A bill to be entitled

An act relating to drugs, devices, and cosmetics; amending s. 499.003, F.S.; providing, revising, and deleting definitions for purposes of the Florida Drug and Cosmetic Act; amending s. 499.005, F.S.; revising prohibited acts related to the distribution of prescription drugs; conforming a cross-reference; amending s. 499.0051, F.S.; prohibiting the distribution of prescription drugs without delivering a transaction history, transaction information, and transaction statement; providing penalties; deleting provisions and revising terminology related to pedigree papers, to conform to changes made by the act; amending s. 499.006, F.S.; conforming provisions; amending s. 499.01, F.S.; requiring nonresident prescription drug repackagers to obtain an operating permit; authorizing a manufacturer to engage in the wholesale distribution of prescription drugs; providing for the issuance of virtual prescription drug manufacturer permits and virtual nonresident prescription drug manufacturer permits to certain persons; providing exceptions from certain virtual manufacturer requirements; requiring a nonresident prescription drug repackager permit for certain persons; deleting surety bond requirements for prescription drug wholesale distributors; requiring

that certain persons obtain an out-of-state prescription drug wholesale distributor permit; requiring certain third party logistic providers to be licensed; requiring research and development labeling on certain prescription drug active pharmaceutical ingredient packaging; requiring certain manufacturers to create and maintain certain records; requiring certain prescription drug distributors to provide certain information to health care entities for which they repackage prescription drugs; amending s. 499.012, F.S.; providing for issuance of a prescription drug manufacturer permit or retail pharmacy drug wholesale distributor permit when an applicant at the same address is a licensed nuclear pharmacy or community pharmacy; providing for the expiration of deficient permit applications; requiring trade secret information submitted by an applicant to be maintained as a trade secret; authorizing the quadrennial renewal of permits; providing for calculation of fees for such permit renewals; revising procedures and application requirements for permit renewals; providing for late renewal fees; allowing a permittee who submits a renewal application to continue operations; removing certain application requirements for renewal of a permit; requiring bonds or other surety of a specified amount; requiring proof

of inspection of establishments used in wholesale distribution; authorizing the Department of Business and Professional Regulation to contract for the collection of electronic fingerprints under certain circumstances; providing information that may be submitted in lieu of certain application requirements for specified permits and certifications; removing provisions relating to annual renewal and expiration of permits; conforming cross-references; amending s. 499.01201, F.S.; conforming provisions; amending s. 499.0121, F.S.; revising prescription drug recordkeeping requirements; requiring inventories and records of transactions for active pharmaceutical ingredients; conforming provisions; amending s. 499.015, F.S.; removing cosmetics from registration requirements; authorizing voluntary registration of cosmetics; providing application and fee requirements for cosmetics; restricting those persons who may register a product with the department; providing for the expiration, renewal, and issuance of certain product registrations; providing for product registration fees; amending ss. 499.03, 499.05, and 499.051, F.S.; conforming provisions to changes made by the act; amending s. 499.066, F.S.; authorizing the issuance of nondisciplinary citations; authorizing the department to adopt rules designating violations for

which a citation may be issued; authorizing the department to recover investigative costs pursuant to the citation; specifying a time limitation for issuance of a citation; providing for service of a citation; amending s. 499.82, F.S.; revising the definition of "wholesale distribution" for purposes of medical gas requirements; amending s. 499.89, F.S.; conforming provisions; repealing s. 499.01212, F.S., relating to pedigree papers; amending ss. 409.9201, 794.075, and 921.0022, F.S.; conforming provisions to changes made by the act; providing an effective date.

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

Section 1. Section 499.003, Florida Statutes, is amended to read:

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

(1) "Active pharmaceutical ingredient" includes any substance or mixture of substances intended, represented, or labeled for use in drug manufacturing that furnishes or is intended to furnish, in a finished dosage form, any pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or to affect the structure or any function of the body of humans or animals.

(2)~~(1)~~ "Advertisement" means any representation disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of drugs, devices, or cosmetics.

(3) "Affiliate" means a business entity that has a relationship with another business entity in which, directly or indirectly:

(a) The business entity controls, or has the power to control, the other business entity; or

(b) A third party controls, or has the power to control, both business entities.

~~(2) "Affiliated group" means an affiliated group as defined by s. 1504 of the Internal Revenue Code of 1986, as amended, which is composed of chain drug entities, including at least 50 retail pharmacies, warehouses, or repackagers, which are members of the same affiliated group. The affiliated group must disclose the names of all its members to the department.~~

(4)~~(3)~~ "Affiliated party" means:

(a) A director, officer, trustee, partner, or committee member of a permittee or applicant or a subsidiary or service corporation of the permittee or applicant;

(b) A person who, directly or indirectly, manages, controls, or oversees the operation of a permittee or applicant, regardless of whether such person is a partner, shareholder, manager, member, officer, director, independent contractor, or

employee of the permittee or applicant;

(c) A person who has filed or is required to file a personal information statement pursuant to s. 499.012(9) or is required to be identified in an application for a permit or to renew a permit pursuant to s. 499.012(8); or

(d) The five largest natural shareholders that own at least 5 percent of the permittee or applicant.

(5) ~~(4)~~ "Applicant" means a person applying for a permit or certification under this part.

~~(5) "Authenticate" means to affirmatively verify upon receipt of a prescription drug that each transaction listed on the pedigree paper has occurred.~~

~~(a) A wholesale distributor is not required to open a sealed, medical convenience kit to authenticate a pedigree paper for a prescription drug contained within the kit.~~

~~(b) Authentication of a prescription drug included in a sealed, medical convenience kit shall be limited to verifying the transaction and pedigree information received.~~

(6) "Certificate of free sale" means a document prepared by the department which certifies a drug, device, or cosmetic, that is registered with the department, as one that can be legally sold in the state.

(7) "Chain pharmacy warehouse" means a ~~wholesale~~ distributor permitted pursuant to s. 499.01 that maintains a physical location for prescription drugs that functions solely as a central warehouse to perform intracompany transfers of such

drugs between members of an affiliate ~~to a member of its affiliated group~~.

(8) "Closed pharmacy" means a pharmacy that is licensed under chapter 465 and purchases prescription drugs for use by a limited patient population and not for wholesale distribution or sale to the public. The term does not include retail pharmacies.

(9) "Color" includes black, white, and intermediate grays.

(10) "Color additive" means, with the exception of any material that has been or hereafter is exempt under the federal act, a material that:

(a) Is a dye pigment, or other substance, made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity from a vegetable, animal, mineral, or other source; or

(b) When added or applied to a drug or cosmetic or to the human body, or any part thereof, is capable alone, or through reaction with other substances, of imparting color thereto.

(11) "Contraband prescription drug" means any adulterated drug, as defined in s. 499.006, any counterfeit drug, as defined in this section, and also means any prescription drug for which a transaction history, transaction information, or transaction statement ~~pedigree paper~~ does not exist, or for which the transaction history, transaction information, or transaction statement ~~pedigree paper~~ in existence has been forged, counterfeited, falsely created, or contains any altered, false,

or misrepresented matter.

(12) "Cosmetic" means an article, with the exception of soap, that is:

(a) Intended to be rubbed, poured, sprinkled, or sprayed on; introduced into; or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance; or

(b) Intended for use as a component of any such article.

(13) "Counterfeit drug," "counterfeit device," or "counterfeit cosmetic" means a drug, device, or cosmetic which, or the container, seal, or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug, device, or cosmetic manufacturer, processor, packer, or distributor other than the person that in fact manufactured, processed, packed, or distributed that drug, device, or cosmetic and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, that other drug, device, or cosmetic manufacturer, processor, packer, or distributor.

(14) "Department" means the Department of Business and Professional Regulation.

(15) "Device" means any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including its components, parts, or accessories, which is:

(a) Recognized in the current edition of the United States Pharmacopoeia and National Formulary, or any supplement thereof,

(b) Intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or

(c) Intended to affect the structure or any function of the body of humans or other animals,

and that does not achieve any of its principal intended purposes through chemical action within or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

(16) "Distribute" or "distribution" means sale, purchase, trade, delivery, handling, storage, or receipt ~~to sell; offer to sell; give away; transfer, whether by passage of title, physical movement, or both; deliver; or offer to deliver~~. The term does not mean to administer or dispense ~~and does not include the billing and invoicing activities that commonly follow a wholesale distribution transaction~~.

~~(17) "Drop shipment" means the sale of a prescription drug from a manufacturer 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 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.~~

(17)~~(18)~~ "Drug" means an article that is:

(a) Recognized in the current edition of the United States Pharmacopoeia and National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of those publications;

(b) Intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals;

(c) Intended to affect the structure or any function of the body of humans or other animals; or

(d) Intended for use as a component of any article specified in paragraph (a), paragraph (b), or paragraph (c), and includes active pharmaceutical ingredients, but does not include devices or their nondrug components, parts, or accessories. ~~For purposes of this paragraph, an "active pharmaceutical ingredient" includes any substance or mixture of substances intended, represented, or labeled for use in drug manufacturing that furnishes or is intended to furnish, in a finished dosage form, any pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or to affect the structure or any function of the body of humans or other animals.~~

(18)~~(19)~~ "Establishment" means a place of business which is at one general physical location and may extend to one or

more contiguous suites, units, floors, or buildings operated and controlled exclusively by entities under common operation and control. Where multiple buildings are under common exclusive ownership, operation, and control, an intervening thoroughfare does not affect the contiguous nature of the buildings. For purposes of permitting, each suite, unit, floor, or building must be identified in the most recent permit application.

(19) ~~(20)~~ "Federal act" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

(20) ~~(21)~~ "Freight forwarder" means a person who receives prescription drugs which are owned by another person and designated by that person for export, and exports those prescription drugs.

(21) ~~(22)~~ "Health care entity" means a closed pharmacy or any person, organization, or business entity that provides diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care, but does not include any wholesale distributor or retail pharmacy licensed under state law to deal in prescription drugs. However, a blood establishment is a health care entity that may engage in the wholesale distribution of prescription drugs under s. 499.01(2)(h)1.c. ~~499.01(2)(g)1.c.~~

(22) ~~(23)~~ "Health care facility" means a health care facility licensed under chapter 395.

(23) ~~(24)~~ "Hospice" means a corporation licensed under part IV of chapter 400.

(24)~~(25)~~ "Hospital" means a facility as defined in s. 395.002 and licensed under chapter 395.

(25)~~(26)~~ "Immediate container" does not include package liners.

(26)~~(27)~~ "Label" means a display of written, printed, or graphic matter upon the immediate container of any drug, device, or cosmetic. A requirement made by or under authority of this part or rules adopted under this part that any word, statement, or other information appear on the label is not complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such drug, device, or cosmetic or is easily legible through the outside container or wrapper.

(27)~~(28)~~ "Labeling" means all labels and other written, printed, or graphic matters:

(a) Upon a drug, device, or cosmetic, or any of its containers or wrappers; or

(b) Accompanying or related to such drug, device, or cosmetic.

(28)~~(29)~~ "Manufacture" means the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any drug, device, or cosmetic.

(29)~~(30)~~ "Manufacturer" means:

(a) A person who holds a New Drug Application, an Abbreviated New Drug Application, a Biologics License Application, or a New Animal Drug Application approved under the

federal act or a license issued under s. 351 of the Public Health Service Act, 42 U.S.C. s. 262, for such drug or biologics, or if such drug or biologics is not the subject of an approved application or license, the person who manufactured the drug or biologics ~~prepares, derives, manufactures, or produces a drug, device, or cosmetic~~;

(b) A co-licensed partner of the person described in paragraph (a) who obtains the drug or biologics directly from a person described in paragraph (a), paragraph (c), or this paragraph ~~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) An affiliate of a person described in paragraph (a), paragraph (b), or this paragraph that receives the drug or biologics directly from a person described in paragraph (a), paragraph (b), or this paragraph ~~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

(d) A person that manufactures a device or a cosmetic. ~~A person registered under the federal act as a manufacturer of a prescription drug, who is described in paragraph (a), paragraph (b), or paragraph (c), who has entered into a written agreement with another prescription drug manufacturer that authorizes~~

~~either manufacturer to distribute the prescription drug identified in the agreement as the manufacturer of that drug consistent with the federal act and its implementing regulations;~~

~~(e) A member of an affiliated group that includes, but is not limited to, persons described in paragraph (a), paragraph (b), paragraph (c), or paragraph (d), which member distributes prescription drugs, whether or not obtaining title to the drugs, only for the manufacturer of the drugs who is also a member of the affiliated group. As used in this paragraph, the term "affiliated group" means an affiliated group as defined in s. 1504 of the Internal Revenue Code of 1986, as amended. The manufacturer must disclose the names of all of its affiliated group members to the department; or~~

~~(f) A person permitted as a third party logistics provider, only while providing warehousing, distribution, or other logistics services on behalf of a person described in paragraph (a), paragraph (b), paragraph (c), paragraph (d), or paragraph (e).~~

The term does not include a pharmacy that is operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.

(30) ~~(31)~~ "Medical convenience kit" means packages or units that contain combination products as defined in 21 C.F.R. s. 3.2(e)(2).

(31) ~~(32)~~ "Medical gas" means any liquefied or vaporized gas that is a prescription drug, whether alone or in combination with other gases, and as defined in the federal act.

(32) ~~(33)~~ "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) "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 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.~~

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

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

~~(37) "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.~~

(35)~~(38)~~ "Permittee" means any person holding a permit issued under this chapter ~~pursuant to s. 499.012~~.

(36)~~(39)~~ "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.

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

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

(39)~~(42)~~ "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.

(40) ~~(43)~~ "Prescription drug" means a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active pharmaceutical ingredients subject to, defined by, or described by s. 503(b) of the federal act or s. 465.003(8), s. 499.007(13), subsection (31) ~~(32)~~, or subsection (47) ~~(52)~~, except that an active pharmaceutical ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in this state are also prescription drugs.

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

(42) ~~(45)~~ "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) "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.~~

(43) ~~(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.

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

(45) ~~(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.

(46) ~~(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.

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

(47) ~~(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."

(48) ~~(53)~~ "Wholesale distribution" means the distribution of a prescription drug to a person ~~drugs to persons~~ other than a consumer or patient, or the receipt of a prescription drug by a

person other than the 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)(h) ~~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 distribution ~~sale, purchase, or trade~~ of a prescription drug or an offer to distribute ~~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 distribution ~~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 distribution ~~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 distribution ~~sale, purchase, trade, or other transfer~~ of a prescription drug under this subparagraph from the Secretary of Business and Professional Regulation 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. 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.

e. 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 d.

f. 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 distribution ~~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 distribution ~~sale, purchase, or trade~~ of a prescription drug or ~~an~~ offer to distribute ~~sell, purchase, or trade~~ a prescription drug for emergency medical reasons, which may include~~. 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. For purposes of this subparagraph, a drug shortage not caused by a public health emergency does not constitute an emergency medical reason.

3. The distribution ~~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.~~

4.~~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.

5.~~6.~~ The distribution ~~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.

6.~~7.~~ The distribution ~~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 distributes ~~transfers~~ prescription drugs pursuant to this subparagraph must reconcile all drugs distributed ~~transferred~~ and returned and resolve any discrepancies in a timely manner.

(c) Intracompany distribution of any drug between members of an affiliate or within a manufacturer.

(d) The distribution of a prescription drug by the manufacturer of the prescription drug.

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

(f) The distribution of a prescription drug by a third-party logistics provider permitted or licensed pursuant to and operating in compliance with the laws of this state and federal law if such third-party logistics provider does not take ownership of the prescription drug.

(g) The distribution of a prescription drug, or an offer to distribute a prescription drug by a repackager registered as a drug establishment with the United States Food and Drug Administration that has taken ownership or possession of the

prescription drug and repacks it in accordance with this part.

(h) The purchase or other acquisition by a dispenser, hospital, or other health care entity of a prescription drug for use by such dispenser, hospital, or other health care entity.

(i) The distribution of a prescription drug by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager 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 drug remains with the hospital or other health care entity at all times.

(j) ~~(d)~~ The distribution ~~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.

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

(l) ~~(f)~~ The distribution ~~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.

(m) The distribution of minimal quantities of prescription drugs by a licensed retail pharmacy to a licensed practitioner for office use in compliance with chapter 465 and rules adopted thereunder.

(n) The distribution of an intravenous prescription drug that, by its formulation, is intended for the replenishment of fluids and electrolytes, such as sodium, chloride, and potassium or calories, such as dextrose and amino acids.

(o) The distribution of an intravenous prescription drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions.

(p) The distribution of a prescription drug that is intended for irrigation or sterile water, whether intended for such purposes or for injection.

(q) The distribution of an exempt medical convenience kit pursuant to 21 U.S.C. s. 353(e)(4)(M).

(r) A common carrier that transports a prescription drug, if the common carrier does not take ownership of the prescription drug.

(s) Saleable drug returns when conducted by a dispenser.

(t) Facilitating the distribution of a prescription drug by providing solely administrative services, including processing of orders and payments.

(u) The distribution by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of

prescription drugs donated to or supplied at a reduced price to the charitable organization to:

1. A licensed health care practitioner, as defined in s. 456.001, who is authorized under the appropriate practice act to prescribe and administer prescription drugs;

2. A health care clinic establishment permitted pursuant to chapter 499; or

3. The Department of Health or the licensed medical director of a government agency health care entity, authorized to possess prescription drugs, for storage and use in the treatment of persons in need of emergency medical services, including controlling communicable diseases or providing protection from unsafe conditions that pose an imminent threat to public health,

if the distributor and the receiving entity receive no direct or indirect financial benefit other than tax benefits related to charitable contributions. Distributions under this section that involve controlled substances must comply with all state and federal regulations pertaining to the handling of controlled substances.

(v) The distribution of medical gas pursuant to part III of this chapter.

(49) ~~(54)~~ "Wholesale distributor" means a ~~any~~ person, other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or a repackager, who is 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 2. Subsections (21), (28), and (29) of section 499.005, Florida Statutes, are amended to read:

499.005 Prohibited acts.—It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

(21) The wholesale distribution of any prescription drug that was:

(a) Purchased by a public or private hospital or other health care entity; or

(b) Donated or supplied at a reduced price to a charitable organization,

unless the wholesale distribution of the prescription drug is authorized in s. 499.01(2)(h)1.c. ~~499.01(2)(g)1.c.~~

(28) Failure to acquire or deliver a transaction history, transaction information, or transaction statement ~~pedigree paper~~ as required under this part and rules adopted under this part.

~~(29) The receipt of a prescription drug pursuant to a~~

~~wholesale distribution without having previously received or simultaneously receiving a pedigree paper that was attested to as accurate and complete by the wholesale distributor as required under this part.~~

Section 3. Subsections (4) through (17) of section 499.0051, Florida Statutes, are renumbered as subsections (3) through (16), respectively, and subsections (1) and (2), present subsection (3), paragraphs (h) and (i) of present subsection (12), and paragraph (d) of present subsection (13) of that section are amended, to read:

499.0051 Criminal acts.—

(1) FAILURE TO MAINTAIN OR DELIVER TRANSACTION HISTORY, TRANSACTION INFORMATION, OR TRANSACTION STATEMENT ~~PEDIGREE PAPERS~~.—

(a) A person~~, other than a manufacturer,~~ engaged in the ~~wholesale~~ distribution of prescription drugs who fails to deliver to another person a complete and accurate transaction history, transaction information, or transaction statement ~~pedigree papers~~ concerning a prescription drug or contraband prescription drug, as required by this chapter and rules adopted under this chapter, before ~~prior to~~, or simultaneous with, the transfer of the prescription drug or contraband prescription drug to another person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b) A person engaged in the ~~wholesale~~ distribution of prescription drugs who fails to acquire a complete and accurate

transaction history, transaction information, or transaction statement ~~pedigree papers~~ concerning a prescription drug or contraband prescription drug, as required by this chapter and rules adopted under this chapter, before ~~prior to~~, or simultaneous with, the receipt of the prescription drug or contraband prescription drug from another person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(c) Any person who knowingly destroys, alters, conceals, or fails to maintain a complete and accurate transaction history, transaction information, or transaction statement ~~pedigree papers~~ concerning any prescription drug or contraband prescription drug, as required by this chapter and rules adopted under this chapter, in his or her possession commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

~~(2) FAILURE TO AUTHENTICATE PEDIGREE PAPERS.—Effective July 1, 2006:~~

~~(a) A person engaged in the wholesale distribution of prescription drugs who is in possession of pedigree papers concerning prescription drugs or contraband prescription drugs and who fails to authenticate the matters contained in the pedigree papers and who nevertheless attempts to further distribute prescription drugs or contraband prescription drugs commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.~~

~~(b) A person in possession of pedigree papers concerning prescription drugs or contraband prescription drugs who falsely swears or certifies that he or she has authenticated the matters contained in the pedigree papers commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.~~

(2)~~(3)~~ KNOWING FORGERY OF TRANSACTION HISTORY, TRANSACTION INFORMATION, OR TRANSACTION STATEMENT ~~PEDIGREE PAPERS~~.—A person who knowingly forges, counterfeits, or falsely creates any transaction history, transaction information, or transaction statement ~~pedigree paper~~; who falsely represents any factual matter contained on any transaction history, transaction information, or transaction statement ~~pedigree paper~~; or who knowingly omits to record material information required to be recorded in a transaction history, transaction information, or transaction statement ~~pedigree paper~~, commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(11)~~(12)~~ ADULTERATED AND MISBRANDED DRUGS; FALSE ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS.—Any person who violates any of the following provisions commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083; but, if the violation is committed after a conviction of such person under this subsection has become final, such person commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, or as

otherwise provided in this part:

(h) The failure to maintain records related to a drug as required by this part and rules adopted under this part, except for transaction histories, transaction information, or transaction statements ~~pedigree papers~~, invoices, or shipping documents related to prescription drugs.

(i) The possession of any drug in violation of this part, except if the violation relates to a deficiency in transaction histories, transaction information, or transaction statements ~~pedigree papers~~.

(12)~~(13)~~ REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING, OR TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO PRESCRIPTION DRUGS.—Any person who violates any of the following provisions commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in this part:

(d) The failure to receive, maintain, or provide invoices and shipping documents~~, other than pedigree papers,~~ if applicable, related to the distribution of a prescription drug.

Section 4. Subsection (10) of section 499.006, Florida Statutes, is amended to read:

499.006 Adulterated drug or device.—A drug or device is adulterated:

(10) If it is a prescription drug for which the required transaction history, transaction information, or transaction statement ~~pedigree paper~~ is nonexistent, fraudulent, or

incomplete under the requirements of this part or applicable rules, or that has been purchased, held, sold, or distributed at any time by a person not authorized under federal or state law to do so; or

Section 5. Section 499.01, Florida Statutes, is amended to read:

499.01 Permits.—

(1) Before ~~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 nonresident prescription drug repackager;

(e) ~~(d)~~ A prescription drug wholesale distributor;

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

(g) ~~(f)~~ A retail pharmacy drug wholesale distributor;

(h) ~~(g)~~ A restricted prescription drug distributor;

(i) ~~(h)~~ A complimentary drug distributor;

(j) ~~(i)~~ A freight forwarder;

(k) ~~(j)~~ A veterinary prescription drug retail establishment;

(l) ~~(k)~~ A veterinary prescription drug wholesale distributor;

(m) ~~(l)~~ A limited prescription drug veterinary wholesale distributor;

(n) ~~(m)~~ An over-the-counter drug manufacturer;

(o) ~~(n)~~ A device manufacturer;

(p) ~~(o)~~ A cosmetic manufacturer;

(q) ~~(p)~~ A third party logistics provider; or

(r) ~~(q)~~ A health care clinic establishment.

(2) The following permits are established:

(a) Prescription drug manufacturer permit.—A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.

1. A person that operates an establishment permitted as a prescription drug manufacturer may engage in wholesale distribution of prescription drugs for which the person is the manufacturer ~~manufactured at that establishment~~ and must comply with s. 499.0121 and all other ~~of the~~ provisions of this part~~,~~ ~~except s. 499.01212,~~ and ~~the~~ rules adopted under this part~~,~~ ~~except s. 499.01212, which apply to a wholesale distributor~~. The department shall adopt rules for issuing a virtual prescription drug manufacturer permit to a person who engages in the manufacture of prescription drugs but does not make or take physical possession of any prescription drugs. The rules adopted by the department under this section may exempt virtual manufacturers from certain establishment, security, and storage requirements set forth in s. 499.0121.

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

3. A blood establishment, as defined in s. 381.06014, operating in a manner consistent with the provisions of 21 C.F.R. parts 211 and 600-640, and manufacturing only the prescription drugs described in s. 499.003(48)(j) ~~499.003(53)(d)~~ is not required to be permitted as a prescription drug manufacturer under this paragraph or to register products under s. 499.015.

(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 of the provisions of this part and the rules adopted under this part that apply to a prescription drug manufacturer ~~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, unless permitted as a third party logistics provider, located outside of this state or outside the United States and that engages in the ~~wholesale~~ distribution in this state of such prescription drugs. Each such manufacturer must be permitted by the department and comply with all of the provisions required of

a prescription drug manufacturer ~~wholesale distributor~~ under this part~~, except s. 499.01212~~. The department shall adopt rules for issuing a virtual nonresident prescription drug manufacturer permit to a person who engages in the manufacture of prescription drugs but does not make or take physical possession of any prescription drugs. The rules adopted by the department under this section may exempt virtual nonresident manufacturers from certain establishment, security, and storage requirements set forth in s. 499.0121.

1. A person that distributes prescription drugs for which the person is not the manufacturer must also obtain an out-of-state prescription drug wholesale distributor permit or third party logistics provider permit pursuant to this section to engage in the ~~wholesale~~ distribution of such prescription drugs when required by this part. This subparagraph does not apply to a manufacturer that distributes prescription drugs only for the manufacturer of the prescription drugs where both manufacturers are affiliates ~~as defined in s. 499.003(30)(c)~~.

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 prescription drug distributed ~~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.

(d) Nonresident prescription drug repackager permit.—A nonresident prescription drug repackager permit is required for any person located outside of this state, but within the United States or its territories, that repackages prescription drugs and engages in the distribution of such prescription drugs into this state.

1. A nonresident prescription drug repackager must comply with all of the provisions of this section and the rules adopted under this section that apply to a prescription drug manufacturer.

2. A nonresident prescription drug repackager must be permitted by the department and comply with all appropriate state and federal good manufacturing practices.

3. A nonresident prescription drug repackager must be registered as a drug establishment with the United States Food and Drug Administration.

(e) ~~(d)~~ Prescription drug wholesale distributor permit.—A prescription drug wholesale distributor permit is required for any person who is a wholesale distributor of prescription drugs and that ~~may engage in the~~ wholesale distributes such ~~distribution of~~ prescription drugs in this state. ~~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 Professional Regulation 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.

(f) ~~(e)~~ Out-of-state prescription drug wholesale distributor permit.—An out-of-state prescription drug wholesale distributor permit is required for any person that is a wholesale distributor located outside this state, but within the United States or its territories, 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 Professional Regulation 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 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. If the state from which the wholesale distributor distributes prescription drugs does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor as required by the federal act.

(g) ~~(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.

(h) ~~(g)~~ Restricted prescription drug distributor permit.—

1. A restricted prescription drug distributor permit is required for:

a. Any person located in this state who engages in the distribution of a prescription drug, which distribution is not considered "wholesale distribution" under s. 499.003(48)(a)

~~499.003(53)(a)~~.

b. Any person located in this state who engages in the receipt or distribution of a prescription drug in this state for the purpose of processing its return or its destruction 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.

c. A blood establishment located in this state which collects blood and blood components only from volunteer donors as defined in s. 381.06014 or pursuant to an authorized practitioner's order for medical treatment or therapy and engages in the wholesale distribution of a prescription drug not described in s. 499.003(48)(j) ~~499.003(53)(d)~~ to a health care entity. A mobile blood unit operated by a blood establishment permitted under this sub-subparagraph is not required to be separately permitted. The health care entity receiving a prescription drug distributed under this sub-subparagraph must be licensed as a closed pharmacy or provide health care services at that establishment. The blood establishment must operate in accordance with s. 381.06014 and may distribute only:

(I) Prescription drugs indicated for a bleeding or clotting disorder or anemia;

(II) Blood-collection containers approved under s. 505 of the federal act;

(III) Drugs that are blood derivatives, or a recombinant or synthetic form of a blood derivative;

(IV) Prescription drugs that are identified in rules adopted by the department and that are essential to services performed or provided by blood establishments and authorized for distribution by blood establishments under federal law; or

(V) To the extent authorized by federal law, drugs necessary to collect blood or blood components from volunteer blood donors; for blood establishment personnel to perform therapeutic procedures under the direction and supervision of a licensed physician; and to diagnose, treat, manage, and prevent any reaction of a volunteer blood donor or a patient undergoing a therapeutic procedure performed under the direction and supervision of a licensed physician,

as long as all of the health care services provided by the blood establishment are related to its activities as a registered blood establishment or the health care services consist of collecting, processing, storing, or administering human hematopoietic stem cells or progenitor cells or performing diagnostic testing of specimens if such specimens are tested together with specimens undergoing routine donor testing. The blood establishment may purchase and possess the drugs described in this sub-subparagraph without a health care clinic establishment permit.

2. Storage, handling, and recordkeeping of these distributions by a person required to be permitted as a restricted prescription drug distributor must be in accordance

with the requirements for wholesale distributors under s. 499.0121~~, but not those set forth in s. 499.01212 if the distribution occurs pursuant to sub-subparagraph 1.a. or sub-subparagraph 1.b~~.

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, other persons not involved in wholesale distribution, and blood establishments, which rules are necessary for the protection of the public health, safety, and welfare.

(i) ~~(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.

(j) ~~(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.

(k) ~~(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.

(l) ~~(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~~.

(m) ~~(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 Professional Regulation 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 s. ~~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 s. ~~ss.~~ 499.0121(6) ~~and 499.01212~~ must be followed for this transaction.

(n) ~~(m)~~ 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.

(o) ~~(n)~~ Device manufacturer permit.—

1. 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:

a. The person is engaged only in manufacturing, repackaging, or assembling a medical device pursuant to a practitioner's order for a specific patient; or

b. The person does not manufacture, repackage, or assemble any medical devices or components for such devices, except those devices or components which are exempt from registration pursuant to s. 499.015(8).

2. 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.

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

(p) ~~(o)~~ 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.

(q) ~~(p)~~ Third party logistics provider permit.—A 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, or dispenser, but who does not take title to the prescription drug or have responsibility to direct the sale or disposition of the prescription drug. A third party logistics provider located outside of this state, must be licensed in the state or territory from which the prescription drug is distributed by the third party logistics provider. If the state or territory from which the third party logistics provider originates does not require a license to operate as a third party logistics provider, the third party logistic provider must be licensed as a third party logistics provider as required by the federal act. Each third party logistics provider permittee shall comply with s. ~~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.

(r) ~~(q)~~ 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 that provides health care or veterinary services, which is owned and operated by a business entity that has been issued a federal employer tax identification number. 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 apply to the purchase of a prescription drug by a licensed practitioner under his or her license.

(3) A nonresident prescription drug manufacturer permit is not required for a manufacturer to distribute 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 claiming to be exempt from the permit requirements of this subsection 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; if available, the out-of-state

license, permit, or registration number; and, if available, a copy of the most current FDA inspection report, for all manufacturers from whom they purchase active pharmaceutical ingredients under this section. ~~The department shall define the term "limited quantities" by rule, and may include the allowable number of transactions within a given period of time and the amount of prescription drugs distributed into the state for purposes of this exemption.~~ The failure to comply with the requirements of this subsection, or rules adopted by the department to administer this subsection, for the purchase of prescription drug active pharmaceutical ingredients is a violation of s. 499.005(14), and a knowing failure is a violation of s. 499.0051(4).

(a) The immediate package or container of a prescription drug active pharmaceutical ingredient distributed into the state that is intended for research and development under this subsection shall bear a label prominently displaying the statement: "Caution: Research and Development Only—Not for Manufacturing, Compounding, or Resale."

(b) A prescription drug manufacturer that obtains a prescription drug active pharmaceutical ingredient under this subsection for use in clinical trials and or biostudies authorized and regulated by federal law must create and maintain records detailing the specific clinical trials or biostudies for which the prescription drug active pharmaceutical ingredient was obtained.

(4)(a) A permit issued under this part is not required to distribute a prescription drug active pharmaceutical ingredient from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for use by the recipient in preparing, deriving, processing, producing, or fabricating a prescription drug finished dosage form at the establishment in this state where the product is received under an approved and otherwise valid New Drug Approval Application, Abbreviated New Drug Application, New Animal Drug Application, or Therapeutic Biologic Application, provided that the application, active pharmaceutical ingredient, or finished dosage form has not been withdrawn or removed from the market in this country for public health reasons.

1. Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit, or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed. If the state from which the prescription drugs are distributed does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor as required by the federal act.

2. Any distributor claiming exemption from permitting requirements pursuant to this paragraph 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~~.

(b) A permit issued under this part is not required to distribute ~~limited quantities of~~ a prescription drug that has not been repackaged from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for research and development or to a holder of a letter of exemption issued by the department under s. 499.03(4) for research, teaching, or testing. ~~The department shall define "limited quantities" by rule and may include the allowable number of transactions within a given period of time and the amounts of prescription drugs distributed into the state for purposes of this exemption.~~

1. Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit, or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed. If the state from which the prescription drugs are distributed does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor as required by the federal act.

2. All purchasers and recipients of any prescription drugs distributed pursuant to this paragraph shall ensure that the products are not resold or used, directly or indirectly, on

humans except in lawful clinical trials and biostudies authorized and regulated by federal law.

3. Any distributor claiming exemption from permitting requirements pursuant to this paragraph, and the purchaser and recipient of the prescription drug, shall comply with the recordkeeping requirements of s. 499.0121(6)~~, but not the requirements of s. 499.01212~~.

4. The immediate package or container of any active pharmaceutical ingredient distributed into the state that is intended for teaching, testing, research, and development shall bear a label prominently displaying the statement: "Caution: Research, Teaching, or Testing Only - Not for Manufacturing, Compounding, or Resale."

(c) 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 s. ~~ss.~~ 499.0121(6) ~~and 499.01212~~ must be followed for such transactions.

(d) Persons receiving prescription drugs from a source claimed to be exempt from permitting requirements under this subsection shall maintain on file:

1. A record of the FDA establishment registration number, if any;

2. The resident state or federal license, registration, or permit that authorizes the source to distribute prescription drugs ~~drug wholesale distribution license, permit, or registration number~~; and

3. A copy of the most recent resident state or FDA inspection report, for all distributors and establishments from whom they purchase or receive prescription drugs under this subsection.

(e) All persons claiming exemption from permitting requirements pursuant to this subsection who engage in the distribution of prescription drugs within or into the state are subject to this part, including ss. 499.005 and 499.0051, and shall make available, within 48 hours, to the department on request all records related to any prescription drugs distributed under this subsection, including those records described in s. 499.051(4), regardless of the location where the records are stored.

(f) A person purchasing and receiving a prescription drug from a person claimed to be exempt from licensing requirements pursuant to this subsection shall report to the department in writing within 14 days after receiving any product that is misbranded or adulterated or that fails to meet minimum standards set forth in the official compendium or state or federal good manufacturing practices for identity, purity,

potency, or sterility, regardless of whether the product is thereafter rehabilitated, quarantined, returned, or destroyed.

(g) The department may adopt rules to administer this subsection which are necessary for the protection of the public health, safety, and welfare. Failure to comply with the requirements of this subsection, or rules adopted by the department to administer this subsection, is a violation of s. 499.005(14), and a knowing failure is a violation of s. 499.0051(4).

(h) This subsection does not relieve any person from any requirement prescribed by law with respect to controlled substances as defined in the applicable federal and state laws.

(5) A prescription drug repackager permit issued under this part is not required for a restricted prescription drug distributor permitholder that is a health care entity to repackage prescription drugs in this state for its own use or for distribution to hospitals or other health care entities in the state for their own use, pursuant to s. 499.003(48)(a)3. ~~499.003(53)(a)3.~~, if:

(a) The prescription drug distributor notifies the department, in writing, of its intention to engage in repackaging under this exemption, 30 days before engaging in the repackaging of prescription drugs at the permitted establishment;

(b) The prescription drug distributor is under common control with the hospitals or other health care entities to

which the prescription drug distributor is distributing prescription drugs. As used in this paragraph, "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, voting rights, contract, or otherwise;

(c) The prescription drug distributor repackages the prescription drugs in accordance with current state and federal good manufacturing practices; and

(d) The prescription drug distributor labels the prescription drug it repackages in accordance with state and federal laws and rules.

The prescription drug distributor is exempt from the product registration requirements of s. 499.015 with regard to the prescription drugs that it repackages and distributes under this subsection. A prescription drug distributor that repackages and distributes prescription drugs under this subsection to a not-for-profit rural hospital, as defined in s. 395.602, is not required to comply with paragraph (c) or paragraph (d), but must provide to each health care entity for which it repackages, for each prescription drug that is repackaged and distributed, the information required by department rule for labeling prescription drugs. The prescription drug distributor shall also provide the additional current packaging and label information for the prescription drug by hard copy or by electronic means.

Section 6. Section 499.012, Florida Statutes, is amended

to read:

499.012 Permit application requirements.—

(1)(a) A permit issued pursuant to this part may be issued only to a natural person who is at least 18 years of age or to an applicant that is not a natural person if each person who, directly or indirectly, manages, controls, or oversees the operation of that applicant is at least 18 years of age.

(b) An establishment that is a place of residence may not receive a permit and may not operate under this part.

(c) A person that applies for or renews a permit to manufacture or distribute prescription drugs may not use a name identical to the name used by any other establishment or licensed person authorized to purchase prescription drugs in this state, except that a restricted drug distributor permit issued to a health care entity will be issued in the name in which the institutional pharmacy permit is issued and a retail pharmacy drug wholesale distributor will be issued a permit in the name of its retail pharmacy permit.

(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 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, even if the nuclear pharmacy holds a special sterile compounding permit under chapter 465, 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, even if the community pharmacy holds a special sterile compounding permit under chapter 465, as long as the community pharmacy ~~which~~ does not meet the definition of a closed pharmacy in s. 499.003.

(e) A county or municipality may not issue an occupational license for ~~any licensing period beginning on or after October 1, 2003, for~~ any establishment that requires a permit pursuant to this part, unless the establishment exhibits a current permit issued by the department for the establishment. Upon presentation of the requisite permit issued by the department, an occupational license may be issued by the municipality or county in which application is made. The department shall furnish to local agencies responsible for issuing occupational licenses a current list of all establishments licensed pursuant

to this part.

(2) Notwithstanding subsection (6), a permitted person in good standing may change the type of permit issued to that person by completing a new application for the requested permit, paying the amount of the difference in the permit fees if the fee for the new permit is more than the fee for the original permit, and meeting the applicable permitting conditions for the new permit type. The new permit expires on the expiration date of the original permit being changed; however, a new permit for a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, or a retail pharmacy drug wholesale distributor shall expire on the expiration date of the original permit or 1 year after the date of issuance of the new permit, whichever is earlier. A refund may not be issued if the fee for the new permit is less than the fee that was paid for the original permit.

(3)(a) A written application for a permit or to renew a permit must be filed with the department on forms furnished by the department. The department shall establish, by rule, the form and content of the application to obtain or renew a permit. The applicant must submit to the department with the application a statement that swears or affirms that the information is true and correct.

(b) Upon a determination that 2 years have elapsed since the department notified an applicant for permit, certification, or product registration of a deficiency in the application and

that the applicant has failed to cure the deficiency, the application shall expire. The determination regarding the 2-year lapse of time shall be based on documentation that the department notified the applicant of the deficiency in accordance with s. 120.60.

(c) Information submitted by an applicant on an application required pursuant to this subsection which is a trade secret, as defined in s. 812.081, shall be maintained by the department as trade secret information pursuant to s. 499.051(7).

(4)(a) Except for a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor, an application for a permit must include:

1. The name, full business address, and telephone number of the applicant;

2. All trade or business names used by the applicant;

3. The address, telephone numbers, and the names of contact persons for each facility used by the applicant for the storage, handling, and distribution of prescription drugs;

4. The type of ownership or operation, such as a partnership, corporation, or sole proprietorship; and

5. The names of the owner and the operator of the establishment, including:

a. If an individual, the name of the individual;

b. If a partnership, the name of each partner and the name of the partnership;

c. If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation;

d. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;

e. If a limited liability company, the name of each member, the name of each manager, the name of the limited liability company, and the name of the state in which the limited liability company was organized; and

f. Any other relevant information that the department requires.

(b) Upon approval of the application by the department and payment of the required fee, the department shall issue a permit to the applicant, if the applicant meets the requirements of this part and rules adopted under this part.

(c) Any change in information required under paragraph (a) must be submitted to the department before the change occurs.

(d) The department shall consider, at a minimum, the following factors in reviewing the qualifications of persons to be permitted under this part:

1. The applicant's having been found guilty, regardless of adjudication, in a court of this state or other jurisdiction, of a violation of a law that directly relates to a drug, device, or cosmetic. A plea of nolo contendere constitutes a finding of guilt for purposes of this subparagraph.

2. The applicant's having been disciplined by a regulatory

agency in any state for any offense that would constitute a violation of this part.

3. Any felony conviction of the applicant under a federal, state, or local law;

4. The applicant's past experience in manufacturing or distributing drugs, devices, or cosmetics;

5. The furnishing by the applicant of false or fraudulent material in any application made in connection with manufacturing or distributing drugs, devices, or cosmetics;

6. Suspension or revocation by a federal, state, or local government of any permit currently or previously held by the applicant for the manufacture or distribution of any drugs, devices, or cosmetics;

7. Compliance with permitting requirements under any previously granted permits;

8. Compliance with requirements to maintain or make available to the state permitting authority or to federal, state, or local law enforcement officials those records required under this section; and

9. Any other factors or qualifications the department considers relevant to and consistent with the public health and safety.

(5) ~~Except for a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor:~~

(a) The department shall adopt rules for the biennial

renewal of permits; however, the department may issue up to a 4-year permit to selected permittees notwithstanding any other provision of law. Fees for such renewal may not exceed the fee caps set forth in s. 499.041 on an annualized basis as authorized by law.

(b) The department shall renew a permit upon receipt of the renewal application and renewal fee if the applicant meets the requirements established under this part and ~~the~~ rules adopted under this part.

(c) At least 90 days before the expiration date of a permit, the department shall forward a permit renewal notification to the permittee at the mailing address of the permitted establishment on file with the department. The permit renewal notification must state conspicuously the date on which the permit for the establishment will expire and that the establishment may not operate unless the permit for the establishment is renewed timely. ~~A permit, unless sooner suspended or revoked, automatically expires 2 years after the last day of the anniversary month in which the permit was originally issued.~~

(d) A permit issued under this part may be renewed by making application for renewal on forms furnished by the department and paying the appropriate fees.

1. If a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor renewal application and fee are submitted and postmarked later than 45

days before the expiration date of the permit, the permit may be renewed only upon payment of a late renewal fee of $100, plus the required renewal fee.

2. If any other ~~a~~ renewal application and fee are submitted and postmarked after the expiration date of the permit, the permit may be renewed only upon payment of a late renewal delinquent fee of $100, plus the required renewal fee, not later than 60 days after the expiration date.

3. A permittee who submits a renewal application in accordance with this paragraph may continue to operate under its permit, unless the permit is suspended or revoked, until final disposition of the renewal application.

4.~~(d)~~ Failure to renew a permit in accordance with this section precludes any future renewal of that permit. If a permit issued pursuant to this part has expired and cannot be renewed, before an establishment may engage in activities that require a permit under this part, the establishment must submit an application for a new permit, pay the applicable application fee, the initial permit fee, and all applicable penalties, and be issued a new permit by the department.

(6) A permit issued by the department is nontransferable. Each permit is valid only for the person or governmental unit to which it is issued and is not subject to sale, assignment, or other transfer, voluntarily or involuntarily; nor is a permit valid for any establishment other than the establishment for which it was originally issued.

(a) A person permitted under this part must notify the department before making a change of address. The department shall set a change of location fee not to exceed $100.

(b)1. An application for a new permit is required when a majority of the ownership or controlling interest of a permitted establishment is transferred or assigned or when a lessee agrees to undertake or provide services to the extent that legal liability for operation of the establishment will rest with the lessee. The application for the new permit must be made before the date of the sale, transfer, assignment, or lease.

2. A permittee that is authorized to distribute prescription drugs may transfer such drugs to the new owner or lessee under subparagraph 1. only after the new owner or lessee has been approved for a permit to distribute prescription drugs.

(c) If an establishment permitted under this part closes, the owner must notify the department in writing before the effective date of closure and must:

1. Return the permit to the department;

2. If the permittee is authorized to distribute prescription drugs, indicate the disposition of such drugs, including the name, address, and inventory, and provide the name and address of a person to contact regarding access to records that are required to be maintained under this part. Transfer of ownership of prescription drugs may be made only to persons authorized to possess prescription drugs under this part.

The department may revoke the permit of any person that fails to comply with the requirements of this subsection.

(7) A permit must be posted in a conspicuous place on the licensed premises.

(8) An application for a permit or to renew a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor submitted to the department must include:

(a) The name, full business address, and telephone number of the applicant.

(b) All trade or business names used by the applicant.

(c) The address, telephone numbers, and the names of contact persons for each facility used by the applicant for the storage, handling, and distribution of prescription drugs.

(d) The type of ownership or operation, such as a partnership, corporation, or sole proprietorship.

(e) The names of the owner and the operator of the establishment, including:

1. If an individual, the name of the individual.

2. If a partnership, the name of each partner and the name of the partnership.

3. If a corporation:

a. The name, address, and title of each corporate officer and director.

b. The name and address of the corporation, resident agent of the corporation, the resident agent's address, and the

corporation's state of incorporation.

c. The name and address of each shareholder of the corporation that owns 5 percent or more of the outstanding stock of the corporation.

4. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

5. If a limited liability company:

a. The name and address of each member.

b. The name and address of each manager.

c. The name and address of the limited liability company, the resident agent of the limited liability company, and the name of the state in which the limited liability company was organized.

(f) If applicable, the name and address of each affiliate of ~~member of the affiliated group of which~~ the applicant ~~is a member~~.

(g)~~1.~~ The applicant's gross annual receipts attributable to prescription drug wholesale distribution activities for the previous tax year. ~~For an application for a new permit, the estimated annual dollar volume of prescription drug sales of the applicant, the estimated annual percentage of the applicant's total company sales that are prescription drugs, the applicant's estimated annual total dollar volume of purchases of prescription drugs, and the applicant's estimated annual total dollar volume of prescription drug purchases directly from manufacturers.~~

~~2. For an application to renew a permit, the total dollar volume of prescription drug sales in the previous year, the total dollar volume of prescription drug sales made in the previous 6 months, the percentage of total company sales that were prescription drugs in the previous year, the total dollar volume of purchases of prescription drugs in the previous year, and the total dollar volume of prescription drug purchases directly from manufacturers in the previous year.~~

~~Such portions of the information required pursuant to this paragraph which are a trade secret, as defined in s. 812.081, shall be maintained by the department as trade secret information is required to be maintained under s. 499.051.~~

(h) The tax year of the applicant.

(i) A copy of the deed for the property on which applicant's establishment is located, if the establishment is owned by the applicant, or a copy of the applicant's lease for the property on which applicant's establishment is located that has an original term of not less than 1 calendar year, if the establishment is not owned by the applicant.

(j) A list of all licenses and permits issued to the applicant by any other state which authorize the applicant to purchase or possess prescription drugs.

(k) The name of the manager of the establishment that is applying for the permit or to renew the permit, the next four highest ranking employees responsible for prescription drug

wholesale operations for the establishment, and the name of all affiliated parties for the establishment, together with the personal information statement and fingerprints required pursuant to subsection (9) for each of such persons.

(l) The name of each of the applicant's designated representatives as required by subsection (15) ~~(16)~~, together with the personal information statement and fingerprints required pursuant to subsection (9) for each such person.

(m) Evidence of a surety bond in this state or any other state in the United States in the amount of $100,000. If the annual gross receipts of the applicant's previous tax year is $10 million or less, evidence of a surety bond in the amount of $25,000. The specific language of the surety bond must include the State of Florida as a beneficiary, payable to the Professional Regulation Trust Fund. In lieu of the surety bond, the applicant may provide other equivalent security, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, that includes the State of Florida as a beneficiary, payable to the Professional Regulation Trust Fund. The purpose of the bond or other security 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. ~~For an applicant that is a secondary wholesale distributor, each of the following:~~

~~1. A personal background information statement containing the background information and fingerprints required pursuant to subsection (9) for each person named in the applicant's response to paragraphs (k) and (l) and for each affiliated party of the applicant.~~

~~2. If any of the five largest shareholders of the corporation seeking the permit is a corporation, the name, address, and title of each corporate officer and director of each such corporation; the name and address of such corporation; the name of such corporation's resident agent, such corporation's resident agent's address, and such corporation's state of its incorporation; and the name and address of each shareholder of such corporation that owns 5 percent or more of the stock of such corporation.~~

~~3. The name and address of all financial institutions in which the applicant has an account which is used to pay for the operation of the establishment or to pay for drugs purchased for the establishment, together with the names of all persons that are authorized signatories on such accounts. The portions of the information required pursuant to this subparagraph which are a trade secret, as defined in s. 812.081, shall be maintained by~~

~~the department as trade secret information is required to be maintained under s. 499.051.~~

~~4. The sources of all funds and the amounts of such funds used to purchase or finance purchases of prescription drugs or to finance the premises on which the establishment is to be located.~~

~~5. If any of the funds identified in subparagraph 4. were borrowed, copies of all promissory notes or loans used to obtain such funds.~~

(n) For establishments used in wholesale distribution, proof of an inspection conducted by the department, the United States Food and Drug Administration, or another governmental entity charged with the regulation of good manufacturing practices related to wholesale distribution of prescription drugs, within timeframes set forth by the department in departmental rules, which demonstrates substantial compliance with current good manufacturing practices applicable to wholesale distribution of prescription drugs. The department may recognize another state's inspection of a wholesale distributor located in that state if such state's laws are deemed to be substantially equivalent to the law of this state by the department. The department may accept an inspection by a third-party accreditation or inspection service which meets the criteria set forth in department rule.

(o) ~~(n)~~ Any other relevant information that the department requires~~, including, but not limited to, any information related~~

~~to whether the applicant satisfies the definition of a primary wholesale distributor or a secondary wholesale distributor~~.

(p) ~~(o)~~ Documentation of the credentialing policies and procedures required by s. 499.0121(15).

(9)(a) Each person required by subsection (8) or subsection (15) to provide a personal information statement and fingerprints shall provide the following information to the department on forms prescribed by the department:

1. The person's places of residence for the past 7 years.

2. The person's date and place of birth.

3. The person's occupations, positions of employment, and offices held during the past 7 years.

4. The principal business and address of any business, corporation, or other organization in which each such office of the person was held or in which each such occupation or position of employment was carried on.

5. Whether the person has been, during the past 7 years, the subject of any proceeding for the revocation of any license and, if so, the nature of the proceeding and the disposition of the proceeding.

6. Whether, during the past 7 years, the person has been enjoined, temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs, together with details concerning any such event.

7. A description of any involvement by the person with any

business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past 4 ~~7~~ years, which manufactured, administered, prescribed, distributed, or stored pharmaceutical products and any lawsuits in which such businesses were named as a party.

8. A description of any felony criminal offense of which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendere. A criminal offense committed in another jurisdiction which would have been a felony in this state must be reported. If the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of that criminal offense, the applicant must, within 15 days after the disposition of the appeal, submit to the department a copy of the final written order of disposition.

9. A photograph of the person taken in the previous 180 ~~30~~ days.

10. A set of fingerprints for the person on a form and under procedures specified by the department, together with payment of an amount equal to the costs incurred by the department for the criminal record check of the person.

11. The name, address, occupation, and date and place of birth for each member of the person's immediate family who is 18 years of age or older. As used in this subparagraph, the term "member of the person's immediate family" includes the person's spouse, children, parents, siblings, the spouses of the person's

children, and the spouses of the person's siblings.

12. Any other relevant information that the department requires.

(b) The information required pursuant to paragraph (a) shall be provided under oath.

(c) The department shall submit the fingerprints provided by a person for initial licensure to the Department of Law Enforcement for a statewide criminal record check and for forwarding to the Federal Bureau of Investigation for a national criminal record check of the person. The department shall submit the fingerprints provided by a person as a part of a renewal application to the Department of Law Enforcement for a statewide criminal record check, and for forwarding to the Federal Bureau of Investigation for a national criminal record check, for the initial renewal of a permit after January 1, 2004; for any subsequent renewal of a permit, the department shall submit the required information for a statewide and national criminal record check of the person. Any person who as a part of an initial permit application or initial permit renewal after January 1, 2004, submits to the department a set of fingerprints required for the criminal record check required in this paragraph are ~~shall~~ not ~~be~~ required to provide a subsequent set of fingerprints for a criminal record check to the department, if the person has undergone a criminal record check as a condition of the issuance of an initial permit or the initial renewal of a permit of an applicant after January 1, 2004. The

department is authorized to contract with private vendors, or enter into interagency agreements, to collect electronic fingerprints where fingerprints are required for registration, certification, or the licensure process or where criminal history record checks are required.

(d) For purposes of applying for renewal of a permit under subsection (8) or certification under subsection (16), a person may submit the following in lieu of satisfying the requirements of paragraphs (a), (b), and (c):

1. A photograph of the individual taken within 180 days; and

2. A copy of the personal information statement form most recently submitted to the department and a certification under oath, on a form specified by the department, that the individual has reviewed the previously submitted personal information statement form and that the information contained therein remains unchanged.

(10) The department may deny an application for a permit or refuse to renew a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor if:

(a) The applicant has not met the requirements for the permit.

(b) The management, officers, or directors of the applicant or any affiliated party are found by the department to be incompetent or untrustworthy.

(c) The applicant is so lacking in experience in managing a wholesale distributor as to make the issuance of the proposed permit hazardous to the public health.

(d) The applicant is so lacking in experience in managing a wholesale distributor as to jeopardize the reasonable promise of successful operation of the wholesale distributor.

(e) The applicant is lacking in experience in the distribution of prescription drugs.

(f) The applicant's past experience in manufacturing or distributing prescription drugs indicates that the applicant poses a public health risk.

(g) The applicant is affiliated directly or indirectly through ownership, control, or other business relations, with any person or persons whose business operations are or have been detrimental to the public health.

(h) The applicant, or any affiliated party, has been found guilty of or has pleaded guilty or nolo contendere to any felony or crime punishable by imprisonment for 1 year or more under the laws of the United States, any state, or any other country, regardless of whether adjudication of guilt was withheld.

(i) The applicant or any affiliated party has been charged with a felony in a state or federal court and the disposition of that charge is pending during the application review or renewal review period.

(j) The applicant has furnished false or fraudulent information or material in any application made in this state or

any other state in connection with obtaining a permit or license to manufacture or distribute drugs, devices, or cosmetics.

(k) That a federal, state, or local government permit currently or previously held by the applicant, or any affiliated party, for the manufacture or distribution of any drugs, devices, or cosmetics has been disciplined, suspended, or revoked and has not been reinstated.

(l) The applicant does not possess the financial or physical resources to operate in compliance with the permit being sought, this chapter, and the rules adopted under this chapter.

(m) The applicant or any affiliated party receives, directly or indirectly, financial support and assistance from a person who was an affiliated party of a permittee whose permit was subject to discipline or was suspended or revoked, other than through the ownership of stock in a publicly traded company or a mutual fund.

(n) The applicant or any affiliated party receives, directly or indirectly, financial support and assistance from a person who has been found guilty of any violation of this part or chapter 465, chapter 501, or chapter 893, any rules adopted under this part or those chapters, any federal or state drug law, or any felony where the underlying facts related to drugs, regardless of whether the person has been pardoned, had her or his civil rights restored, or had adjudication withheld, other than through the ownership of stock in a publicly traded company

or a mutual fund.

(o) The applicant for renewal of a permit under s. 499.01(2)(e) or (f) ~~499.01(2)(d) or (e)~~ has not actively engaged in the wholesale distribution of prescription drugs, as demonstrated by the regular and systematic distribution of prescription drugs throughout the year as evidenced by not fewer than 12 wholesale distributions in the previous year and not fewer than three wholesale distributions in the previous 6 months.

(p) Information obtained in response to s. 499.01(2)(e) or (f) ~~499.01(2)(d) or (e)~~ demonstrates it would not be in the best interest of the public health, safety, and welfare to issue a permit.

(q) The applicant does not possess the financial standing and business experience for the successful operation of the applicant.

(r) The applicant or any affiliated party has failed to comply with the requirements for manufacturing or distributing prescription drugs under this part, similar federal laws, similar laws in other states, or the rules adopted under such laws.

(11) Upon approval of the application by the department and payment of the required fee, the department shall issue or renew a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor permit to the applicant.

~~(12) For a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor:~~

~~(a) The department shall adopt rules for the annual renewal of permits. At least 90 days before the expiration of a permit, the department shall forward a permit renewal notification and renewal application to the prescription drug wholesale distributor or out-of-state prescription drug wholesale distributor at the mailing address of the permitted establishment on file with the department. The permit renewal notification must state conspicuously the date on which the permit for the establishment will expire and that the establishment may not operate unless the permit for the establishment is renewed timely.~~

~~(b) A permit, unless sooner suspended or revoked, automatically expires 1 year after the last day of the anniversary month in which the permit was originally issued. A permit may be renewed by making application for renewal on forms furnished by the department and paying the appropriate fees. If a renewal application and fee are submitted and postmarked after 45 days prior to the expiration date of the permit, the permit may be renewed only upon payment of a late renewal fee of $100, plus the required renewal fee. A permittee that has submitted a renewal application in accordance with this paragraph may continue to operate under its permit, unless the permit is suspended or revoked, until final disposition of the renewal~~

~~application.~~

~~(c) Failure to renew a permit in accordance with this section precludes any future renewal of that permit. If a permit issued pursuant to this section has expired and cannot be renewed, before an establishment may engage in activities that require a permit under this part, the establishment must submit an application for a new permit; pay the applicable application fee, initial permit fee, and all applicable penalties; and be issued a new permit by the department.~~

(12) ~~(13)~~ A person that engages in wholesale distribution of prescription drugs in this state must have a wholesale distributor's permit issued by the department, except as noted in this section. Each establishment must be separately permitted except as noted in this subsection.

(a) A separate establishment permit is not required when a permitted prescription drug wholesale distributor consigns a prescription drug to a pharmacy that is permitted under chapter 465 and located in this state, provided that:

1. The consignor wholesale distributor notifies the department in writing of the contract to consign prescription drugs to a pharmacy along with the identity and location of each consignee pharmacy;

2. The pharmacy maintains its permit under chapter 465;

3. The consignor wholesale distributor, which has no legal authority to dispense prescription drugs, complies with all wholesale distribution requirements of s. ~~ss.~~ 499.0121 ~~and~~

~~499.01212~~ with respect to the consigned drugs and maintains records documenting the transfer of title or other completion of the wholesale distribution of the consigned prescription drugs;

4. The distribution of the prescription drug is otherwise lawful under this chapter and other applicable law;

5. Open packages containing prescription drugs within a pharmacy are the responsibility of the pharmacy, regardless of how the drugs are titled; and

6. The pharmacy dispenses the consigned prescription drug in accordance with the limitations of its permit under chapter 465 or returns the consigned prescription drug to the consignor wholesale distributor. In addition, a person who holds title to prescription drugs may transfer the drugs to a person permitted or licensed to handle the reverse distribution or destruction of drugs. Any other distribution by and means of the consigned prescription drug by any person, not limited to the consignor wholesale distributor or consignee pharmacy, to any other person is prohibited.

(b) A wholesale distributor's permit is not required for the one-time transfer of title of a pharmacy's lawfully acquired prescription drug inventory by a pharmacy with a valid permit issued under chapter 465 to a consignor prescription drug wholesale distributor, permitted under this chapter, in accordance with a written consignment agreement between the pharmacy and that wholesale distributor if the permitted pharmacy and the permitted prescription drug wholesale

distributor comply with all of the provisions of paragraph (a) and the prescription drugs continue to be within the permitted pharmacy's inventory for dispensing in accordance with the limitations of the pharmacy permit under chapter 465. A consignor drug wholesale distributor may not use the pharmacy as a wholesale distributor through which it distributes the prescription drugs to other pharmacies. Nothing in this section is intended to prevent a wholesale distributor from obtaining this inventory in the event of nonpayment by the pharmacy.

(c) A separate establishment permit is not required when a permitted prescription drug wholesale distributor operates temporary transit storage facilities for the sole purpose of storage, for up to 16 hours, of a delivery of prescription drugs when the wholesale distributor was temporarily unable to complete the delivery to the recipient.

(d) The department shall require information from each wholesale distributor as part of the permit and renewal of such permit, as required under this section.

(13) ~~(14)~~ Personnel employed in wholesale distribution must have appropriate education and experience to enable them to perform their duties in compliance with state permitting requirements.

(14) ~~(15)~~ The name of a permittee or establishment on a prescription drug wholesale distributor permit or an out-of-state prescription drug wholesale distributor permit may not include any indicia of attainment of any educational degree, any

indicia that the permittee or establishment possesses a professional license, or any name or abbreviation that the department determines is likely to cause confusion or mistake or that the department determines is deceptive, including that of any other entity authorized to purchase prescription drugs.

(15) ~~(16)~~ (a) Each establishment that is issued an initial or renewal permit as a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor must designate in writing to the department at least one natural person to serve as the designated representative of the wholesale distributor. Such person must have an active certification as a designated representative from the department.

(b) To be certified as a designated representative, a natural person must:

1. Submit an application on a form furnished by the department and pay the appropriate fees.

2. Be at least 18 years of age.

3. Have at least 2 years of verifiable full-time:

a. Work experience in a pharmacy licensed in this state or another state, where the person's responsibilities included, but were not limited to, recordkeeping for prescription drugs;

b. Managerial experience with a prescription drug wholesale distributor licensed in this state or in another state; or

c. Managerial experience with the United States Armed

Forces, where the person's responsibilities included, but were not limited to, recordkeeping, warehousing, distributing, or other logistics services pertaining to prescription drugs.

4. Receive a passing score of at least 75 percent on an examination given by the department regarding federal laws governing distribution of prescription drugs and this part and the rules adopted by the department governing the wholesale distribution of prescription drugs. This requirement shall be effective 1 year after the results of the initial examination are mailed to the persons that took the examination. The department shall offer such examinations at least four times each calendar year.

5. Provide the department with a personal information statement and fingerprints pursuant to subsection (9).

(c) The department may deny an application for certification as a designated representative or may suspend or revoke a certification of a designated representative pursuant to s. 499.067.

(d) A designated representative:

1. Must be actively involved in and aware of the actual daily operation of the wholesale distributor.

2. Must be employed full time in a managerial position by the wholesale distributor.

3. Must be physically present at the establishment during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation, or

other authorized absence.

4. May serve as a designated representative for only one wholesale distributor at any one time.

(e) A wholesale distributor must notify the department when a designated representative leaves the employ of the wholesale distributor. Such notice must be provided to the department within 10 business days after the last day of designated representative's employment with the wholesale distributor.

(f) A wholesale distributor may not operate under a prescription drug wholesale distributor permit or an out-of-state prescription drug wholesale distributor permit for more than 10 business days after the designated representative leaves the employ of the wholesale distributor, unless the wholesale distributor employs another designated representative and notifies the department within 10 business days of the identity of the new designated representative.

Section 7. Section 499.01201, Florida Statutes, is amended to read:

499.01201 Agency for Health Care Administration review and use of statute and rule violation or compliance data.—Notwithstanding any other provision ~~provisions~~ of law ~~to the contrary~~, the Agency for Health Care Administration may not:

(1) Review or use any violation or alleged violation of s. 499.0121(6) ~~or s. 499.01212~~, or any rules adopted under that section ~~those sections~~, as a ground for denying or withholding

any payment of a Medicaid reimbursement to a pharmacy licensed under chapter 465; or

(2) Review or use compliance with s. 499.0121(6) ~~or s. 499.01212~~, or any rules adopted under that section ~~those sections~~, as the subject of any audit of Medicaid-related records held by a pharmacy licensed under chapter 465.

Section 8. Paragraph (d) of subsection (4) and 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(37).~~

(6) RECORDKEEPING.—The department shall adopt rules that require keeping such records of prescription drugs, including active pharmaceutical ingredients, as are necessary for the

protection of the public health.

(a) ~~Wholesale~~ Distributors of prescription drugs and active pharmaceutical ingredients must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs and active pharmaceutical ingredients. These records must provide a complete audit trail from receipt to sale or other disposition, be readily retrievable for inspection, and include, at a minimum, the following information:

1. The source of the prescription drugs or active pharmaceutical ingredients, including the name and principal address of the seller or transferor, and the address of the location from which the prescription drugs were shipped;

2. The name, principal address, and state license permit or registration number of the person authorized to purchase prescription drugs or active pharmaceutical ingredients;

3. The name, strength, dosage form, and quantity of the prescription drugs received and distributed or disposed of;

4. The dates of receipt and distribution or other disposition of the prescription drugs or active pharmaceutical ingredients; and

5. Any financial documentation supporting the transaction.

(b) Inventories and records must be made available for inspection and photocopying by authorized federal, state, or local officials for a period of 2 years following disposition of the drugs or 3 years after the creation of the records,

whichever period is longer.

(c) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means must be readily available for authorized inspection during the retention period. Records that are kept at a central location outside of this state and that are not electronically retrievable must be made available for inspection within 2 working days after a request by an authorized official of a federal, state, or local law enforcement agency. Records that are maintained at a central location within this state must be maintained at an establishment that is permitted pursuant to this part and must be readily available.

(d) Each manufacturer or repackager of medical devices, over-the-counter drugs, or cosmetics must maintain records that include the name and principal address of the seller or transferor of the product, the address of the location from which the product was shipped, the date of the transaction, the name and quantity of the product involved, and the name and principal address of the person who purchased the product.

~~(e) When pedigree papers are required by this part, a wholesale distributor must maintain the pedigree papers separate and distinct from other records required under this part.~~

Section 9. Subsections (1), (3), (4), and (6) of section 499.015, Florida Statutes, are amended to read:

499.015 Registration of drugs, devices, and cosmetics;

issuance of certificates of free sale.—

(1)(a) Except for those persons exempted from the definition of manufacturer in s. 499.003, any person who manufactures, packages, repackages, labels, or relabels a drug or a~~,~~ device~~, or cosmetic~~ in this state must register such drug or~~,~~ device~~, or cosmetic~~ biennially with the department; pay a fee in accordance with the fee schedule provided by s. 499.041; and comply with this section. The registrant must list each separate and distinct drug or~~,~~ device~~, or cosmetic~~ at the time of registration.

(b) Any person who manufactures, packages, repackages, labels, or relabels a cosmetic in this state may voluntarily register such cosmetic biennially with the department. A person registering a cosmetic must submit a completed application to register the cosmetic, pay a fee in accordance with the fee schedule provided by s. 499.041, comply with the provisions of this section, and must list each separate and distinct cosmetic at the time of registration.

(c)~~(b)~~ The department may not register any product that does not comply with the Federal Food, Drug, and Cosmetic Act, as amended, or Title 21 C.F.R. Registration of a product by the department does not mean that the product does in fact comply with all provisions of the Federal Food, Drug, and Cosmetic Act, as amended.

(d) A person may not register a product with the department if that person is not legally authorized to

manufacture, package, repackage, label, or relabel the product in this state.

(3) Except for those persons exempted from the definition of manufacturer in s. 499.003, a person may not sell any product that he or she has failed to register in conformity with this section. Such failure to register subjects such drug or~~,~~ device~~, or cosmetic product~~ to seizure and condemnation as provided in s. 499.062, and subjects such person to the penalties and remedies provided in this part.

(4) Unless a registration is renewed, it expires 2 years after the last day of the month in which it was issued. Any product registration issued or renewed on or after July 1, 2016, shall expire on the same date as the manufacturer or repackager permit of the person seeking to register the product. If the first product registration issued to a person on or after July 1, 2016, expires less than 366 days after issuance, the fee for product registration shall be $15. If the first product registration issued to a person on or after July 1, 2016, expires more than 365 days after issuance, the fee for product registration shall be $30. The department may issue a stop-sale notice or order against a person that is subject to the requirements of this section and that fails to comply with this section within 31 days after the date the registration expires. The notice or order shall prohibit such person from selling or causing to be sold any drugs, devices, or cosmetics covered by this part until he or she complies with the requirements of this

section.

(6) The department may only issue a certificate of free sale for any product that is ~~required to be~~ registered under this part.

Section 10. 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) ~~499.003(33)~~, or prescription drug as defined in s. 499.003(40) ~~499.003(43)~~, 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 11. Paragraphs (i) through (p) of subsection (1) of section 499.05, Florida Statutes, are amended to read:

499.05 Rules.—

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

(i) Additional conditions that qualify as an emergency medical reason under s. 499.003(48)(b)2. ~~499.003(53)(b)2.~~ or s. 499.82.

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

(j)~~(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.

(k) ~~(l)~~ Information required from each retail establishment pursuant to s. 499.012(3) or s. 499.83(2)(c), including requirements for prescriptions or orders.

(l) ~~(m)~~ The recordkeeping, storage, and handling with respect to each of the distributions of prescription drugs specified in s. 499.003(48)(a)-(v) ~~499.003(53)(a)-(d)~~ or s. 499.82(14).

~~(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.~~

(m) ~~(o)~~ Wholesale distributor reporting requirements of s. 499.0121(14).

(n) ~~(p)~~ Wholesale distributor credentialing and distribution requirements of s. 499.0121(15).

Section 12. Subsection (7) of section 499.051, Florida Statutes, is amended to read:

499.051 Inspections and investigations.—

(7) The complaint and all information obtained pursuant to the investigation by the department are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution until the investigation and the enforcement action are completed. However, trade secret information contained therein as defined by s. 812.081(1)(c) shall remain confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I

of the State Constitution, as long as the information is retained by the department. This subsection does not prohibit the department from using such information for regulatory or enforcement proceedings under this chapter or from providing such information to any law enforcement agency or any other regulatory agency. However, the receiving agency shall keep such records confidential and exempt as provided in this subsection. ~~In addition, this subsection is not intended to prevent compliance with the provisions of s. 499.01212, and the pedigree papers required in that section shall not be deemed a trade secret.~~

Section 13. Subsection (8) is added to section 499.066, Florida Statutes, to read:

499.066 Penalties; remedies.—In addition to other penalties and other enforcement provisions:

(8)(a) The department shall adopt rules to permit the issuance of remedial, nondisciplinary citations. A citation shall be issued to the person alleged to have committed a violation and contain the person's name, address, and license number, if applicable, a brief factual statement, the sections of the law allegedly violated, and the monetary assessment and or other remedial measures imposed. The citation must clearly state that the person may choose, in lieu of accepting the citation, to have the department rescind the citation and conduct an investigation pursuant to s. 499.051. If the person does not dispute the matter in the citation with the department

within 30 days after the citation is served, the citation becomes a final order and does not constitute discipline.

(b) The department shall adopt rules designating violations for which a citation may be issued. The rules shall designate as citable those violations for which there is no substantial threat to the public health, safety, or welfare.

(c) The department is entitled to recover the costs of investigation, in addition to any penalty provided according to department rule, as part of the penalty levied pursuant to the citation.

(d) A citation must be issued within 12 months after the filing of the complaint that is the basis for the citation.

(e) Service of a citation may be made by personal service or certified mail, restricted delivery, to the person at the person's last known address of record with the department or to the person's Florida registered agent.

(f) The department has authority to, and shall adopt rules to, designate those violations for which a person is subject to the issuance of a citation and designate the monetary assessments and or other remedial measures that must be taken for those violations. The department has continuous authority to amend its rules adopted pursuant to this section.

Section 14. Subsection (14) of section 499.82, Florida Statutes, is amended to read:

499.82 Definitions.—As used in this part, the term:

(14) "Wholesale distribution" means the distribution of

medical gas to a person other than a consumer or patient. Wholesale distribution of medical gases does not include:

(a) The sale, purchase, or trade of a medical gas; an offer to sell, purchase, or trade a medical gas; or the dispensing of a medical gas pursuant to a prescription;

(b) Activities exempt from the definition of wholesale distribution in s. 499.003; or

(c) The sale, purchase, or trade of a medical gas or an offer to sell, purchase, or trade a medical gas for emergency medical reasons~~; or~~

~~(d) Other transactions excluded from the definition of wholesale distribution under the federal act or regulations implemented under the federal act related to medical gas~~.

Section 15. Subsection (4) of section 499.89, Florida Statutes, is amended to read:

499.89 Recordkeeping.—

~~(4) A pedigree paper is not required for distributing or dispensing medical gas.~~

Section 16. Section 499.01212, Florida Statutes, is repealed.

Section 17. 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 in, or described in s. 503(b) of the Federal Food, Drug, and Cosmetic Act or in s. 465.003(8), s. 499.003(47) ~~499.003(52)~~, s. 499.007(13), or s. 499.82(10).

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 18. 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(40) ~~499.003(43)~~, for the purpose of treating erectile dysfunction if the person is designated as a sexual predator under s. 775.21.

Section 19. Paragraphs (d) and (f) of subsection (3) of section 921.0022, Florida Statutes, are amended to read:

921.0022 Criminal Punishment Code; offense severity ranking chart.—

(3) OFFENSE SEVERITY RANKING CHART

(d) LEVEL 4

Florida Statute	Felony Degree	Description

316.1935(3)(a)	2nd	Driving at high speed or with wanton disregard for safety while fleeing or attempting to elude law enforcement officer who is in a patrol vehicle with siren and lights activated.
499.0051(1)	3rd	Failure to maintain or deliver transaction history, transaction information, or transaction statements ~~pedigree papers~~.
~~499.0051(2)~~	~~3rd~~	~~Failure to authenticate pedigree papers.~~
499.0051(5) ~~499.0051(6)~~	2nd	Knowing sale or delivery, or possession with intent to sell, contraband prescription drugs.
517.07(1)	3rd	Failure to register securities.
517.12(1)	3rd	Failure of dealer, associated person, or issuer of securities to register.

784.07(2)(b)	3rd	Battery of law enforcement officer, firefighter, etc.
784.074(1)(c)	3rd	Battery of sexually violent predators facility staff.
784.075	3rd	Battery on detention or commitment facility staff.
784.078	3rd	Battery of facility employee by throwing, tossing, or expelling certain fluids or materials.
784.08(2)(c)	3rd	Battery on a person 65 years of age or older.
784.081(3)	3rd	Battery on specified official or employee.
784.082(3)	3rd	Battery by detained person on visitor or other detainee.
784.083(3)	3rd	Battery on code inspector.
784.085	3rd	Battery of child by throwing, tossing, projecting, or

			expelling certain fluids or materials.
2613			
	787.03(1)	3rd	Interference with custody; wrongly takes minor from appointed guardian.
2614			
	787.04(2)	3rd	Take, entice, or remove child beyond state limits with criminal intent pending custody proceedings.
2615			
	787.04(3)	3rd	Carrying child beyond state lines with criminal intent to avoid producing child at custody hearing or delivering to designated person.
2616			
	787.07	3rd	Human smuggling.
2617			
	790.115(1)	3rd	Exhibiting firearm or weapon within 1,000 feet of a school.
2618			
	790.115(2)(b)	3rd	Possessing electric weapon or device, destructive device, or other weapon on school

		property.
790.115(2)(c)	3rd	Possessing firearm on school property.
800.04(7)(c)	3rd	Lewd or lascivious exhibition; offender less than 18 years.
810.02(4)(a)	3rd	Burglary, or attempted burglary, of an unoccupied structure; unarmed; no assault or battery.
810.02(4)(b)	3rd	Burglary, or attempted burglary, of an unoccupied conveyance; unarmed; no assault or battery.
810.06	3rd	Burglary; possession of tools.
810.08(2)(c)	3rd	Trespass on property, armed with firearm or dangerous weapon.
812.014(2)(c)3.	3rd	Grand theft, 3rd degree $10,000 or more but less than $20,000.

812.014 (2)(c)4.-10.	3rd	Grand theft, 3rd degree, a will, firearm, motor vehicle, livestock, etc.
812.0195(2)	3rd	Dealing in stolen property by use of the Internet; property stolen $300 or more.
817.563(1)	3rd	Sell or deliver substance other than controlled substance agreed upon, excluding s. 893.03(5) drugs.
817.568(2)(a)	3rd	Fraudulent use of personal identification information.
817.625(2)(a)	3rd	Fraudulent use of scanning device or reencoder.
828.125(1)	2nd	Kill, maim, or cause great bodily harm or permanent breeding disability to any registered horse or cattle.
837.02(1)	3rd	Perjury in official

		proceedings.
837.021(1)	3rd	Make contradictory statements in official proceedings.
838.022	3rd	Official misconduct.
839.13(2)(a)	3rd	Falsifying records of an individual in the care and custody of a state agency.
839.13(2)(c)	3rd	Falsifying records of the Department of Children and Families.
843.021	3rd	Possession of a concealed handcuff key by a person in custody.
843.025	3rd	Deprive law enforcement, correctional, or correctional probation officer of means of protection or communication.
843.15(1)(a)	3rd	Failure to appear while on bail for felony (bond estreature or

		bond jumping).
847.0135(5)(c)	3rd	Lewd or lascivious exhibition using computer; offender less than 18 years.
874.05(1)(a)	3rd	Encouraging or recruiting another to join a criminal gang.
893.13(2)(a)1.	2nd	Purchase of cocaine (or other s. 893.03(1)(a), (b), or (d), (2)(a), (2)(b), or (2)(c)4. drugs).
914.14(2)	3rd	Witnesses accepting bribes.
914.22(1)	3rd	Force, threaten, etc., witness, victim, or informant.
914.23(2)	3rd	Retaliation against a witness, victim, or informant, no bodily injury.
918.12	3rd	Tampering with jurors.

Florida Statute	Felony Degree	Description
934.215	3rd	Use of two-way communications device to facilitate commission of a crime.

(f) LEVEL 6

Florida Statute	Felony Degree	Description
316.027(2)(b)	2nd	Leaving the scene of a crash involving serious bodily injury.
316.193(2)(b)	3rd	Felony DUI, 4th or subsequent conviction.
400.9935(4)(c)	2nd	Operating a clinic, or offering services requiring licensure, without a license.
499.0051(2) ~~499.0051(3)~~	2nd	Knowing forgery of transaction history, transaction information, or transaction statement ~~pedigree papers~~.
499.0051(3)	2nd	Knowing purchase or receipt of

~~499.0051(4)~~		prescription drug from unauthorized person.
499.0051(4) ~~499.0051(5)~~	2nd	Knowing sale or transfer of prescription drug to unauthorized person.
775.0875(1)	3rd	Taking firearm from law enforcement officer.
784.021(1)(a)	3rd	Aggravated assault; deadly weapon without intent to kill.
784.021(1)(b)	3rd	Aggravated assault; intent to commit felony.
784.041	3rd	Felony battery; domestic battery by strangulation.
784.048(3)	3rd	Aggravated stalking; credible threat.
784.048(5)	3rd	Aggravated stalking of person under 16.
784.07(2)(c)	2nd	Aggravated assault on law

		enforcement officer.
784.074(1)(b)	2nd	Aggravated assault on sexually violent predators facility staff.
784.08(2)(b)	2nd	Aggravated assault on a person 65 years of age or older.
784.081(2)	2nd	Aggravated assault on specified official or employee.
784.082(2)	2nd	Aggravated assault by detained person on visitor or other detainee.
784.083(2)	2nd	Aggravated assault on code inspector.
787.02(2)	3rd	False imprisonment; restraining with purpose other than those in s. 787.01.
790.115(2)(d)	2nd	Discharging firearm or weapon on school property.

790.161(2)	2nd	Make, possess, or throw destructive device with intent to do bodily harm or damage property.
790.164(1)	2nd	False report of deadly explosive, weapon of mass destruction, or act of arson or violence to state property.
790.19	2nd	Shooting or throwing deadly missiles into dwellings, vessels, or vehicles.
794.011(8)(a)	3rd	Solicitation of minor to participate in sexual activity by custodial adult.
794.05(1)	2nd	Unlawful sexual activity with specified minor.
800.04(5)(d)	3rd	Lewd or lascivious molestation; victim 12 years of age or older but less than 16 years of age; offender less than 18 years.

800.04(6)(b)	2nd	Lewd or lascivious conduct; offender 18 years of age or older.
806.031(2)	2nd	Arson resulting in great bodily harm to firefighter or any other person.
810.02(3)(c)	2nd	Burglary of occupied structure; unarmed; no assault or battery.
810.145(8)(b)	2nd	Video voyeurism; certain minor victims; 2nd or subsequent offense.
812.014(2)(b)1.	2nd	Property stolen $20,000 or more, but less than $100,000, grand theft in 2nd degree.
812.014(6)	2nd	Theft; property stolen $3,000 or more; coordination of others.
812.015(9)(a)	2nd	Retail theft; property stolen $300 or more; second or subsequent conviction.

812.015(9)(b)	2nd	Retail theft; property stolen $3,000 or more; coordination of others.
812.13(2)(c)	2nd	Robbery, no firearm or other weapon (strong-arm robbery).
817.4821(5)	2nd	Possess cloning paraphernalia with intent to create cloned cellular telephones.
825.102(1)	3rd	Abuse of an elderly person or disabled adult.
825.102(3)(c)	3rd	Neglect of an elderly person or disabled adult.
825.1025(3)	3rd	Lewd or lascivious molestation of an elderly person or disabled adult.
825.103(3)(c)	3rd	Exploiting an elderly person or disabled adult and property is valued at less than $10,000.

827.03(2)(c)	3rd	Abuse of a child.
827.03(2)(d)	3rd	Neglect of a child.
827.071(2) & (3)	2nd	Use or induce a child in a sexual performance, or promote or direct such performance.
836.05	2nd	Threats; extortion.
836.10	2nd	Written threats to kill or do bodily injury.
843.12	3rd	Aids or assists person to escape.
847.011	3rd	Distributing, offering to distribute, or possessing with intent to distribute obscene materials depicting minors.
847.012	3rd	Knowingly using a minor in the production of materials harmful to minors.
847.0135(2)	3rd	Facilitates sexual conduct of

			or with a minor or the visual depiction of such conduct.
2700			
	914.23	2nd	Retaliation against a witness, victim, or informant, with bodily injury.
2701			
	944.35(3)(a)2.	3rd	Committing malicious battery upon or inflicting cruel or inhuman treatment on an inmate or offender on community supervision, resulting in great bodily harm.
2702			
	944.40	2nd	Escapes.
2703			
	944.46	3rd	Harboring, concealing, aiding escaped prisoners.
2704			
	944.47(1)(a)5.	2nd	Introduction of contraband (firearm, weapon, or explosive) into correctional facility.
2705			
	951.22(1)	3rd	Intoxicating drug, firearm, or weapon introduced into county facility.

Section 20. This act shall take effect July 1, 2016.