plus payment of the check within 30 days.
(j) Failing to comply with the Educational course requirements for Human immunodeficiency virus and Acquired immune deficiency syndrome (HIV/AIDS), or medical errors. (Section 465.033(1), F.S.)	\$500
(k) Failure to correct Minor violation as listed in rule 64B16-30.002, F.A.C.	\$250
(l) First time failure to report controlled substance dispensing information to the Prescription Drug Monitoring Program Controlled Substance Dispensing Information Electronic System. (Section 893.055(3)(a), F.S.)	\$100
(m) First time (initial) failure to consult the Prescription Drug Monitoring Program Controlled Substance Dispensing Information Electronic System prior to dispensing a controlled substance. (Section 893.055(8), F.S.)	\$100
(n) Failure to request photo of other verification of identity prior to dispensing a controlled substance to a person not known. (Section 465.0155(2), F.S.)	\$100
(o) Failure to inform customers of less expensive drug when cost sharing obligation to customer exceeds retail price. (Section 465.0244(2), F.S.)	\$100
(p) Failure to comply with pharmacist to registered pharmacist technician ratio for activities not involving sterile compounding; no injury to patient/customer. (Rule 64B16-27.410(5) or (6), F.A.C.)	\$250
(q) Failure to remove from active stock and properly quarantine outdated prescription drugs. (Section 499.006(9) through 499.005(2), F.S.) (Section 499.0121(5)(a)2., F.S.) (Rule 64B16-28.110, F.A.C.)	\$250

(3) Once the citation becomes a final order, the citation and complaint become a public record pursuant to chapter 119, F.S., unless otherwise exempt from the provisions thereof. The citation and complaint may be considered as aggravating circumstances in future disciplinary actions pursuant to paragraph 64B16-30.001(3)(a), F.A.C.

(4) The procedures described herein apply only for an initial offense of the alleged violation. Subsequent violation(s) of the same rule or statute shall require the procedures of section 456.073, F.S., to be applied. In addition, should an initial offense for which a citation could be issued occur in conjunction with violations not described herein, then the procedures of section 456.073, F.S., shall apply.

*Rulemaking Authority 456.073, 456.077, 465.005 FS. Law Implemented 456.077 FS. History—New 12-22-91, Formerly 21S-30.003, 61F10-30.003, 59X-30.003, Amended 4-3-00, 1-2-02, 8-26-02, 1-12-03, 2-1-12, 9-27-18, 1-16-19, 4-4-19.*

**64B16-30.0035 Mediation.**

(1) "Mediation" means a process whereby a mediator appointed by the Department acts to encourage and facilitate resolution of a legally sufficient complaint. It is an informal and nonadversarial process with the objective of assisting the parties to reach a mutually acceptable agreement.

(2) The Board finds that mediation is an acceptable method of dispute resolution for the following violation as it is economic in nature or can be remedied by the licensee: failure of the licensee to timely pay any assessed administrative fines or costs.

(3) A "mediator" means a person who is certified in mediation by the Florida Bar, the Florida Supreme Court, or the Division of Administrative Hearings.

*Rulemaking Authority 456.078 FS. Law Implemented 456.078 FS. History—New 11-21-94, Formerly 59X-30.0035.*

**CHAPTER 64B16-32  
NONRESIDENT PHARMACIES**

- 64B16-32.001 Nonresident Pharmacy Permit
- 64B16-32.003 Nonresident Pharmacy Permit – Mandatory Notification for Change in Location, Change in Pharmacy Name,  
Change in Corporate Officer and Change in PDM
- 64B16-32.005 Nonresident Pharmacy Exemption “Isolated Transactions”
- 64B16-32.007 Nonresident Sterile Compounding Permit for Nonresident Pharmacies
- 64B16-32.009 Nonresident Sterile Compounding Permit for an Outsourcing Facility
- 64B16-32.011 Nonresident Sterile Compounding Permits – Mandatory Notification for a Change in Pharmacy Name and Change  
in Prescription Department Manager
- 64B16-32.013 Nonresident Sterile Compounding Permits – Change in Location or Change in Ownership
- 64B16-32.015 Nonresident Sterile Compounding Permit Inspections; Approved Inspection Entities
- 64B16-32.021 Initial Application/Permit and Permit Renewal Fees for all Nonresident Pharmacies

**64B16-32.001 Nonresident Pharmacy Permit.**

This permit is required before a pharmacy that is located outside the geographical boundaries of Florida can ship, mail, or deliver, in any manner, a dispensed medicinal drug into Florida.

(1) This permit does not authorize the nonresident pharmacy to ship, mail, deliver, or dispense, in any manner, a compounded sterile product into Florida.

(2) An applicant for a nonresident pharmacy permit shall submit an application using Form DH-MQA 1217 (eff. 07/16), “Nonresident Pharmacy Permit Application,” which is hereby incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-07519> or <http://floridapharmacy.gov>. Applicants for a nonresident pharmacy permit must comply with all requirements in Section 465.0156, F.S.

*Rulemaking Authority 465.005, 465.0156 FS. Law Implemented 465.0156, 456.065(3), 456.0635 FS. History–New 11-3-16.*

**64B16-32.003 Nonresident Pharmacy Permit – Mandatory Notification for Change in Location, Change in Pharmacy Name, Change in Corporate Officer and Change in PDM.**

(1) A change in pharmacy location, pharmacy name, corporate officer, or pharmacist serving as the prescription department manager shall be timely reported to the Board Office within 30 calendar days.

(2) If there is a change in the name of the pharmacy or the location of the pharmacy, or both, the department shall issue an updated duplicate permit that reflects the change or changes.

(3) If a duplicate permit is required to be issued pursuant to subsection (2), the permit holder shall pay a \$25.00 duplicate permit fee before the duplicate permit shall be released.

(4) Any notification required by this section shall be mailed to Florida Board of Pharmacy, Bin #C-04, Tallahassee, Florida 32399. If a duplicate permit is required, make the check or money order payable to the Department of Health.

*Rulemaking Authority 456.025(10), 465.005 FS. Law Implemented 465.0156, 456.025(10) FS. History–New 8-21-16.*

**64B16-32.005 Nonresident Pharmacy Exemption “Isolated Transactions.”**

(1) A nonresident pharmacy is exempt from obtaining a nonresident pharmacy permit if the nonresident pharmacy limits its dispensing activity to a one time, per calendar year, isolated transaction.

(2) An isolated transaction is defined as making a one-time delivery of a dispensed medicinal drug(s) to a single identifiable patient in Florida.

(3) This exemption is not applicable to the delivery of a dispensed medicinal drug that is a compounded sterile product.

*Rulemaking Authority 465.0156(2) FS. Law Implemented 465.0156(2) FS. History–New 8-21-16.*

#### **64B16-32.007 Nonresident Sterile Compounding Permit for Nonresident Pharmacies.**

This permit is required before a nonresident pharmacy ships, mails, delivers, or dispenses, in any manner, a patient-specific compounded sterile product into Florida.

(1) A nonresident pharmacy that obtains a nonresident sterile compounding permit may only ship, mail, deliver, or dispense a patient-specific compounded sterile product into Florida.

(2) A permit issued pursuant to this section shall be issued with the following conspicuously displayed on the front of the license: Nonresident Sterile Compounding Permit – Patient Specific Prescription Compounding Only.

(3) A nonresident pharmacy applicant seeking a nonresident sterile compounding permit shall submit an application using Form DH5003-MQA (eff. 07/16), "Nonresident Sterile Compounding Permit Application for Nonresident Pharmacies," which is hereby incorporated by reference. The Form is available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-08096>, or <http://floridaspharmacy.gov>. An applicant for this permit must comply with all provisions of Section 465.0158, F.S.

*Rulemaking Authority 456.0158 FS. Law Implemented 465.0158, 456.065 (3), 456.0635, 465.0156 FS History–New 4-12-17.*

#### **64B16-32.009 Nonresident Sterile Compounding Permit for an Outsourcing Facility.**

This permit is required before an outsourcing facility that is located outside of Florida, ships, mails, delivers, or dispenses, in any manner a compounded sterile product into Florida.

(1) An outsourcing facility that obtains a nonresident sterile compounding permit may ship, mail, or deliver a sterile compounded product into Florida for office-use and may ship, mail, deliver, or dispense a patient-specific compounded sterile product into Florida. This permit does not authorize the shipping, mailing, delivering, or dispensing of a non-compounded medicinal drug into Florida.

(2) A permit issued pursuant to this section shall be issued with the following conspicuously displayed on the front of the license: Outsourcing Facility Nonresident Sterile Compounding Permit – Patient Specific Prescription Compounding and Office-Use Compounding.

(3) An outsourcing facility applicant seeking a nonresident sterile compounding permit shall submit an application using Form DH5004-MQA (eff. 07/16), "Nonresident Sterile Compounding Permit Application for Outsourcing Facilities" which is hereby incorporated by reference. This Form is available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-08097>, or <http://floridaspharmacy.gov>.

*Rulemaking Authority 456.0158 FS. Law Implemented 465.0158, 456.065(3) FS. History–New 4-12-17.*

#### **64B16-32.011 Nonresident Sterile Compounding Permits – Mandatory Notification for a Change in Pharmacy Name and Change in Prescription Department Manager.**

(1) A change in the pharmacy name or a change in the prescription department manager, pharmacist in charge, or the equivalent (i.e., supervising pharmacist) for a nonresident sterile compounding permit for nonresident pharmacies and for nonresident sterile compounding permit for outsourcing facilities shall be timely reported to the board office within 30 calendar days.

(2) If there is a change in the pharmacy name, the department shall issue an updated duplicate permit that reflects the name change.

(3) If a duplicate permit is required to be issued pursuant to subsection (2), the permit holder shall pay a \$25.00 duplicate permit fee before the duplicate permit shall be released.

(4) Any notification required by this section shall be mailed to the Florida Board of Pharmacy, Bin #C-04, Tallahassee, Florida 32399. If a duplicate permit is required, make the check or money order payable to the Department of Health.

*Rulemaking Authority 456.025(10), 465.005, 465.0158(8) FS. Law Implemented 456.025(10), 465.0158 FS. History—New 8-21-16.*

**64B16-32.013 Nonresident Sterile Compounding Permits – Change in Location or Change in Ownership.**

(1) Change in Location: A change in location for a nonresident sterile compounding permit for nonresident pharmacies and a nonresident sterile compounding permit for outsourcing facilities shall require a new permit. Therefore, in the event of a change of location, the permit holder shall submit an application for a new permit.

(2) Change of Ownership: A nonresident sterile compounding permit for nonresident pharmacies and a nonresident sterile compounding permit for outsourcing facilities are non-transferable; therefore, if the ownership changes, a new permit shall be required. To determine what constitutes a change of ownership, please review Rule 64B16-28.2021, F.A.C.

*Rulemaking Authority 465.005, 465.0158(8) FS. Law Implemented 465.0158 FS. History—New 8-21-16.*

**64B16-32.015 Nonresident Sterile Compounding Permit Inspections; Approved Inspection Entities.**

All applicants for a nonresident sterile compounding permit must have and present a current and satisfactory inspection report, and all nonresident sterile compounding permit holders seeking biennial renewal of the permit must have and present a current and satisfactory inspection report, as mandated by Section 465.0158, F.S.

(1) Current and Satisfactory Inspection Report: An inspection report is current if the inspection report establishes that the inspection took place within the time frames established in Section 465.0158(3)(e), F.S. An inspection report will be deemed satisfactory when the report reflects that the applicant or permit holder compounds all sterile products in compliance with minimum practice and quality standards (minimum standards). The minimum standards are different for those who are only registered as a nonresident pharmacy pursuant to Section 465.0156, F.S., and for those who are registered as an outsourcing facility pursuant to Section 21 U.S.C. 353b.

(2) Minimum Standards: Applicants for an initial permit or applicants for biennial renewal that are both a registered nonresident pharmacy and a registered outsourcing facility must meet the minimum standards applicable to a registered outsourcing facility.

(a) Registered Outsourcing Facility: The minimum standards for a registered outsourcing facility are the Current Good Manufacturing Practices (cGMP) that are adopted and incorporated by reference in subsection 64B16-27.797(3), F.A.C.

(b) Registered Nonresident Pharmacies: The minimum standards for a registered nonresident pharmacy are Chapters 797, 71, 85, and 731 of the United States Pharmacopeia that are adopted and incorporated by reference in subsection 64B16-27.797(1), F.A.C.

(3) Mandatory State Inspection Report: The current and satisfactory inspection report must be generated from an inspection that is performed by the regulatory or licensing authority of the state, territory, or district (hereinafter "state") where the applicant is geographically located, unless the applicant meets the acceptable circumstances established herein. The board hereby deems the following as acceptable circumstances for the department's acceptance of a current and satisfactory inspection report performed pursuant to Sections 465.0158(3)(e)1.-3., F.S., in lieu of the state inspection report:

(a) In the event that state or federal law prohibits the submission of the state inspection report;

(b) In the event that the state refuses to perform the inspection or generates an inspection report after completion of the inspection;



(c) In the event that the state is unable to perform an inspection within a reasonable time period from the date requested. Reasonable time period means within 180 days from the date that the applicant requested an inspection be performed. A failure by the applicant to request an inspection within 180 days from the date of permit renewal is deemed not to be an acceptable circumstance;

(d) In the event that the state inspection report documents that the applicant fails to meet the minimum standards adopted in this rule or when the inspection report merely lists an overall pass or fail and does not have the minimum standards enumerated within the inspection report with an appropriate indication of pass, fail, or not applicable, next to each enumerated standard;

(e) In the event the state inspection report would not be admissible in an administrative proceeding pursuant to the provisions of Chapter 120, F.S., or when state or federal inspectors advise they will not testify to the contents, results thereof, or authentication of the state inspection report;

(f) In the event that the applicant is able to submit a current inspection report from the United States Food and Drug Administration that concludes or establishes the applicant is in compliance with cGMP.

(4) Approved Inspection Entities for Registered Nonresident Pharmacies: This section is not applicable to inspection reports for registered outsourcing facilities. The board must approve entities for which the department will accept a current and satisfactory inspection report in lieu of an onsite inspection by the department or an inspection by the licensing or regulatory authority of the state, territory, or district where the applicant is located. An entity that wants to be approved as an inspection entity must submit an Approval Request with attached documentation to the board office. The Approval Request, and attached documentation, shall demonstrate compliance with the following requirements:

(a) The entity must be a legally recognizable business entity that possesses a separate existence for tax purposes. An Approval Request must be submitted with business formation documents that establish compliance with this paragraph;

(b) The entity is formed, established, or created to avoid a reoccurring conflict of interest between the entity and those whom the entity will be inspecting. A conflict of interest is a real or seeming incompatibility between the entity's private interests and the entity's duty to conduct an impartial inspection;

(c) The entity will not conduct any inspection in which the entity or an employed inspector of the entity has a conflict of interest;

(d) The entity must have a customized inspection report. The inspection report must enumerate all minimum standards of each of the chapters of the United States Pharmacopeia that are listed in paragraph (2)(b), of this rule. Each enumerated minimum standard must have a place for the inspector to mark compliant or yes; non-compliant, deficient or no; and not applicable. Each enumerated minimum standard must also have room for the inspector to document observations or comments. An Approval Request must be submitted with a copy of the customized inspection report;

(e) The entity must submit any completed inspection report with digital photography capturing each enumerated minimum standard if the enumerated minimum standard is subject to being captured by photography;

(f) With the Approval Request, the entity must submit an inspection history report. The inspection history report must reflect that the applicant has experience performing inspections for compliance with the required minimum standards. To be approved, an entity must have a minimum of 2 years' experience performing inspections and must have performed a minimum of 20 inspections. The required inspection experience may be demonstrated through the experience of the employed inspectors, if the entity has not been in existence for 2 years prior to submitting an Approval Request;

(g) The entity must agree in writing that the entity will not make a recommendation for the granting, denial, or discipline of a permit;

(h) The entity shall have a written policies and procedures manual. The policies and procedures shall at a minimum address the timely completion and proper performance of inspections and must establish protocols and procedures to ensure compliance with this rule. The policy and procedures manual must be submitted with the

Approval Request. The policies and procedures shall require the inspections to be unannounced and that the costs of any inspection shall not be based on or differ in the amount based on the results of the inspection;

(i) The entity must agree in writing that it will testify to the contents of the inspection report in any civil, criminal, or administrative proceeding and that the entity agrees that it and any employed inspectors will not request an expert witness fee (Section 92.231, F.S.) for the testimony of the inspector who performed the inspection;

(j) The entity shall maintain all inspection reports and related records for a period of no less than 4 years from the date inspection was concluded;

(k) The entity shall, within 60 days prior to closing, notify the department or the board when it will close or cease performing inspection services and make arrangements with the department for preserving inspections records that are still within the 4 year retention requirement.

(5) Employed Inspectors: The entities' employed inspectors must meet the following criteria:

(a) Any employed inspector must hold an active license to practice pharmacy in any state, territory or district of the United States. Proof of the license shall be submitted with the Approval Request. The employed inspectors may not have any disciplinary history related to the practice of a health profession within 5 years prior to the Approval Request and may have never been disciplined for an offense related to compounding. This provision shall not prohibit the entity from retaining or employing any person that does not hold a pharmacy license for the purposes of assisting the inspectors. For example, it is acceptable to hire a microbiologist or chemist to assist the inspectors in completing the inspection and inspection report;

(b) Any employed inspector must have a minimum of 4 years' experience in the practice of sterile compounding. At least 2 of the 4 years of experience must be obtained through the active practice of compounding sterile products in all risk categories (low, medium, and high risk sterile compounding). The other 2 years may be obtained by one or more of the following: 1) Being employed by a state or federal agency to perform inspections of pharmacies or pharmaceutical manufacturers to determine compliance with minimum sterile compounding standards or current good manufacturing practices standards; 2) Being employed as a full-time instructor at an accredited university for the purpose of instructing students in didactic and clinical instruction on sterile compounding; 3) Being employed to conduct research related to sterile compounding; or 4) Being published in a peer review journal when the article is related to sterile compounding. Three months of credit will be awarded for each published article related to sterile compounding;

(c) At least one of the employed inspectors must have a minimum of 1 year, of the 4 years required, supervisory experience related to the practice of sterile compounding. Supervisory experience is being employed as a supervisor of other pharmacists, not just technicians, in a pharmacy setting that engaged in sterile compounding;

(d) Those employed inspectors which do not have at least 6 months of experience in performing inspections related to sterile compounding must first attend 2 inspections, as a subordinate inspector in training, before being allowed to perform an inspection independently;

(e) The entity must submit a copy of each inspector's employment history and a copy of the each inspector's curriculum vitae (CV) with the Approval Request. The CV must demonstrate that the inspectors are compliant with the experience requirements of this rule;

(f) During the period of employment as an inspector for the entity, the inspectors must have documented training related to sterile compounding and performing sterile compounding inspections. At a minimum, the training must consist of at least 10 clock hours of training annually. The training documentation shall be made available to the board upon written request.

(6) Once an entity is approved by the board, the applicant will be required to maintain compliance with the provisions of this rule or the approval is subject to revocation in compliance with the provisions of Chapter 120, F.S. The department will randomly require documentation of each approved entity to ensure continued compliance with the provision of this rule.

(7) All approved entities shall be listed on the Department's website.

*Rulemaking Authority 465.0158 FS. Law Implemented 465.0158 FS. History–New 12-24-15, Formerly 64B16-28.905.*

**64B16-32.021 Fees – Initial Application/Permit and Permit Renewal Fees for all Nonresident Pharmacies.**

(1) The initial application/permit fee for a nonresident pharmacy shall be \$250.00 and the biennial renewal fee shall be \$250.00. The initial application/permit fee and the renewal fee do not include the mandatory \$5.00 unlicensed fee that is to be imposed pursuant to Section 456.065(3), F.S.

(2) The initial application/permit fee for a nonresident sterile compounding permit for a nonresident pharmacy and for a nonresident sterile compounding permit for an outsourcing facility shall be \$250.00 and the biennial renewal fee shall be \$250.00. The application fee and the renewal fee do not include the mandatory \$5.00 unlicensed activity fee that is to be imposed by Section 456.065(3), F.S.

*Rulemaking Authority 465.005, 465.0158(3), 465.022(14) FS. Law Implemented 465.0156(3), 465.0158(3), 465.022(14) FS. History—New 4-19-17.*