By the Committees on Health and Human Services Appropriations; and Health Regulation; and Senator Peaden

603-05115-09 20091144c2

A bill to be entitled

An act relating to manufacturers and purchasers of prescription drugs; amending ss. 409.9201 and 465.0265, F.S.; conforming cross-references; amending s. 499.003, F.S.; defining new terms and redefining terms related to the Florida Drug and Cosmetic Act; amending s. 499.01, F.S.; authorizing a prescription drug manufacturer's distributor permit and revising the requirements related to certain other permits; conforming a cross-reference; amending s. 499.012, F.S.; restricting issuance of a permit for a prescription drug manufacturer's distributor at certain addresses; amending s. 499.0121, F.S.; eliminating cross-references to defined terms and clarifying a recordkeeping requirement related to pedigree papers; amending s. 499.01211, F.S.; eliminating cross-references for certain defined terms; amending s. 499.01212, F.S.; revising requirements for a pedigree paper; amending s. 499.03, F.S.; eliminating cross-references for certain defined terms; amending s. 499.041, F.S.; establishing a fee for the prescription drug manufacturer's distributor permit; authorizing the Department of Health to retain a specified monetary amount as a fee if an application submitted under the Florida Drug and Cosmetic Act is withdrawn or becomes void; amending ss. 499.05 and 794.075, F.S.; conforming cross-references; authorizing certain statements to be used on certain pedigree papers until a specified date; providing an

appropriation and authorizing additional positions; providing an effective date.

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

Section 1. 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(46) or (53) ~~s. 499.003(45) or (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 2. 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 3. Subsection (18) and subsections (31) through

(54) of section 499.003, Florida Statutes, are amended to read:

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

(18) "Drop shipment" means the sale of a prescription drug from a manufacturer or the manufacturer's distributor to a wholesale distributor, where the wholesale distributor takes title to, but not possession of, the prescription drug, and the manufacturer of the prescription drug, the manufacturer's distributor, or the manufacturer's third-party logistics provider ships the prescription drug directly to a chain pharmacy warehouse or a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug, as defined in s. 465.003.

(31) "Manufacturer" means:

(a) A person who prepares, derives, manufactures, or produces a drug, device, or cosmetic.

(b) The holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), a Biologics License Application (BLA), or a New Animal Drug Application (NADA), provided such application has become effective or is otherwise approved consistent with s. 499.023.~~;~~

(c) A private label distributor for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged~~; or the distribution point for the manufacturer, contract manufacturer, or private label distributor whether the establishment is a member of the manufacturer's affiliated group or is a contract distribution site~~.

(d) A person registered under the federal act as a

manufacturer who has entered into a written agreement with another manufacturer that authorizes either manufacturer to distribute a prescription drug, which is identified in the agreement, as the manufacturer of that drug consistent with the federal act.

The term excludes pharmacies that are operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.

(32) "Manufacturer's distributor" means a person permitted under this part as a prescription drug manufacturer's distributor.

(33) ~~(32)~~ "New drug" means:

(a) Any drug the composition of which is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling of that drug; or

(b) Any drug the composition of which is such that the drug, as a result of investigations to determine its safety and effectiveness for use under certain conditions, has been recognized for use under such conditions, but which drug has not, other than in those investigations, been used to a material extent or for a material time under such conditions.

(34) ~~(33)~~ "Normal distribution chain" means a wholesale distribution of a prescription drug in which the wholesale distributor or its wholly owned subsidiary purchases ~~and receives~~ the specific unit of the prescription drug directly

from the manufacturer or manufacturer's distributor; receives the specific unit of the prescription drug directly from the manufacturer, manufacturer's distributor, or manufacturer's third-party logistics provider; and distributes the prescription drug directly, or through up to two intracompany transfers, to a chain pharmacy warehouse or a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug, as defined in s. 465.003. For purposes of this subsection, the term "intracompany" means any transaction or transfer between any parent, division, or subsidiary wholly owned by a corporate entity.

(35) ~~(34)~~ "Nursing home" means a facility licensed under part II of chapter 400.

(36) ~~(35)~~ "Official compendium" means the current edition of the official United States Pharmacopoeia and National Formulary, or any supplement thereto.

(37) ~~(36)~~ "Pedigree paper" means a document in written or electronic form approved by the department which contains information required by s. 499.01212 regarding the sale and distribution of any given prescription drug.

(38) ~~(37)~~ "Permittee" means any person holding a permit issued pursuant to s. 499.012.

(39) ~~(38)~~ "Person" means any individual, child, joint venture, syndicate, fiduciary, partnership, corporation, division of a corporation, firm, trust, business trust, company, estate, public or private institution, association, organization, group, city, county, city and county, political subdivision of this state, other governmental agency within this state, and any representative, agent, or agency of any of the

foregoing, or any other group or combination of the foregoing.

(40) ~~(39)~~ "Pharmacist" means a person licensed under chapter 465.

(41) ~~(40)~~ "Pharmacy" means an entity licensed under chapter 465.

(42) ~~(41)~~ "Prepackaged drug product" means a drug that originally was in finished packaged form sealed by a manufacturer and that is placed in a properly labeled container by a pharmacy or practitioner authorized to dispense pursuant to chapter 465 for the purpose of dispensing in the establishment in which the prepackaging occurred.

(43) ~~(42)~~ "Prescription drug" means a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active ingredients subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act or s. 465.003(8), s. 499.007(13), or subsection (11), subsection (48) ~~(47)~~, or subsection (53) ~~(52)~~.

(44) ~~(43)~~ "Prescription drug label" means any display of written, printed, or graphic matter upon the immediate container of any prescription drug prior to its dispensing to an individual patient pursuant to a prescription of a practitioner authorized by law to prescribe.

(45) ~~(44)~~ "Prescription label" means any display of written, printed, or graphic matter upon the immediate container of any prescription drug dispensed pursuant to a prescription of a practitioner authorized by law to prescribe.

(46) ~~(45)~~ "Prescription medical oxygen" means oxygen USP which is a drug that can only be sold on the order or prescription of a practitioner authorized by law to prescribe.

The label of prescription medical oxygen must comply with current labeling requirements for oxygen under the Federal Food, Drug, and Cosmetic Act.

(47) ~~(46)~~ "Primary wholesale distributor" means any wholesale distributor that:

(a) Purchased 90 percent or more of the total dollar volume of its purchases of prescription drugs directly from manufacturers in the previous year; and

(b)1. Directly purchased prescription drugs from not fewer than 50 different prescription drug manufacturers in the previous year; or

2. Has, or the affiliated group, as defined in s. 1504 of the Internal Revenue Code, of which the wholesale distributor is a member has, not fewer than 250 employees.

(c) For purposes of this subsection, "directly from manufacturers" means:

1. Purchases made by the wholesale distributor directly from the manufacturer of prescription drugs; and

2. Transfers from a member of an affiliated group, as defined in s. 1504 of the Internal Revenue Code, of which the wholesale distributor is a member, if:

a. The affiliated group purchases 90 percent or more of the total dollar volume of its purchases of prescription drugs from the manufacturer in the previous year; and

b. The wholesale distributor discloses to the department the names of all members of the affiliated group of which the wholesale distributor is a member and the affiliated group agrees in writing to provide records on prescription drug purchases by the members of the affiliated group not later than

48 hours after the department requests access to such records, regardless of the location where the records are stored.

(48) ~~(47)~~ "Proprietary drug," or "OTC drug," means a patent or over-the-counter drug in its unbroken, original package, which drug is sold to the public by, or under the authority of, the manufacturer or primary distributor thereof, is not misbranded under the provisions of this part, and can be purchased without a prescription.

(49) ~~(48)~~ "Repackage" includes repacking or otherwise changing the container, wrapper, or labeling to further the distribution of the drug, device, or cosmetic.

(50) ~~(49)~~ "Repackager" means a person who repackages. The term excludes pharmacies that are operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.

(51) ~~(50)~~ "Retail pharmacy" means a community pharmacy licensed under chapter 465 that purchases prescription drugs at fair market prices and provides prescription services to the public.

(52) ~~(51)~~ "Secondary wholesale distributor" means a wholesale distributor that is not a primary wholesale distributor.

(53) ~~(52)~~ "Veterinary prescription drug" means a prescription drug intended solely for veterinary use. The label of the drug must bear the statement, "Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian."

(54) ~~(53)~~ "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient,

but does not include:

(a) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with s. 499.01(2)(g):

1. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of that organization.

2. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended and revised, to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

3. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control. For purposes of this subparagraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise.

4. The sale, purchase, trade, or other transfer of a prescription drug from or for any federal, state, or local government agency or any entity eligible to purchase prescription drugs at public health services prices pursuant to Pub. L. No. 102-585, s. 602 to a contract provider or its subcontractor for eligible patients of the agency or entity

under the following conditions:

a. The agency or entity must obtain written authorization for the sale, purchase, trade, or other transfer of a prescription drug under this subparagraph from the State Surgeon General or his or her designee.

b. The contract provider or subcontractor must be authorized by law to administer or dispense prescription drugs.

c. In the case of a subcontractor, the agency or entity must be a party to and execute the subcontract.

d. A contract provider or subcontractor must maintain separate and apart from other prescription drug inventory any prescription drugs of the agency or entity in its possession.

e. The contract provider and subcontractor must maintain and produce immediately for inspection all records of movement or transfer of all the prescription drugs belonging to the agency or entity, including, but not limited to, the records of receipt and disposition of prescription drugs. Each contractor and subcontractor dispensing or administering these drugs must maintain and produce records documenting the dispensing or administration. Records that are required to be maintained include, but are not limited to, a perpetual inventory itemizing drugs received and drugs dispensed by prescription number or administered by patient identifier, which must be submitted to the agency or entity quarterly.

f. The contract provider or subcontractor may administer or dispense the prescription drugs only to the eligible patients of the agency or entity or must return the prescription drugs for or to the agency or entity. The contract provider or subcontractor must require proof from each person seeking to

fill a prescription or obtain treatment that the person is an eligible patient of the agency or entity and must, at a minimum, maintain a copy of this proof as part of the records of the contractor or subcontractor required under sub-subparagraph e.

g. In addition to the departmental inspection authority set forth in s. 499.051, the establishment of the contract provider and subcontractor and all records pertaining to prescription drugs subject to this subparagraph shall be subject to inspection by the agency or entity. All records relating to prescription drugs of a manufacturer under this subparagraph shall be subject to audit by the manufacturer of those drugs, without identifying individual patient information.

(b) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with rules established by the department:

1. The sale, purchase, or trade of a prescription drug among federal, state, or local government health care entities that are under common control and are authorized to purchase such prescription drug.

2. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug for emergency medical reasons. For purposes of this subparagraph, the term "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.

3. The transfer of a prescription drug acquired by a medical director on behalf of a licensed emergency medical services provider to that emergency medical services provider and its transport vehicles for use in accordance with the

provider's license under chapter 401.

4. The revocation of a sale or the return of a prescription drug to the person's prescription drug wholesale supplier.

5. The donation of a prescription drug by a health care entity to a charitable organization that has been granted an exemption under s. 501(c)(3) of the Internal Revenue Code of 1986, as amended, and that is authorized to possess prescription drugs.

6. The transfer of a prescription drug by a person authorized to purchase or receive prescription drugs to a person licensed or permitted to handle reverse distributions or destruction under the laws of the jurisdiction in which the person handling the reverse distribution or destruction receives the drug.

7. The transfer of a prescription drug by a hospital or other health care entity to a person licensed under this part to repackage prescription drugs for the purpose of repackaging the prescription drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the prescription drugs remains with the hospital or other health care entity at all times. In addition to the recordkeeping requirements of s. 499.0121(6), the hospital or health care entity that transfers prescription drugs pursuant to this subparagraph must reconcile all drugs transferred and returned and resolve any discrepancies in a timely manner.

(c) The distribution of prescription drug samples by manufacturers' representatives or distributors' representatives conducted in accordance with s. 499.028.

(d) The sale, purchase, or trade of blood and blood components intended for transfusion. As used in this paragraph, the term "blood" means whole blood collected from a single donor and processed for transfusion or further manufacturing, and the term "blood components" means that part of the blood separated by physical or mechanical means.

(e) The lawful dispensing of a prescription drug in accordance with chapter 465.

(f) The sale, purchase, or trade of a prescription drug between pharmacies as a result of a sale, transfer, merger, or consolidation of all or part of the business of the pharmacies from or with another pharmacy, whether accomplished as a purchase and sale of stock or of business assets.

(55) ~~(54)~~ "Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs in or into this state, including, but not limited to, manufacturers; repackagers; own-label distributors; jobbers; private-label distributors; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; exporters; retail pharmacies; and the agents thereof that conduct wholesale distributions.

Section 4. Section 499.01, Florida Statutes, is 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;

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

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

(u) A prescription drug manufacturer's distributor.

(2) The following permits are established:

(a) *Prescription drug manufacturer permit.*—A prescription drug manufacturer permit is required for any person or entity that is a manufacturer of ~~manufactures~~ a prescription drug and manufactures or distributes its prescription drugs at or from an establishment in this state.

1. A person that operates an establishment permitted as a prescription drug manufacturer may engage in wholesale

distribution of prescription drugs manufactured at that establishment and must comply with all the provisions of this part and the rules adopted under this part that apply to a wholesale distributor, except the provisions in s. 499.01212.

2. A prescription drug manufacturer must comply with all appropriate state and federal good manufacturing practices.

(b) *Prescription drug repackager permit.*—A prescription drug repackager permit is required for any person that repackages a prescription drug in this state.

1. A person that operates an establishment permitted as a prescription drug repackager may engage in wholesale distribution of prescription drugs repackaged at that establishment and must comply with all the provisions of this part and the rules adopted under this part that apply to a wholesale distributor.

2. A prescription drug repackager must comply with all appropriate state and federal good manufacturing practices.

(c) *Nonresident prescription drug manufacturer permit.*—A nonresident prescription drug manufacturer permit is required for any person that is a manufacturer of prescription drugs~~, or the distribution point for a manufacturer of prescription drugs unless permitted as a third party logistics provider, and~~ located outside of this state~~, or that is an entity to whom an approved new drug application has been issued by the United States Food and Drug Administration, or the contracted manufacturer of the approved new drug application holder, and located outside the United States,~~ which engages in the wholesale distribution in this state of the prescription drugs it manufactures or is responsible for manufacturing. Each such

manufacturer ~~or entity~~ must be permitted by the department and comply with all the provisions required of a wholesale distributor under this part, except s. 499.01212.

1. A person that distributes prescription drugs for which he or she is not the manufacturer ~~that it did not manufacture~~ must also obtain an out-of-state prescription drug wholesale distributor permit, third-party logistics provider permit, or prescription drug manufacturer's distributor permit, as applicable, pursuant to this section to engage in the wholesale distribution of the prescription drugs for which it is not the manufacturer ~~manufactured by another person~~ and comply with the requirements of that permit for the wholesale distribution of those prescription drugs for which the person is not the manufacturer ~~an out-of-state prescription drug wholesale distributor~~.

2. Any such person must comply with the licensing or permitting requirements of the jurisdiction in which the establishment is located and the federal act, and any product wholesaled into this state must comply with this part. If a person intends to import prescription drugs from a foreign country into this state, the nonresident prescription drug manufacturer must provide to the department a list identifying each prescription drug it intends to import and document approval by the United States Food and Drug Administration for such importation.

3. A nonresident prescription drug manufacturer permit, prescription drug manufacturer's distributor permit, or third-party logistics provider permit is not required for a manufacturer to distribute, directly or through the

manufacturer's distributor or third-party logistics provider, a prescription drug active pharmaceutical ingredient that it manufactures to a prescription drug manufacturer permitted in this state in limited quantities intended for research and development and not for resale, or human use other than lawful clinical trials and biostudies authorized and regulated by federal law. A manufacturer, manufacturer's distributor, or third-party logistics provider claiming to be exempt from the permit requirements of this subparagraph and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212. The prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall maintain on file a record of the FDA registration number; the out-of-state license, permit, or registration number; and, if available, a copy of the most current FDA inspection report, for all manufacturers, manufacturer's distributors, or third-party logistics providers from whom they purchase and receive active pharmaceutical ingredients under this section. The department shall specify by rule the allowable number of transactions within a given period of time and the amount of active pharmaceutical ingredients that qualify as limited quantities for purposes of this exemption. The failure to comply with the requirements of this subparagraph, or rules adopted by the department to administer this subparagraph, for the purchase of prescription drug active pharmaceutical ingredients is a violation of s. 499.005(14).

(d) *Prescription drug wholesale distributor permit.*—A

prescription drug wholesale distributor is a wholesale distributor that may engage in the wholesale distribution of prescription drugs. A prescription drug wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $100,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later. The department may adopt rules for issuing a prescription drug wholesale distributor-broker permit to a person who engages in the wholesale distribution of prescription drugs and does not take physical possession of any prescription drugs.

(e) *Out-of-state prescription drug wholesale distributor permit.*—An out-of-state prescription drug wholesale distributor is a wholesale distributor located outside this state which engages in the wholesale distribution of prescription drugs into this state and which must be permitted by the department and comply with all the provisions required of a wholesale distributor under this part. An out-of-state prescription drug

wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $100,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later.

1. The out-of-state prescription drug wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident.

2. An out-of-state prescription drug wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed as a prescription drug wholesale distributor, in its state of residence, to a licensed prescription drug wholesale distributor in this state, if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of ss. 499.0121(6) and 499.01212 must be followed

for this transaction.

(f) *Retail pharmacy drug wholesale distributor permit.*—A retail pharmacy drug wholesale distributor is a retail pharmacy engaged in wholesale distribution of prescription drugs within this state under the following conditions:

1. The pharmacy must obtain a retail pharmacy drug wholesale distributor permit pursuant to this part and the rules adopted under this part.

2. The wholesale distribution activity does not exceed 30 percent of the total annual purchases of prescription drugs. If the wholesale distribution activity exceeds the 30-percent maximum, the pharmacy must obtain a prescription drug wholesale distributor permit.

3. The transfer of prescription drugs that appear in any schedule contained in chapter 893 is subject to chapter 893 and the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

4. The transfer is between a retail pharmacy and another retail pharmacy, or a Modified Class II institutional pharmacy, or a health care practitioner licensed in this state and authorized by law to dispense or prescribe prescription drugs.

5. All records of sales of prescription drugs subject to this section must be maintained separate and distinct from other records and comply with the recordkeeping requirements of this part.

(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.

(h) *Complimentary drug distributor permit.*—A complimentary drug distributor permit is required for any person that engages in the distribution of a complimentary drug, subject to the requirements of s. 499.028.

(i) *Freight forwarder permit.*—A freight forwarder permit is required for any person that engages in the distribution of a prescription drug as a freight forwarder unless the person is a common carrier. The storage, handling, and recordkeeping of such

distributions must comply with the requirements for wholesale distributors under s. 499.0121, but not those set forth in s. 499.01212. A freight forwarder must provide the source of the prescription drugs with a validated airway bill, bill of lading, or other appropriate documentation to evidence the exportation of the product.

(j) *Veterinary prescription drug retail establishment permit.*—A veterinary prescription drug retail establishment permit is required for any person that sells veterinary prescription drugs to the public but does not include a pharmacy licensed under chapter 465.

1. The sale to the public must be based on a valid written order from a veterinarian licensed in this state who has a valid client-veterinarian relationship with the purchaser's animal.

2. Veterinary prescription drugs may not be sold in excess of the amount clearly indicated on the order or beyond the date indicated on the order.

3. An order may not be valid for more than 1 year.

4. A veterinary prescription drug retail establishment may not purchase, sell, trade, or possess human prescription drugs or any controlled substance as defined in chapter 893.

5. A veterinary prescription drug retail establishment must sell a veterinary prescription drug in the original, sealed manufacturer's container with all labeling intact and legible. The department may adopt by rule additional labeling requirements for the sale of a veterinary prescription drug.

6. A veterinary prescription drug retail establishment must comply with all of the wholesale distribution requirements of s. 499.0121.

7. Prescription drugs sold by a veterinary prescription drug retail establishment pursuant to a practitioner's order may not be returned into the retail establishment's inventory.

(k) *Veterinary prescription drug wholesale distributor permit.*—A veterinary prescription drug wholesale distributor permit is required for any person that engages in the distribution of veterinary prescription drugs in or into this state. A veterinary prescription drug wholesale distributor that also distributes prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which it did not manufacture must obtain a permit as a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, or a limited prescription drug veterinary wholesale distributor in lieu of the veterinary prescription drug wholesale distributor permit. A veterinary prescription drug wholesale distributor must comply with the requirements for wholesale distributors under s. 499.0121, but not those set forth in s. 499.01212.

(l) *Limited prescription drug veterinary wholesale distributor permit.*—Unless engaging in the activities of and permitted as a prescription drug manufacturer, nonresident prescription drug manufacturer, prescription drug wholesale distributor, or out-of-state prescription drug wholesale distributor, a limited prescription drug veterinary wholesale distributor permit is required for any person that engages in the distribution in or into this state of veterinary prescription drugs and prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act under the following conditions:

1. The person is engaged in the business of wholesaling prescription and veterinary prescription drugs to persons:

a. Licensed as veterinarians practicing on a full-time basis;

b. Regularly and lawfully engaged in instruction in veterinary medicine;

c. Regularly and lawfully engaged in law enforcement activities;

d. For use in research not involving clinical use; or

e. For use in chemical analysis or physical testing or for purposes of instruction in law enforcement activities, research, or testing.

2. No more than 30 percent of total annual prescription drug sales may be prescription drugs approved for human use which are subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.

3. The person does not distribute in any jurisdiction prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act to any person who is authorized to sell, distribute, purchase, trade, or use these drugs on or for humans.

4. A limited prescription drug veterinary wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $20,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the

department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later.

5. A limited prescription drug veterinary wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident.

6. A limited prescription drug veterinary wholesale distributor must comply with the requirements for wholesale distributors under ss. 499.0121 and 499.01212, except that a limited prescription drug veterinary wholesale distributor is not required to provide a pedigree paper as required by s. 499.01212 upon the wholesale distribution of a prescription drug to a veterinarian.

7. A limited prescription drug veterinary wholesale distributor may not return to inventory for subsequent wholesale distribution any prescription drug subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian.

8. A limited prescription drug veterinary wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed to engage in the wholesale distribution of prescription drugs in its state of residence to

a licensed limited prescription drug veterinary wholesale distributor in this state if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of ss. 499.0121(6) and 499.01212 must be followed for this transaction.

(m) *Medical oxygen retail establishment permit.*—A medical oxygen retail establishment permit is required for any person that sells medical oxygen to patients only. The sale must be based on an order from a practitioner authorized by law to prescribe. The term does not include a pharmacy licensed under chapter 465.

1. A medical oxygen retail establishment may not possess, purchase, sell, or trade any prescription drug other than medical oxygen.

2. A medical oxygen retail establishment may refill medical oxygen for an individual patient based on an order from a practitioner authorized by law to prescribe. A medical oxygen retail establishment that refills medical oxygen must comply with all appropriate state and federal good manufacturing practices.

3. A medical oxygen retail establishment must comply with all of the wholesale distribution requirements of s. 499.0121.

4. Prescription medical oxygen sold by a medical oxygen retail establishment pursuant to a practitioner’s order may not be returned into the retail establishment’s inventory.

(n) *Compressed medical gas wholesale distributor permit.*—A compressed medical gas wholesale distributor is a wholesale distributor that is limited to the wholesale distribution of compressed medical gases to other than the consumer or patient.

The compressed medical gas must be in the original sealed container that was purchased by that wholesale distributor. A compressed medical gas wholesale distributor may not possess or engage in the wholesale distribution of any prescription drug other than compressed medical gases. The department shall adopt rules that govern the wholesale distribution of prescription medical oxygen for emergency use. With respect to the emergency use of prescription medical oxygen, those rules may not be inconsistent with rules and regulations of federal agencies unless the Legislature specifically directs otherwise.

(o) *Compressed medical gas manufacturer permit.*—A compressed medical gas manufacturer permit is required for any person that engages in the manufacture of compressed medical gases or repackages compressed medical gases from one container to another.

1. A compressed medical gas manufacturer may not manufacture or possess any prescription drug other than compressed medical gases.

2. A compressed medical gas manufacturer may engage in wholesale distribution of compressed medical gases manufactured at that establishment and must comply with all the provisions of this part and the rules adopted under this part that apply to a wholesale distributor.

3. A compressed medical gas manufacturer must comply with all appropriate state and federal good manufacturing practices.

(p) *Over-the-counter drug manufacturer permit.*—An over-the-counter drug manufacturer permit is required for any person that engages in the manufacture or repackaging of an over-the-counter drug.

1. An over-the-counter drug manufacturer may not possess or purchase prescription drugs.

2. A pharmacy is exempt from obtaining an over-the-counter drug manufacturer permit if it is operating in compliance with pharmacy practice standards as defined in chapter 465 and the rules adopted under that chapter.

3. An over-the-counter drug manufacturer must comply with all appropriate state and federal good manufacturing practices.

(q) *Device manufacturer permit.*—A device manufacturer permit is required for any person that engages in the manufacture, repackaging, or assembly of medical devices for human use in this state, except that a permit is not required if the person is engaged only in manufacturing, repackaging, or assembling a medical device pursuant to a practitioner's order for a specific patient.

1. A manufacturer or repackager of medical devices in this state must comply with all appropriate state and federal good manufacturing practices and quality system rules.

2. The department shall adopt rules related to storage, handling, and recordkeeping requirements for manufacturers of medical devices for human use.

(r) *Cosmetic manufacturer permit.*—A cosmetic manufacturer permit is required for any person that manufactures or repackages cosmetics in this state. A person that only labels or changes the labeling of a cosmetic but does not open the container sealed by the manufacturer of the product is exempt from obtaining a permit under this paragraph.

(s) *Third-party ~~Third party~~ logistics provider permit.*—A third-party ~~third party~~ logistics provider permit is required

for any person that contracts with a prescription drug wholesale distributor or prescription drug manufacturer to provide warehousing, distribution, or other logistics services on behalf of a manufacturer or wholesale distributor, but who does not take title to the prescription drug or have responsibility to direct the sale or disposition of the prescription drug. Each third-party ~~third party~~ logistics provider permittee shall comply with the requirements for wholesale distributors under ss. 499.0121 and 499.01212, with the exception of those wholesale distributions described in s. 499.01212(3)(a), and other rules that the department requires.

(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 legal business entity that has been issued a federal tax identification number and through which qualified practitioners practice their profession under state law ~~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 <u>licensed</u> ~~qualifying~~ practitioner <u>whose professional license authorizes the</u>

practitioner to prescribe prescription drugs from purchasing prescription drugs under his or her practice license.

7. This paragraph does not authorize the holder of this permit to purchase or possess controlled substances listed in s. 893.03 or federal law.

8. Prescription drugs that may be distributed to the holder of this permit are limited to those prescription drugs that can be lawfully prescribed by the qualifying practitioner.

(u) *Prescription drug manufacturer's distributor permit.*—A prescription drug manufacturer's distributor permit is required for any person who engages in the wholesale distribution of prescription drugs in or into this state of which a member of the person's affiliated group is the manufacturer of the prescription drug, unless the person is permitted as a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, or a third-party logistics provider. A person permitted as a prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, or a third-party logistics provider may change to a prescription drug manufacturer's distributor permit as provided in s. 499.012(2). A prescription drug manufacturer's distributor permitee shall distribute only prescription drugs manufactured by members of its affiliated group and shall acquire title to the prescription drugs before distributing them. Each prescription drug manufacturer's distributor permittee or applicant shall:

1. Identify, by name, address, and federal tax identification number, all affiliated group members on a document that is signed by a state-licensed certified public

accountant who certifies that the applicant is a member of the affiliated group and each member has been identified on the document. This document must be submitted as a part of the application for a prescription drug manufacturer's distributor permit and within 30 days after any change in the membership of the affiliated group; and

2. Comply with the requirements for wholesale distributors under s. 499.0121

As used in this paragraph, the term "affiliated group" means an affiliated group as defined in 26 U.S.C. s. 1504, as amended.

Section 5. Paragraph (d) of subsection (1) of section 499.012, Florida Statutes, is amended to read:

499.012 Permit application requirements.—

(1)

(d) A permit for a prescription drug manufacturer, prescription drug repackager, prescription drug wholesale distributor, limited prescription drug veterinary wholesale distributor, ~~or~~ retail pharmacy drug wholesale distributor, or prescription drug manufacturer's distributor may not be issued to the address of a health care entity or to a pharmacy licensed under chapter 465, except as provided in this paragraph. The department may issue a prescription drug manufacturer permit to an applicant at the same address as a licensed nuclear pharmacy, which is a health care entity, for the purpose of manufacturing prescription drugs used in positron emission tomography or other radiopharmaceuticals, as listed in a rule adopted by the department pursuant to this paragraph. The purpose of this exemption is to assure availability of state-of-the-art

pharmaceuticals that would pose a significant danger to the public health if manufactured at a separate establishment address from the nuclear pharmacy from which the prescription drugs are dispensed. The department may also issue a retail pharmacy drug wholesale distributor permit to the address of a community pharmacy licensed under chapter 465 which does not meet the definition of a closed pharmacy in s. 499.003.

Section 6. Paragraph (d) of subsection (4) and paragraph (e) of subsection (6) of section 499.0121, Florida Statutes, are amended 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.

(4) EXAMINATION OF MATERIALS AND RECORDS.—

(d) Upon receipt, a wholesale distributor must review records required under this section for the acquisition of prescription drugs for accuracy and completeness, considering the total facts and circumstances surrounding the transactions and the wholesale distributors involved. This includes authenticating each transaction listed on a pedigree paper~~, as defined in s. 499.003(36)~~.

(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.

(e) When a pedigree paper is required by this part, a

wholesale distributor must maintain pedigree papers separate and distinct from other records required under this part ~~chapter~~.

Section 7. Paragraphs (a) and (b) of subsection (2) of section 499.01211, Florida Statutes, are 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:

(a) Three different persons each of whom is employed by a different prescription drug wholesale distributor licensed under this part which operates nationally and is a primary wholesale distributor~~, as defined in s. 499.003(46)~~.

(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(51)~~.

Section 8. Section 499.01212, Florida Statutes, is amended to read:

499.01212 Pedigree paper.—

(1) APPLICATION.—Each person who is engaged in the wholesale distribution of a prescription drug must, prior to or simultaneous with each wholesale distribution, provide a pedigree paper to the person who receives the drug.

(2) FORMAT.—A pedigree paper must contain the following information:

(a) For the wholesale distribution of a prescription drug within the normal distribution chain:

1. The following statement: "This wholesale distributor

purchased the specific unit of the prescription drug directly from the manufacturer or manufacturer's distributor."

2. The manufacturer's national drug code identifier and the name and address of the wholesale distributor and the purchaser of the prescription drug.

3. The name of the prescription drug as it appears on the label.

4. The quantity, dosage form, and strength of the prescription drug.

The wholesale distributor must also maintain and make available to the department, upon request, the point of origin of the prescription drugs, including intracompany transfers, the date of the shipment from the manufacturer, manufacturer's distributor, or manufacturer's third-party logistics provider to the wholesale distributor, the lot numbers of such drugs, and the invoice numbers from the manufacturer or manufacturer's distributor.

(b) For all other wholesale distributions of prescription drugs:

1. The quantity, dosage form, and strength of the prescription drugs.

2. The lot numbers of the prescription drugs.

3. The name and address of each owner of the prescription drug and his or her signature.

4. Shipping information, including the name and address of each person certifying delivery or receipt of the prescription drug.

5. An invoice number, a shipping document number, or

another number uniquely identifying the transaction. When a manufacturer uses a manufacturer's distributor to sell the manufacturer's prescription drugs, the invoice number, shipping document number, or other number uniquely identifying the transaction between the manufacturer and manufacturer's distributor may be omitted from the pedigree paper.

6. A certification that the recipient wholesale distributor has authenticated the pedigree papers.

7. The unique serialization of the prescription drug, if the manufacturer or repackager has uniquely serialized the individual prescription drug unit.

8. The name, address, telephone number, and, if available, e-mail contact information of each wholesale distributor, including each third-party logistics provider and manufacturer's distributor involved in the chain of the prescription drug's custody.

(3) EXCEPTIONS.—A pedigree paper is not required for:

(a) The wholesale distribution of a prescription drug by the manufacturer, by the manufacturer's distributor, or by a third-party ~~third party~~ logistics provider performing a wholesale distribution of a prescription drug for a manufacturer.

(b) The wholesale distribution of a prescription drug by a freight forwarder within the authority of a freight forwarder permit.

(c) The wholesale distribution of a prescription drug by a limited prescription drug veterinary wholesale distributor to a veterinarian.

(d) The wholesale distribution of a compressed medical gas.

(e) The wholesale distribution of a veterinary prescription drug.

(f) A drop shipment, provided:

1. The wholesale distributor delivers to the recipient of the prescription drug, within 14 days after the shipment notification from the manufacturer or manufacturer's distributor, an invoice and the following sworn statement: "This wholesale distributor purchased the specific unit of the prescription drug listed on the invoice directly from the manufacturer or manufacturer's distributor, and the specific unit of prescription drug was shipped by the manufacturer, manufacturer's distributor, or manufacturer's third-party logistics provider directly to a person authorized by law to administer or dispense the legend drug, as defined in s. 465.003, Florida Statutes, or a member of an affiliated group, with the exception of a repackager." The invoice must contain a unique cross-reference to the shipping document sent by the manufacturer, manufacturer's distributor, or manufacturer's third-party logistics provider to the recipient of the prescription drug.

2. The manufacturer or manufacturer's distributor of the prescription drug shipped directly to the recipient provides and the recipient of the prescription drug acquires, within 14 days after receipt of the prescription drug, a shipping document from the manufacturer, manufacturer's distributor, or manufacturer's third-party logistics provider which ~~that~~ contains, at a minimum:

a. The name and address of the manufacturer or manufacturer's distributor, including the point of origin of the

shipment, and the names and addresses of the wholesale distributor and the purchaser.

b. The name of the prescription drug as it appears on the label.

c. The quantity, dosage form, and strength of the prescription drug.

d. The date of the shipment from the manufacturer, manufacturer's distributor, or manufacturer's third-party logistics provider.

3. The wholesale distributor maintains and makes available to the department, upon request, the lot number of such drug if not contained in the shipping document acquired by the recipient.

4. The wholesale distributor that takes title to, but not possession of, the prescription drug is not a member of the affiliated group that receives the prescription drug directly from the manufacturer.

Failure of the manufacturer, manufacturer's distributor, or manufacturer's third-party logistics provider to provide, the recipient to acquire, or the wholesale distributor to deliver the documentation required under this paragraph shall constitute failure to acquire or deliver a pedigree paper under ss. 499.005(28) and 499.0051. Forgery by the manufacturer, manufacturer's distributor, or manufacturer's third-party logistics provider, the recipient, or the wholesale distributor of the documentation required to be acquired or delivered under this paragraph shall constitute forgery of a pedigree paper under s. 499.0051.

(g) The wholesale distribution of a prescription drug by a warehouse within an affiliated group to a warehouse or retail pharmacy within its affiliated group, provided:

1. 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 s. 499.0121(4), regardless of whether the affiliated group member is directly subject to regulation under this part; and

2. The affiliated group makes available, within 48 hours, to the department on request to one or more of its members 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.

(h) The repackaging of prescription drugs by a repackager 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.

1. The repackager must:

a. 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, manufacturer's distributor, or from a prescription drug wholesale distributor that purchased

the prescription drugs directly from the manufacturer or manufacturer's distributor."

b. Purchase all prescription drugs it repackages:

(I) Directly from the manufacturer or manufacturer's distributor; or

(II) From a prescription drug wholesale distributor that purchased the prescription drugs directly from the manufacturer or manufacturer's distributor.

c. Maintain records in accordance with this section to document that it purchased the prescription drugs directly from the manufacturer, manufacturer's distributor, or that its prescription drug wholesale supplier purchased the prescription drugs directly from the manufacturer or manufacturer's distributor.

2. All members of the affiliated group must provide, within 48 hours, to agents of the department on request to one or more of its members records of purchases by all members of the affiliated group of prescription drugs that have been repackaged, regardless of the location at which the records are stored or at which the repackager is located.

Section 9. 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.

Section 10. Subsection (2) of section 499.041, Florida Statutes, is amended, and subsection (11) is added to that section, to read:

499.041 Schedule of fees for drug, device, and cosmetic

applications and permits, product registrations, and free-sale certificates.—

(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 ~~third party~~ logistics

provider permit may not be less than $200 or more than $300 annually.

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

(11) The department shall retain a fee of $150 or 50 percent of the permit or certification fee, whichever is less, from each person applying for a permit or certification if the application is withdrawn or becomes void.

Section 11. Paragraph (m) of 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:

(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)~~.

Section 12. Subsection (1) of section 794.075, Florida Statutes, is amended to read:

794.075 Sexual predators; erectile dysfunction drugs.—

(1) A person may not possess a prescription drug, as defined in s. 499.003(43) ~~s. 499.003(42)~~, for the purpose of treating erectile dysfunction if the person is designated as a sexual predator under s. 775.21.

Section 13. (1) Notwithstanding the purchase of a prescription drug from the manufacturer's distributor, a person who is required to comply with the pedigree paper provisions under s. 499.01212, Florida Statutes, may continue to use the statement provided in s. 499.01212, Florida Statutes (2008),

until September 30, 2010, for the wholesale distribution of a prescription drug that:

(a) Is within the normal distribution chain as provided in s. 499.01212(2)(a), Florida Statutes;

(b) Qualifies as a drop shipment as provided in s. 499.01212(3)(f), Florida Statutes; or

(c) Is a repackaged prescription drug as provided in s. 499.01212(3)(h), Florida Statutes.

(2) This section expires October 1, 2010.

Section 14. The sum of $111,477 is appropriated to the Department of Health from the Drugs, Devices, and Cosmetics Trust Fund for the 2009-2010 fiscal year, and 2.0 full-time equivalent positions along with an associated salary rate of 61,674 are authorized for the purpose of implementing the provisions of this act.

Section 15. This act shall take effect October 1, 2009.