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## The 2014 Florida Statutes

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REGULATION OF PROFESSIONS AND OCCUPATIONS

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PHARMACY

### CHAPTER 465 PHARMACY

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**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 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 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.

(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.

**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.

#### **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 institutional pharmacy or a Modified Class II 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.

**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.

#### **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.

**465.0155 Standards of practice.**—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.

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

**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.

**465.0158 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.

#### **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.

(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.

**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.

(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.

**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.

(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 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 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 institutional 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.

**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.

#### **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.

#### **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.**—Every pharmacy shall make available on its Internet website a link to the performance outcome and financial data that is published by the Agency for Health Care Administration pursuant to s. 408.05(3)(k) 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.

**History.**—s. 39, ch. 2004-297; s. 14, ch. 2006-261.

#### **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 or modified Class II 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.

**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.**—This chapter shall not be construed to prohibit the sale of home remedies

or preparations commonly known as patents or proprietary preparations, when such are 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.

**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.

**465.0275 Emergency prescription refill.**—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 one-time emergency refill of up to a 72-hour supply of the prescribed medication, with the exception of those areas or counties included in an emergency order or proclamation of a state of emergency declared by the Governor, in which the executive order may authorize the pharmacist to dispense up to a 30-day supply, providing that:

- (1) The prescription is not for a medicinal drug listed in Schedule II appearing in chapter 893.
- (2) The medication is essential to the maintenance of life or to the continuation of therapy in a chronic condition.
- (3) In the pharmacist's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences or may cause physical or mental discomfort.
- (4) 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.
- (5) 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.

**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 (5).
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. The amount dispensed pursuant to the subparagraph may not exceed a 14-day supply. This exception 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. For purposes of this subparagraph, the term "surgical procedure" means any procedure in any setting which involves, or reasonably should involve:
  - a. 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



- b. 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.
  - (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.
  - (3) The department shall inspect any facility where a practitioner dispenses medicinal drugs pursuant to subsection (2) in the same manner and with the same frequency as it inspects pharmacies for the purpose of determining whether the practitioner is in compliance with all statutes and rules applicable to her or his dispensing practice.
  - (4) 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.
  - (5) 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.

**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.

**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 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) Influenza vaccine.
- (b) Pneumococcal vaccine.

(c) Meningococcal vaccine.

(d) Shingles vaccine.

(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 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. 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.

**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.