By the Committees on Appropriations; Regulated Industries; and Health Policy

576-04577-14 2014662c2

A bill to be entitled

An act relating to nonresident sterile compounding permits; amending s. 465.003, F.S.; defining the terms "compounding," "outsourcing facility," and "compounded sterile product"; amending s. 465.0156, F.S.; conforming provisions to changes made by the act; expanding penalties to apply to injury to a nonhuman animal; deleting a requirement that the Board of Pharmacy refer regulatory issues affecting a nonresident pharmacy to the state where the pharmacy is located; providing that a nonresident pharmacy is subject to certain health care fraud provisions; creating s. 465.0158, F.S.; requiring registered nonresident pharmacies and outsourcing facilities to obtain a permit in order to ship, mail, deliver, or dispense compounded sterile products into this state; requiring submission of an application and a nonrefundable fee; providing application requirements; authorizing the board to deny, revoke, or suspend a permit, or impose a fine or reprimand for certain actions; providing dates by which certain nonresident pharmacies must obtain a permit; authorizing the board to adopt rules; amending s. 465.017, F.S.; authorizing the department to inspect nonresident pharmacies and nonresident sterile compounding permittees; requiring such pharmacies and permittees to pay for the costs of such inspections; providing an effective date.

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

Section 1. Subsections (18), (19) and (20) are added to section 465.003, Florida Statutes, to read:

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

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

Section 2. Subsections (4) and (5) of section 465.0156, Florida Statutes, are amended, present subsections (6) through (8) of that section are redesignated as subsections (7) through (9), respectively, and a new subsection (6) is added to that section, to read:

465.0156 Registration of nonresident pharmacies.—

(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 ~~the provisions of~~ 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 ~~the provisions of~~ this chapter for conduct which causes or could cause serious bodily ~~injury~~ or ~~serious~~ psychological injury to a human or serious bodily injury to a nonhuman animal in ~~resident of~~ this state ~~if the board has referred the matter to the regulatory or licensing agency in the state in which the pharmacy is located and the regulatory or licensing agency fails to investigate within 180 days of the referral~~.

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

Section 3. Section 465.0158, Florida Statutes, is created to read:

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 if required by the state, territory, or district in which the outsourcing facility is physically located.

(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.

Section 4. Section 465.017, Florida Statutes, is amended to read:

465.017 Authority to inspect; disposal.—

(1) Duly authorized agents and employees of the department may ~~shall have the power to~~ 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 the provisions~~ of this chapter or any rule adopted ~~promulgated~~ 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) ~~(2)(a)~~ 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 ~~shall not~~ be furnished only to ~~any person other than 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 ~~in the event that~~ the patient is incapacitated or unable to request such ~~said~~ 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 ~~to establish~~ 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 ~~shall~~ be consistent with the duty to preserve the confidentiality of such records in accordance with applicable state and federal law.

Section 5. This act shall take effect October 1, 2014.