A bill to be entitled

An act relating to sterile compounding; amending s. 465.003, F.S.; defining "compounding" and "outsourcing facility"; amending s. 465.0156, F.S.; making the failure to comply with s. 465.017(2), F.S., or s. 465.0158, F.S., grounds for administrative discipline of a registered nonresident pharmacy; giving authority to the board to administratively discipline a registered nonresident pharmacy for certain conduct; eliminating the requirement that the board refer the matter to the regulatory or licensing agency where the pharmacy is located and wait 180 days for the regulatory or licensing agency to investigate before administratively disciplining the pharmacy; making a registered nonresident pharmacy subject to certain health care fraud provisions; creating s. 465.0158, F.S.; requiring each nonresident pharmacy and each outsourcing facility to hold a nonresident sterile compounding permit to ship, mail, deliver, or dispense a compounded sterile product into this state; requiring an application for permit to be submitted on a form furnished by the board; requiring an applicant to submit certain information in conjunction with the application for permit; giving the Department of Health authority to conduct an onsite inspection of a nonresident pharmacy or contract with a third party to

conduct the inspection; authorizing the Department of Health to accept a satisfactory inspection report from an entity approved by the board or from the U.S. Federal Drug Administration in lieu of an onsite inspection; prohibiting a permittee from shipping, mailing, delivering, or dispensing a sterile product compounded in violation of certain laws and standards; granting the board authority to administratively discipline a permittee for failing to comply with or violating certain statutes; authorizing a nonresident pharmacy to ship, mail, deliver, or dispense a compounded sterile product into the state if the product is compounded in accordance with certain laws and standards and it applies for and is issued a permit on or before a date certain; prohibiting an applicant for registration as a nonresident pharmacy from shipping, mailing, delivering, or dispensing a compounded sterile product into this state until it receives a permit; granting rulemaking authority; amending s. 465.017, F.S.; granting the Department of Health authority to inspect a registered nonresident pharmacy or permittee; requiring the cost of an inspection of a registered nonresident pharmacy or permittee to be borne by the pharmacy or permittee; providing an effective date.

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

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

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

(18) "Compounding" means a practice in which a licensed pharmacist or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug or product to create another drug or product.

(19) "Outsourcing facility" means a facility at one geographic location or address that is engaged in sterile compounding of a product and is registered as an outsourcing facility pursuant to the Drug Quality and Security Act, Pub. L. No. 113-54.

Section 2. Section 465.0156, Florida Statutes, is amended 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. 465.025, s. 465.017(2), s. 465.0158, 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 an animal ~~resident of this state if the board has referred the matter to the regulatory or licensing agency~~ in this ~~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 the provisions of s. 456.0635.

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

465.0158 Nonresident sterile compounding permit.

(1) Each nonresident pharmacy registered under s. 465.0156 and each outsourcing facility must hold a nonresident sterile compounding permit in order to ship, mail, deliver, or dispense, in any manner, a compounded sterile product into this state. For the purposes of this section only, an outsourcing facility is a nonresident and non-pharmacy facility.

(2) Application for the 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 to the board to obtain an initial permit, or to the department to renew a permit, the

following:

(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 pursuant to the Drug Quality and Security Act, Pub. L. No. 113-54.

(b) Proof of registration as a nonresident pharmacy, as defined in s. 465.0156, unless the applicant is an outsourcing facility, then proof of a valid, unexpired 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 ship, mail, deliver, or dispense a compounded sterile product to this state.

(c) Attestation in writing by an owner or officer, and prescription department manager or pharmacist in charge, of the applicant that:

1. They have read and understand the laws and rules governing sterile compounding in this state;

2. Any compounded sterile product shipped, mailed, delivered, or dispensed into this state will meet or exceed this state's standards for sterile compounding; and

3. Any compounded sterile product shipped, mailed, delivered, or dispensed into this state has not been, and will not be, compounded in violation of the laws and rules of the state in which the applicant is located.

(d) Existing policies and procedures for sterile

compounding which comply with USP 797 standards for a pharmacy, to the extent required by board rule, or current good manufacturing practices for an outsourcing facility.

(e) A current inspection report resulting 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 the requirements of this chapter. The inspection report is current if the inspection was conducted no more than six months prior to the date of submission of the application for the initial permit or no more than one year prior to the date of submission of the application for renewal of the permit. If the applicant cannot submit a current inspection report due to unforeseen or acceptable circumstances, as established by rule, or if the applicant has not been inspected, the department shall:

1. Conduct, or contract with an approved entity to conduct, an onsite inspection, for which all costs shall be borne by the applicant;

2. Accept a satisfactory inspection report, as determined by rule, from an entity approved by the board in lieu of an onsite inspection; or

3. Accept an inspection report from the United States Federal Drug Administration conducted pursuant to the provisions of the Drug Quality and Safety Act, Pub. L. No. 113-54, in lieu of an onsite inspection.

(4) A permittee may not ship, mail, deliver, or dispense

any compounded sterile product into this state which was compounded in violation of the laws and rules of the state in which the permittee is located and 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, or fine or reprimand, a permittee for:

(a) Failing to comply with the requirements of this section;

(b) Violating s. 456.0635, s. 456.065, or s. 456.072;

(c) Failing to comply with s. 465.0156(4) or (5); or

(d) Violating s. 465.016.

(6) A nonresident pharmacy registered under s. 465.0156 and shipping, mailing, delivering, or dispensing 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 law or rule in the state where the pharmacy is located, and the pharmacy applies for and is issued a permit on or before February 28, 2015.

(7) An applicant seeking to register as a nonresident pharmacy under s. 465.0156 on or after October 1, 2014, may not ship, mail, deliver, or dispense a compounded sterile product into this state until it has received a permit.

(8) The board shall by rule:

(a) Develop an application for the permit created by this

section;

(b) Determine how, when and under what circumstances an inspection of a nonresident sterile compounding permittee shall be conducted;

(c) Create a list of approved 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; and

(d) Adopt other rules as necessary to administer this section.

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 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 ~~of the~~ provision~~s~~ 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.

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 subsection.

(2) The costs for inspecting a nonresident pharmacy registered under s. 465.0156 or a nonresident sterile compounding permittee shall be borne by the 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 shall not be furnished 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, in the event that the patient is incapacitated or unable to request said records, her or his spouse except upon the written authorization of such patient. 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 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.