

Committee Substitute for Committee Substitute for
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 Senate Bill No. 1372

An act relating to pharmacy; amending s. 465.003, F.S.; defining the term “Internet pharmacy”; amending s. 465.0156, F.S.; exempting Internet pharmacies from registration requirements applicable to nonresident pharmacies; requiring the registered nonresident pharmacy and the pharmacist designated by that pharmacy to serve as the prescription department manager or its equivalent to be licensed in the state of location; amending s. 465.016, F.S.; providing for disciplinary action for dispensing a medicinal drug when the pharmacist knows or has reason to believe the prescription is not based on a valid practitioner-patient relationship; creating s. 465.0161, F.S.; prohibiting the distribution of medicinal drugs by an Internet pharmacy without a permit; providing penalties; amending s. 465.0196, F.S., relating to special pharmacy permits, to conform; creating s. 465.0197, F.S.; requiring Internet pharmacies to be permitted and providing requirements therefor; requiring the Internet pharmacy and the pharmacist designated by that pharmacy to serve as the prescription department manager or its equivalent to be licensed in the state of location; amending s. 465.023, F.S.; providing an additional ground for which the Board of Pharmacy may take action against a permitted pharmacy; amending s. 465.0255, F.S.; revising requirements for pharmacists to deliver specified disclosures to purchasers when dispensing a medicinal drug; amending s. 465.026, F.S.; creating an exception to the requirements for filling or refilling a transferred prescription for a medicinal drug listed in Schedule II under ch. 893, F.S.; amending s. 499.0121, F.S.; providing recordkeeping requirements relating to the storage and handling of prescription drugs which certain affiliated groups must fulfill; amending s. 895.02, F.S.; including violation of s. 465.0161, F.S., in the definition of the term “racketeering activity” for prosecution under ch. 895, F.S.; providing an appropriation and authorizing positions; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraph (a) of subsection (11) of section 465.003, Florida Statutes, is amended to read:

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

(11)(a) “Pharmacy” includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, ~~and~~ 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).

Section 2. Subsections (7) and (8) are added to section 465.0156, Florida Statutes, to read:

465.0156 Registration of nonresident pharmacies.—

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

(8) 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.

Section 3. Paragraph (s) is added to subsection (1) of section 465.016, Florida Statutes, to read:

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):

(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(20) when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship.

Section 4. Section 465.0161, Florida Statutes, is created to read:

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.

Section 5. Section 465.0196, Florida Statutes, is amended to read:

465.0196 Special pharmacy permits.—Any person desiring a permit to operate a special pharmacy ~~which does not fall within the definitions set forth in s. 465.003(11)(a)1., 2., and 3.~~ 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. No permit shall 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 of any change of the licensed pharmacist responsible for such duties. Every permittee that employs or otherwise utilizes pharmacy technicians shall have a written policy and procedures manual specifying those duties, tasks, and functions which a pharmacy technician is allowed to perform.

Section 6. Section 465.0197, Florida Statutes, is created to read:

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. No permit shall 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 of any change of the licensed pharmacist responsible for such duties. Every permittee that employs or otherwise utilizes pharmacy technicians shall have a written policy and procedures manual specifying those duties, tasks, and functions which a 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.

Section 7. Subsection (1) of section 465.023, Florida Statutes, is amended to read:

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 who 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; or

(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; or

(e) 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(20) 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.

Section 8. Section 465.0255, Florida Statutes, is amended to read:

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;⁵

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

(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) Nothing in~~ This section does not shall 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)(3)~~ 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.

Section 9. Subsection (7) is added to section 465.026, Florida Statutes, to read:

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:

(7) A community pharmacy licensed under this chapter which only receives and transfers prescriptions for dispensing by another pharmacy may transfer a prescription for a medicinal drug listed in Schedule II under chapter 893. The pharmacy receiving the prescription may ship, mail, or deliver into this state, in any manner, the dispensed Schedule II medicinal drug under the following conditions:

(a) The pharmacy receiving and dispensing the transferred prescription 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 pharmacy is located and from which the medicinal drugs are dispensed;

(b) The community pharmacy and the receiving pharmacy are owned and operated by the same person and share a centralized database; and

(c) The community pharmacy assures its compliance with federal laws and subsections (1)-(5).

Section 10. Paragraph (h) is added to subsection (6) of section 499.0121, Florida Statutes, to read:

499.0121 Storage and handling of prescription drugs; recordkeeping.—The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

(6) RECORDKEEPING.—The department shall adopt rules that require keeping such records of prescription drugs as are necessary for the protection of the public health.

(h)1. This paragraph applies only to an affiliated group, as defined by s. 1504 of the Internal Revenue Code of 1986, as amended, which is composed of chain drug entities, including at least 50 retail pharmacies, warehouses, or repackagers, which are members of the same affiliated group, if the affiliated group:

a. Discloses to the department the names of all its members; and

b. Agrees in writing to provide records on prescription drug purchases by members of the affiliated group not later than 48 hours after the department requests such records, regardless of the location where the records are stored.

2. Each warehouse within the affiliated group must comply with all applicable federal and state drug wholesale permit requirements and must purchase, receive, hold, and distribute prescription drugs only to a retail pharmacy or warehouse within the affiliated group. Such a warehouse is exempt from providing a pedigree paper in accordance with paragraphs (d) and (e) to its affiliated group member warehouse, provided that:

a. Any affiliated group member that purchases or receives a prescription drug from outside the affiliated group must receive a pedigree paper if the

prescription drug is distributed in or into this state and a pedigree paper is required under this section and must authenticate the documentation as required in subsection (4), regardless of whether the affiliated group member is directly subject to regulation under this chapter; and

b. The affiliated group makes available to the department on request all records related to the purchase or acquisition of prescription drugs by members of the affiliated group, regardless of the location where the records are stored, if the prescription drugs were distributed in or into this state.

3. If a repackager repackages prescription drugs solely for distribution to its affiliated group members for the exclusive distribution to and among retail pharmacies that are members of the affiliated group to which the repackager is a member:

a. The repackager must:

(I) In lieu of the written statement required by paragraph (d) or paragraph (e), for all repackaged prescription drugs distributed in or into this state, state in writing under oath with each distribution of a repackaged prescription drug to an affiliated group member warehouse or repackager: "All repackaged prescription drugs are purchased by the affiliated group directly from the manufacturer or from a prescription drug wholesaler that purchased the prescription drugs directly from the manufacturer.";

(II) Purchase all prescription drugs it repackages:

(A) Directly from the manufacturer; or

(B) From a prescription drug wholesaler that purchased the prescription drugs directly from the manufacturer; and

(III) Maintain records in accordance with this section to document that it purchased the prescription drugs directly from the manufacturer or that its prescription drug wholesale supplier purchased the prescription drugs directly from the manufacturer.

b. All members of the affiliated group must provide to agents of the department on request records of purchases by all members of the affiliated group of prescription drugs that have been repackaged, regardless of the location where the records are stored or where the repackager is located.

4. This paragraph expires July 1, 2006.

Section 11. Paragraph (a) of subsection (1) of section 895.02, Florida Statutes, is amended to read:

895.02 Definitions.—As used in ss. 895.01-895.08, the term:

(1) "Racketeering activity" means to commit, to attempt to commit, to conspire to commit, or to solicit, coerce, or intimidate another person to commit:

(a) Any crime which is chargeable by indictment or information under the following provisions of the Florida Statutes:

1. Section 210.18, relating to evasion of payment of cigarette taxes.
2. Section 403.727(3)(b), relating to environmental control.
- ~~3.4.~~ Section 409.920, relating to Medicaid provider fraud.
- ~~4.3.~~ Section 414.39, relating to public assistance fraud.
5. Section 440.105 or s. 440.106, relating to workers' compensation.
6. Section 465.0161, relating to distribution of medicinal drugs without a permit as an Internet pharmacy.
- ~~7.6.~~ Sections 499.0051, 499.0052, 499.0053, 499.0054, and 499.0691, relating to crimes involving contraband and adulterated drugs.
- ~~8.7.~~ Part IV of chapter 501, relating to telemarketing.
- ~~9.8.~~ Chapter 517, relating to sale of securities and investor protection.
- ~~10.9.~~ Section 550.235, s. 550.3551, or s. 550.3605, relating to dogracing and horseracing.
- ~~11.10.~~ Chapter 550, relating to jai alai frontons.
- ~~12.11.~~ Chapter 552, relating to the manufacture, distribution, and use of explosives.
- ~~13.12.~~ Chapter 560, relating to money transmitters, if the violation is punishable as a felony.
- ~~14.13.~~ Chapter 562, relating to beverage law enforcement.
- ~~15.14.~~ Section 624.401, relating to transacting insurance without a certificate of authority, s. 624.437(4)(c)1., relating to operating an unauthorized multiple-employer welfare arrangement, or s. 626.902(1)(b), relating to representing or aiding an unauthorized insurer.
- ~~16.15.~~ Section 655.50, relating to reports of currency transactions, when such violation is punishable as a felony.
- ~~17.16.~~ Chapter 687, relating to interest and usurious practices.
- ~~18.17.~~ Section 721.08, s. 721.09, or s. 721.13, relating to real estate time-share plans.
- ~~19.18.~~ Chapter 782, relating to homicide.
- ~~20.19.~~ Chapter 784, relating to assault and battery.
- ~~21.20.~~ Chapter 787, relating to kidnapping.
- ~~22.21.~~ Chapter 790, relating to weapons and firearms.
- ~~23.22.~~ Section 796.03, s. 796.04, s. 796.05, or s. 796.07, relating to prostitution.

- ~~24.23.~~ Chapter 806, relating to arson.
- ~~25.24.~~ Section 810.02(2)(c), relating to specified burglary of a dwelling or structure.
- ~~26.25.~~ Chapter 812, relating to theft, robbery, and related crimes.
- ~~27.26.~~ Chapter 815, relating to computer-related crimes.
- ~~28.27.~~ Chapter 817, relating to fraudulent practices, false pretenses, fraud generally, and credit card crimes.
- ~~29.28.~~ Chapter 825, relating to abuse, neglect, or exploitation of an elderly person or disabled adult.
- ~~30.29.~~ Section 827.071, relating to commercial sexual exploitation of children.
- ~~31.30.~~ Chapter 831, relating to forgery and counterfeiting.
- ~~32.31.~~ Chapter 832, relating to issuance of worthless checks and drafts.
- ~~33.32.~~ Section 836.05, relating to extortion.
- ~~34.33.~~ Chapter 837, relating to perjury.
- ~~35.34.~~ Chapter 838, relating to bribery and misuse of public office.
- ~~36.35.~~ Chapter 843, relating to obstruction of justice.
- ~~37.36.~~ Section 847.011, s. 847.012, s. 847.013, s. 847.06, or s. 847.07, relating to obscene literature and profanity.
- ~~38.37.~~ Section 849.09, s. 849.14, s. 849.15, s. 849.23, or s. 849.25, relating to gambling.
- ~~39.38.~~ Chapter 874, relating to criminal street gangs.
- ~~40.39.~~ Chapter 893, relating to drug abuse prevention and control.
- ~~41.40.~~ Chapter 896, relating to offenses related to financial transactions.
- ~~42.41.~~ Sections 914.22 and 914.23, relating to tampering with a witness, victim, or informant, and retaliation against a witness, victim, or informant.
- ~~43.42.~~ Sections 918.12 and 918.13, relating to tampering with jurors and evidence.

Section 12. The sum of \$590,051 is appropriated from the Medical Quality Assurance Trust Fund to the Department of Health, and nine full-time equivalent positions are authorized, for the 2004-2005 fiscal year for the purpose of implementing this act.

Section 13. This act shall take effect July 1, 2004.

Approved by the Governor June 30, 2004.

Filed in Office Secretary of State June 30, 2004.