A bill to be entitled

An act relating to the purchase of prescription drugs; amending s. 499.003, F.S.; defining the term "qualifying practitioner" as it relates to the Florida Drug and Cosmetic Act; amending s. 499.01, F.S.; deleting provisions requiring a health care clinic establishment permit for the purchase of certain prescription drugs; conforming a cross-reference; amending s. 499.01211, F.S.; conforming a cross-reference; amending s. 499.03, F.S.; authorizing certain establishments to possess prescription drugs; creating s. 499.031, F.S.; establishing criteria for certain business entities to purchase and possess prescription drugs; requiring a qualifying practitioner at the establishment; requiring the registration of certain qualifying practitioners; assigning duties and responsibilities to a qualifying practitioner and business entity; providing for expiration of the registration of a qualifying practitioner and for renewal of the registration; requiring the Department of Health to establish an online registration system and post certain information related to qualifying practitioners on its website; providing additional grounds for discipline of a qualifying practitioner; providing recordkeeping requirements; amending s. 499.041, F.S.; deleting provisions requiring a fee for a health care clinic establishment permit to conform to changes made by the act; requiring a fee to register as a qualifying

practitioner; authorizing a nonrefundable application fee for withdrawn applications or applications that become void; amending s. 499.05, F.S.; requiring the department to adopt rules regarding record retention requirements and procedures for registering and renewing the registration of certain practitioners; conforming cross-references; amending s. 400.9935, F.S.; assigning responsibilities to a medical director who acts as the qualifying practitioner of a licensed health care clinic; amending ss. 409.9201 and 465.0265, F.S.; conforming cross-references; providing an effective date.

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

Section 1. Present subsections (48) through (54) of section 499.003, Florida Statutes, are renumbered as subsections (49) through (55), respectively, and a new subsection (48) is added to that section, to read:

499.003 Definitions of terms used in this part.—As used in this part, the term:

(48) "Qualifying practitioner" means a licensed health care practitioner as defined in s. 456.001, or a veterinarian licensed under chapter 474, who is authorized under the appropriate practice act to prescribe and administer a prescription drug.

Section 2. Subsection (1) and paragraphs (g) and (t) of subsection (2) of section 499.01, Florida Statutes, are amended to read:

499.01 Permits.—

(1) Prior to operating, a permit is required for each person and establishment that intends to operate as:

(a) A prescription drug manufacturer;

(b) A prescription drug repackager;

(c) A nonresident prescription drug manufacturer;

(d) A prescription drug wholesale distributor;

(e) An out-of-state prescription drug wholesale distributor;

(f) A retail pharmacy drug wholesale distributor;

(g) A restricted prescription drug distributor;

(h) A complimentary drug distributor;

(i) A freight forwarder;

(j) A veterinary prescription drug retail establishment;

(k) A veterinary prescription drug wholesale distributor;

(l) A limited prescription drug veterinary wholesale distributor;

(m) A medical oxygen retail establishment;

(n) A compressed medical gas wholesale distributor;

(o) A compressed medical gas manufacturer;

(p) An over-the-counter drug manufacturer;

(q) A device manufacturer;

(r) A cosmetic manufacturer; or

(s) A third party logistics provider.~~; or~~

~~(t) A health care clinic establishment.~~

(2) The following permits are established:

(g) *Restricted prescription drug distributor permit.*—A restricted prescription drug distributor permit is required for any person that engages in the distribution of a prescription

drug, which distribution is not considered "wholesale distribution" under s. 499.003(54)(a) ~~s. 499.003(53)(a)~~.

1. A person who engages in the receipt or distribution of a prescription drug in this state for the purpose of processing its return or its destruction must obtain a permit as a restricted prescription drug distributor if such person is not the person initiating the return, the prescription drug wholesale supplier of the person initiating the return, or the manufacturer of the drug.

2. Storage, handling, and recordkeeping of these distributions must comply with the requirements for wholesale distributors under s. 499.0121, but not those set forth in s. 499.01212.

3. A person who applies for a permit as a restricted prescription drug distributor, or for the renewal of such a permit, must provide to the department the information required under s. 499.012.

4. The department may adopt rules regarding the distribution of prescription drugs by hospitals, health care entities, charitable organizations, or other persons not involved in wholesale distribution, which rules are necessary for the protection of the public health, safety, and welfare.

~~(t) *Health care clinic establishment permit.* Effective January 1, 2009, a health care clinic establishment permit is required for the purchase of a prescription drug by a place of business at one general physical location owned and operated by a professional corporation or professional limited liability company described in chapter 621, or a corporation that employs a veterinarian as a qualifying practitioner. For the purpose of~~

~~this paragraph, the term "qualifying practitioner" means a licensed health care practitioner defined in s. 456.001 or a veterinarian licensed under chapter 474, who is authorized under the appropriate practice act to prescribe and administer a prescription drug.~~

~~1. An establishment must provide, as part of the application required under s. 499.012, designation of a qualifying practitioner who will be responsible for complying with all legal and regulatory requirements related to the purchase, recordkeeping, storage, and handling of the prescription drugs. In addition, the designated qualifying practitioner shall be the practitioner whose name, establishment address, and license number is used on all distribution documents for prescription drugs purchased or returned by the health care clinic establishment. Upon initial appointment of a qualifying practitioner, the qualifying practitioner and the health care clinic establishment shall notify the department on a form furnished by the department within 10 days after such employment. In addition, the qualifying practitioner and health care clinic establishment shall notify the department within 10 days after any subsequent change.~~

~~2. The health care clinic establishment must employ a qualifying practitioner at each establishment.~~

~~3. In addition to the remedies and penalties provided in this part, a violation of this chapter by the health care clinic establishment or qualifying practitioner constitutes grounds for discipline of the qualifying practitioner by the appropriate regulatory board.~~

~~4. The purchase of prescription drugs by the health care~~

~~clinic establishment is prohibited during any period of time when the establishment does not comply with this paragraph.~~

~~5. A health care clinic establishment permit is not a pharmacy permit or otherwise subject to chapter 465. A health care clinic establishment that meets the criteria of a modified Class II institutional pharmacy under s. 465.019 is not eligible to be permitted under this paragraph.~~

~~6. This paragraph does not prohibit a qualifying practitioner from purchasing prescription drugs.~~

Section 3. Paragraph (b) of subsection (2) of section 499.01211, Florida Statutes, is amended to read:

499.01211 Drug Wholesale Distributor Advisory Council.—

(2) The State Surgeon General, or his or her designee, and the Secretary of Health Care Administration, or her or his designee, shall be members of the council. The State Surgeon General shall appoint nine additional members to the council who shall be appointed to a term of 4 years each, as follows:

(b) One person employed by a prescription drug wholesale distributor licensed under this part which is a secondary wholesale distributor, as defined in s. 499.003(52) ~~s. 499.003(51)~~.

Section 4. Subsection (1) of section 499.03, Florida Statutes, is amended to read:

499.03 Possession of certain drugs without prescriptions unlawful; exemptions and exceptions.—

(1) A person may not possess, or possess with intent to sell, dispense, or deliver, any habit-forming, toxic, harmful, or new drug subject to s. 499.003(32), or prescription drug as defined in s. 499.003(42), unless the possession of the drug has

been obtained by a valid prescription of a practitioner licensed by law to prescribe the drug. However, this section does not apply to the delivery of such drugs to persons included in any of the classes named in this subsection, or to the agents or employees of such persons, for use in the usual course of their businesses or practices or in the performance of their official duties, as the case may be; nor does this section apply to the possession of such drugs by those persons or their agents or employees for such use:

(a) A licensed pharmacist or any person under the licensed pharmacist's supervision while acting within the scope of the licensed pharmacist's practice;

(b) A licensed practitioner authorized by law to prescribe prescription drugs or any person under the licensed practitioner's supervision while acting within the scope of the licensed practitioner's practice;

(c) A qualified person who uses prescription drugs for lawful research, teaching, or testing, and not for resale;

(d) A licensed hospital or other institution that procures such drugs for lawful administration or dispensing by practitioners;

(e) An officer or employee of a federal, state, or local government; ~~or~~

(f) A person that holds a valid permit issued by the department pursuant to this part which authorizes that person to possess prescription drugs; or

(g) An establishment of a legal business entity at which qualifying practitioners practice their profession under state law if the establishment complies with s. 499.031.

Section 5. Section 499.031, Florida Statutes, is created to read:

499.031 Medical and veterinary clinics; purchase and possession of prescription drugs; registration and duties of qualifying practitioners.—

(1) An establishment of a legal business entity that has been issued a federal tax identification number and through which qualifying practitioners practice their profession under state law and that:

(a) Has a qualifying practitioner registered with the department who is an owner or member of the entity or an employee of the entity at that establishment; or

(b) Is a health care clinic licensed under part X of chapter 400 which has included in the medical director's written agreement the responsibility to serve as the qualifying practitioner for the clinic,

may purchase and possess prescription drugs in the name of the business entity in accordance with this section.

(2) A health care clinic licensed under part X of chapter 400 which does not have a medical director as provided in subsection (1) for more than 10 days must register a qualifying practitioner who meets the requirements of paragraph (1)(a) with the department in order to purchase and possess prescription drugs.

(3) A qualifying practitioner who is registered with the department for an establishment and the business entity must each notify the department, and any person from whom the business entity has purchased prescription drugs for that

establishment in the previous 6 months, within 10 days after the qualifying practitioner ceases serving as the qualifying practitioner for that establishment. An establishment that is required to have a qualifying practitioner registered with the department must have a new qualifying practitioner registered with the department within 10 days after a registered qualifying practitioner ceases serving in that capacity.

(4) The business entity may purchase only prescription drugs that the registered qualifying practitioner or medical director serving as the qualifying practitioner of the establishment is authorized to prescribe. The authorization to purchase prescription drugs under this section is not a permit that authorizes the purchase and possession of controlled substances, and the business entity and establishment must comply with chapter 893 and applicable federal law related to controlled substances.

(5) The qualifying practitioner is responsible for complying with all legal and regulatory requirements related to the purchase, recordkeeping, storage, and handling of the prescription drugs purchased by the business entity of the establishment for which the health care practitioner or veterinarian is the qualifying practitioner. A qualifying practitioner must ensure that there are policies and procedures for handling prescription drugs at an establishment which protect the integrity of the drugs at the establishment and the public health upon the termination of the qualifying practitioner from serving in that capacity at the establishment.

(6) One qualifying practitioner at an establishment for which a business entity wishes to purchase prescription drugs,

other than the medical director of a health care clinic as described in paragraph (1)(b), must:

(a) Register with the department his or her name and practitioner license number, the name of the business entity that will be purchasing prescription drugs, and the address of the establishment for which he or she is the qualifying practitioner;

(b) Certify acceptance of the responsibilities of a qualifying practitioner; and

(c) Pay the registration fee required in s. 499.041(10).

(7) A registration under this section automatically expires upon the licensure renewal date of the qualifying practitioner's professional license, unless the qualifying practitioner has previously notified the department that he or she has discontinued serving as the qualifying practitioner for an establishment of a business entity or the registration has been previously revoked. The department shall provide for a qualifying practitioner to renew his or her registration as a qualifying practitioner for an establishment of a business entity by a:

(a) Health care practitioner as defined in s. 456.001, as a part of the renewal of the practitioner's professional license; or

(b) Veterinarian through an online registration system.

(8) The department shall establish an online system for the registration of qualifying practitioners. Until the online system is operational, the department must accept any written document that provides the information required in subsection (6), along with the registration fee. The name of the purchasing

business entity; the address of the establishment; and the name, license number, and registration number of the qualifying practitioner must be published on the department's website.

(9) In addition to the remedies and penalties provided in this part, a violation of this part constitutes grounds for discipline against the qualifying practitioner by the appropriate regulatory board.

(10) In addition to other recordkeeping requirements, distribution documents for prescription drugs purchased or returned by:

(a) An establishment that has a registered qualifying practitioner must include the registration number of the qualifying practitioner; or

(b) A health care clinic that has a medical director serving as the qualifying practitioner must include the health care clinic license number,

in order to comply with the requirement under s. 499.0121(6)(a)2. that records include the state license, permit, or registration number of the person authorized to purchase prescription drugs.

(11) This section does not prohibit a licensed practitioner whose professional license authorizes the practitioner to prescribe prescription drugs from purchasing prescription drugs under his or her practice license.

Section 6. Section 499.041, Florida Statutes, is amended to read:

499.041 Schedule of fees for drug, device, and cosmetic applications and permits, product registrations, and free-sale

certificates.—

(1) The department shall assess applicants requiring a manufacturing permit an annual fee within the ranges established in this section for the specific type of manufacturer.

(a) The fee for a prescription drug manufacturer permit may not be less than $500 or more than $750 annually.

(b) The fee for a device manufacturer permit may not be less than $500 or more than $600 annually.

(c) The fee for a cosmetic manufacturer permit may not be less than $250 or more than $400 annually.

(d) The fee for an over-the-counter drug manufacturer permit may not be less than $300 or more than $400 annually.

(e) The fee for a compressed medical gas manufacturer permit may not be less than $400 or more than $500 annually.

(f) The fee for a prescription drug repackager permit may not be less than $500 or more than $750 annually.

(g) A manufacturer may not be required to pay more than one fee per establishment to obtain an additional manufacturing permit, but each manufacturer must pay the highest fee applicable to his or her operation in each establishment.

(2) The department shall assess an applicant that is required to have a wholesaling permit an annual fee within the ranges established in this section for the specific type of wholesaling.

(a) The fee for a prescription drug wholesale distributor permit may not be less than $300 or more than $800 annually.

(b) The fee for a compressed medical gas wholesale distributor permit may not be less than $200 or more than $300 annually.

(c) The fee for an out-of-state prescription drug wholesale distributor permit may not be less than $300 or more than $800 annually.

(d) The fee for a nonresident prescription drug manufacturer permit may not be less than $300 or more than $500 annually.

(e) The fee for a retail pharmacy drug wholesale distributor permit may not be less than $35 or more than $50 annually.

(f) The fee for a freight forwarder permit may not be less than $200 or more than $300 annually.

(g) The fee for a veterinary prescription drug wholesale distributor permit may not be less than $300 or more than $500 annually.

(h) The fee for a limited prescription drug veterinary wholesale distributor permit may not be less than $300 or more than $500 annually.

(i) The fee for a third party logistics provider permit may not be less than $200 or more than $300 annually.

(3) The department shall assess an applicant that is required to have a retail establishment permit an annual fee within the ranges established in this section for the specific type of retail establishment.

(a) The fee for a veterinary prescription drug retail establishment permit may not be less than $200 or more than $300 annually.

(b) The fee for a medical oxygen retail establishment permit may not be less than $200 or more than $300 annually.

~~(c) The fee for a health care clinic establishment permit~~

~~may not be less than $125 or more than $250 annually.~~

(4) The department shall assess an applicant that is required to have a restricted prescription drug distributor permit an annual fee of not less than $200 or more than $300.

(5) In addition to the fee charged for a permit required by this part, the department shall assess applicants an initial application fee of $150 for each new permit issued by the department which requires an onsite inspection.

(6) A person that is required to register drugs, devices, or cosmetic products under s. 499.015 shall pay an annual product registration fee of not less than $5 or more than $15 for each separate and distinct product in package form. The registration fee is in addition to the fee charged for a free-sale certificate.

(7) The department shall assess an applicant that requests a free-sale certificate a fee of $25. A fee of $2 will be charged for each signature copy of a free-sale certificate that is obtained at the same time the free-sale certificate is issued.

(8) The department shall assess an out-of-state prescription drug wholesale distributor applicant or permittee an onsite inspection fee of not less than $1,000 or more than $3,000 annually, to be based on the actual cost of the inspection if an onsite inspection is performed by agents of the department.

(9) The department shall assess each person applying for certification as a designated representative a fee of $150, plus the cost of processing the criminal history record check.

(10) The department shall assess a person registering as a

qualifying practitioner for an establishment under s. 499.031 a fee of $25 for each establishment.

(11) The department shall assess each person applying for a permit or certification as a designated representative a nonrefundable application fee of $150 or 50 percent of the permit or certification fee, whichever is less, if the application is withdrawn or it becomes void.

(12)~~(10)~~ The department shall assess other fees as provided in this part.

Section 7. Subsection (1) of section 499.05, Florida Statutes, is amended to read:

499.05 Rules.—

(1) The department shall adopt rules to implement and enforce this part with respect to:

(a) The definition of terms used in this part, and used in the rules adopted under this part, when the use of the term is not its usual and ordinary meaning.

(b) Labeling requirements for drugs, devices, and cosmetics.

(c) The establishment of fees authorized in this part.

(d) The identification of permits that require an initial application and onsite inspection or other prerequisites for permitting which demonstrate that the establishment and person are in compliance with the requirements of this part.

(e) The application processes and forms for product registration.

(f) Procedures for requesting and issuing certificates of free sale.

(g) Inspections and investigations conducted under s.

499.051, and the identification of information claimed to be a trade secret and exempt from the public records law as provided in s. 499.051(7).

(h) The establishment of a range of penalties, as provided in s. 499.066; requirements for notifying persons of the potential impact of a violation of this part; and a process for the uncontested settlement of alleged violations.

(i) Additional conditions that qualify as an emergency medical reason under s. 499.003(54)(b)2 ~~s. 499.003(53)(b)2~~.

(j) Procedures and forms relating to the pedigree paper requirement of s. 499.01212.

(k) The protection of the public health, safety, and welfare regarding good manufacturing practices that manufacturers and repackagers must follow to ensure the safety of the products.

(l) Information required from each retail establishment pursuant to s. 499.012(3), including requirements for prescriptions or orders.

(m) The recordkeeping, storage, and handling with respect to each of the distributions of prescription drugs specified in s. 499.003(54)(a)-(d) ~~s. 499.003(53)(a)-(d)~~.

(n) Alternatives to compliance with s. 499.01212 for a prescription drug in the inventory of a permitted prescription drug wholesale distributor as of June 30, 2006, and the return of a prescription drug purchased prior to July 1, 2006. The department may specify time limits for such alternatives.

(o) Record retention requirements and procedures for registering and renewing the registration of a qualifying practitioner related to a business entity purchasing and

possessing prescription drugs under s. 499.031.

Section 8. Paragraph (i) is added to subsection (1) of section 400.9935, Florida Statutes, to read:

400.9935 Clinic responsibilities.—

(1) Each clinic shall appoint a medical director or clinic director who shall agree in writing to accept legal responsibility for the following activities on behalf of the clinic. The medical director or the clinic director shall:

(i) Be responsible for complying with all legal and regulatory requirements related to the purchase, recordkeeping, storage, and handling of prescription drugs that have been sold to the clinic using the medical director as the qualifying practitioner under ss. 499.03 and 499.031.

Section 9. Paragraph (a) of subsection (1) of section 409.9201, Florida Statutes, is amended to read:

409.9201 Medicaid fraud.—

(1) As used in this section, the term:

(a) "Prescription drug" means any drug, including, but not limited to, finished dosage forms or active ingredients that are subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act or by s. 465.003(8), s. 499.003(45) or (53) ~~(52)~~, or s. 499.007(13).

The value of individual items of the legend drugs or goods or services involved in distinct transactions committed during a single scheme or course of conduct, whether involving a single person or several persons, may be aggregated when determining the punishment for the offense.

Section 10. Subsection (3) of section 465.0265, Florida

Statutes, is amended to read:

465.0265 Centralized prescription filling.—

(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 set forth in s. 465.026 or as a wholesale distribution as set forth in s. 499.003(54) ~~s. 499.003(53)~~.

Section 11. This act shall take effect July 1, 2009.