A bill to be entitled

An act relating to drugs, devices, and cosmetics; amending s. 499.002, F.S.; amending s. 499.003, F.S.; amending s. 499.005, F.S.; amending s. 499.0051, F.S.; amending s. 499.0054, F.S.; amending s. 499.006, F.S.; amending s. 499.007, F.S.; amending s. 499.008, F.S.; amending s. 499.009, F.S.; amending s. 499.01, F.S.; amending s. 499.012, F.S.; amending s. 499.01201, F.S.; amending s. 499.0121, F.S.; creating s. 499.012111, F.S.; repealing s. 499.0122, F.S.; repealing s. 499.013, F.S.; amending s. 499.014, F.S.; amending s. 499.015, F.S.; amending s. 499.023, F.S.; amending s. 499.024, F.S.; amending s. 499.025, F.S.; amending s. 499.028, F.S.; amending s. 499.029, F.S.; amending s. 499.03, F.S.; amending s. 499.032, F.S.; amending s. 499.033, F.S.; amending s. 499.035, F.S.; amending s. 499.039, F.S.; amending s. 499.04, F.S.; amending s. 499.041, F.S.; amending s. 499.05, F.S.; amending s. 499.051, F.S.; amending s. 499.052, F.S.; amending s. 499.055, F.S.; amending s. 499.057, F.S.; amending s. 499.06, F.S.; amending s. 499.062, F.S.; amending s. 499.065, F.S.; amending s. 499.066, F.S.; amending s. 499.0661, F.S.; amending s. 499.067, F.S.; providing an effective date.

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

Section 1. Section 499.002, Florida Statutes, is amended, section 499.004, Florida Statutes, is renumbered as subsection (2) of that section and amended, section 499.0053, Florida

Statutes, is renumbered as subsection (3) of that section and amended, section 499.07, Florida Statutes, is renumbered as subsection (4) of that section and amended, section 499.071, Florida Statutes, is renumbered as subsection (5) of that section and amended, and section 499.081, Florida Statutes, is renumbered as subsection (6) of that section and amended, to read:

499.002 Purpose, administration, and enforcement of and exemption from this part ~~ss. 499.001-499.081~~.--

(1) This part is ~~Sections 499.001 499.081 are~~ intended to:

(a)~~(1)~~ Safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics.

(b)~~(2)~~ Provide uniform legislation to be administered so far as practicable in conformity with the provisions of, and regulations issued under the authority of, the Federal Food, Drug, and Cosmetic Act and that portion of the Federal Trade Commission Act which expressly prohibits the false advertisement of drugs, devices, and cosmetics.

(c)~~(3)~~ Promote thereby uniformity of such state and federal laws, and their administration and enforcement, throughout the United States.

(2) ~~499.004 Administration and enforcement by department.--~~The department ~~of Health~~ shall administer and enforce this part ~~ss. 499.001 499.081~~ to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics.

(3) ~~499.0053 Power to administer oaths, take depositions, and issue and serve subpoenas.--~~For the purpose of any

investigation or proceeding conducted by the department under this part ~~ss. 499.001-499.081~~, the department may administer oaths, take depositions, issue and serve subpoenas, and compel the attendance of witnesses and the production of books, papers, documents, or other evidence. The department shall exercise this power on its own initiative. Challenges to, and enforcement of, the subpoenas and orders shall be handled as provided in s. 120.569.

(4) ~~499.07 Duty of prosecuting officer.--~~Each state attorney, county attorney, or municipal attorney to whom the department or its designated agent reports any violation of this part ~~ss. 499.001-499.081~~ shall cause appropriate proceedings to be instituted in the proper courts without delay and to be prosecuted in the manner required by law.

(5) ~~499.071 Issuance of warnings for minor violations.--~~This part does ~~Sections 499.001-499.081 do~~ not require the department to report, for the institution of proceedings under this part ~~ss. 499.001-499.081~~, minor violations of this part ~~ss. 499.001-499.081~~ when it believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning.

(6) ~~499.081 Carriers in interstate commerce exempted from ss. 499.001-499.081.--~~Carriers engaged in interstate commerce are not subject to this part ~~ss. 499.001-499.081~~ if they are engaged in the usual course of business as carriers.

Section 2. Section 499.003, Florida Statutes, is amended, paragraphs (a)-(f) of subsection (1) of section 499.012, Florida Statutes, are renumbered as subsections (54), (55), (51), and (47), paragraph (c) of subsection (47), and subsection (52) of

that section and amended, paragraphs (3)(f)-(j) and (l)-(n) of Section 499.029, Florida Statutes, are renumbered as subsections (22), (24), (25), (26), (34), (39), (40), and (42) of that section and amended, and subsection (1) of section 499.0661, Florida Statutes, is renumbered as subsection (37) of that section and amended, to read:

499.003 Definitions of terms used in this part ~~ss. 499.001-499.081~~.--As used in this part ~~ss. 499.001-499.081~~, the term:

(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.

(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.

(3)~~(2)~~ "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)~~(4)~~ or is

required to be identified in an application for a permit or to renew a permit pursuant to s. 499.012(8) ~~(3)~~; or

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

(4) ~~(3)~~ "Applicant" means a person applying for a permit or certification under this part ~~ss. 499.001-499.081~~.

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

(6) ~~(5)~~ "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 to a member of its affiliated group.

(8) ~~(6)~~ "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) ~~(7)~~ "Color" includes black, white, and intermediate grays.

(10)~~(8)~~ "Color additive" means, with the exception of any material which 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.~~;~~

~~except that the term does not include any material which has been or hereafter is exempt under the federal act.~~

(11)~~(9)~~ "Compressed medical gas" means any liquefied or vaporized gas that is a prescription drug, whether it is alone or in combination with other gases.

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

(13)~~(11)~~ "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.~~;~~

~~except that the term does not include soap.~~

(14)~~(12)~~ "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.

(15)~~(13)~~ "Department" means the Department of Health.

(16)~~(14)~~ "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 ~~which~~ 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.

(17) ~~(15)~~ "Distribute" or "distribution" means 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.

(18) "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.

~~(16) "Diverted from the legal channels of distribution for prescription drugs" means an adulterated drug pursuant to s. 499.006(10).~~

(19) ~~(17)~~ "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), but does not include devices or their components, parts, or accessories.

(20) ~~(18)~~ "Establishment" means a place of business at one general physical location.

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

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

(23) ~~(g)~~ "Health care clinic" means a health care clinic licensed under part X of chapter 400.

(24) ~~(21)~~ "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.

(25) ~~(f)~~ "Health care facility" means a health care facility licensed under chapter 395.

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

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

(28)~~(22)~~ "Immediate container" does not include package liners.

(29)~~(23)~~ "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 ~~ss. 499.001 499.081~~ or rules adopted under those sections 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.

(30)~~(24)~~ "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.

~~(25) "Legend drug," "prescription drug," or "medicinal drug" means any drug, including, but not limited to, finished dosage forms, or active ingredients subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act or s. 465.003(8), s. 499.007(12), or s. 499.0122(1)(b) or (c).~~

~~(26) "Legend drug label" means any display of written, printed, or graphic matter upon the immediate container of any legend drug prior to its dispensing to an individual patient pursuant to a prescription of a practitioner authorized by law to prescribe.~~

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

(32) ~~(28)~~ "Manufacturer" means a person who prepares, derives, manufactures, or produces a drug, device, or cosmetic. The term excludes pharmacies that are operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter. "Manufacturer" also means 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 that such application has become effective or is otherwise approved consistent with s. 499.023; a private label distributor for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged; or the distribution point for the manufacturer, contract manufacturer or private label distributor whether the establishment is a member of the manufacturer's affiliated group or is a contract distribution site.

(33) ~~(29)~~ "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 where the wholesale distributor purchases and receives the specific unit of the prescription drug directly from the manufacturer and distributes the prescription drug directly, or through one or more 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, "intracompany" means any transaction or transfer between any parent, division, or subsidiary wholly owned by a corporate entity.

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

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

(37)~~(31)~~ "Pedigree paper" means~~:~~

~~(a) Effective July 1, 2006,~~ a document in written or electronic form approved by the department that contains ~~of Health and containing~~ information required by s. 499.012111 regarding the sale and ~~that records each~~ distribution of any given prescription ~~legend~~ drug.~~, from sale by a pharmaceutical manufacturer, through acquisition and sale by any wholesaler or repackager, until final sale to a pharmacy or other person administering or dispensing the drug. The information required to be included on the form approved by the department pursuant to~~

~~this paragraph must at least detail the amount of the legend drug; its dosage form and strength; its lot numbers; the name and address of each owner of the legend drug and his or her signature; its shipping information, including the name and address of each person certifying delivery or receipt of the legend drug; an invoice number, a shipping document number, or another number uniquely identifying the transaction; and a certification that the recipient wholesaler has authenticated the pedigree papers. If the manufacturer or repackager has uniquely serialized the individual legend drug unit, that identifier must also be included on the form approved pursuant to this paragraph. It must also include the name, address, telephone number and, if available, e-mail contact information of each wholesaler involved in the chain of the legend drug's custody; or~~

~~(b) A statement, under oath, in written or electronic form, confirming that a wholesale distributor purchases and receives the specific unit of the prescription drug directly from the manufacturer of the prescription drug and distributes the prescription drug directly, or through an intracompany transfer, 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 "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 to a member of its affiliated group as described in s. 499.0121(6)(f)1.~~

~~1. The information required to be included pursuant to this paragraph must include:~~

~~a. The following statement: "This wholesale distributor purchased the specific unit of the prescription drug directly from the manufacturer."~~

~~b. The manufacturer's national drug code identifier and the name and address of the wholesaler and the purchaser of the prescription drug.~~

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

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

~~2. The wholesale distributor must also maintain and make available to the department, upon request, the point of origin of the prescription drugs, including intracompany transfers; the date of the shipment from the manufacturer to the wholesale distributor; the lot numbers of such drugs; and the invoice numbers from the manufacturer.~~

(38) ~~(1) DEFINITION. As used in this section, the term~~ "Permittee" means any person holding a permit issued pursuant to s. 499.012.

~~The department may adopt rules and forms relating to the requirements of this subsection.~~

(39) ~~(32)~~ "Person" means any individual, child, joint venture, syndicate, fiduciary, partnership, corporation, division of a corporation, firm, trust, business trust, company, estate, public or private institution, association, organization, group, city, county, city and county, political subdivision of this

state, other governmental agency within this state, and any representative, agent, or agency of any of the foregoing, or any other group or combination of the foregoing.

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

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

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

(43) ~~(n)~~ "Prescribing practitioner" means a physician licensed under chapters ~~chapter~~ 458 or 459 or any other medical professional with authority under state law to prescribe cancer medication.

(44) "Prescription drug" means a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active ingredients subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act or ss. 465.003(8), 499.007(13), or 499.003(11), (47), or (54).

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

(46) ~~(34)~~ "Prescription label" means any display of written, printed, or graphic matter upon the immediate container of any

prescription ~~legend~~ drug dispensed pursuant to a prescription of a practitioner authorized by law to prescribe.

(47)~~(35)~~ "Prescription medical oxygen" means oxygen USP which is a drug that can only be sold on the order or prescription of a practitioner authorized by law to prescribe. The label of prescription medical oxygen must comply with current labeling requirements for oxygen under the Federal Food, Drug, and Cosmetic Act.

(48)~~(d)~~ "Primary wholesale distributor ~~wholesaler~~" means any wholesale distributor that:

(a)~~1.~~ 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.~~2.a.~~ Directly purchased prescription drugs from not fewer than 50 different prescription drug manufacturers in the previous year; or

2.~~b.~~ 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, ~~(e)~~ "directly from manufacturers ~~a manufacturer~~" 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.

(49) ~~(36)~~ "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 ~~ss. 499.001-499.081~~, and can be purchased without a prescription.

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

(51) ~~(38)~~ "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.

(52) ~~(c)~~ "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.

(53) ~~(f)~~ "Secondary wholesale distributor ~~wholesaler~~" means a wholesale distributor that is not a primary wholesaler.

(54) ~~(39)~~ "Veterinary prescription drug" means a prescription ~~legend~~ 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."

~~(40) "Veterinary prescription drug wholesaler" means any person engaged in wholesale distribution of veterinary prescription drugs in or into this state.~~

(55)~~(a)~~ "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(a)~~1.~~ Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with s. 499.014:

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

3.~~c.~~ The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control. For purposes of this section, "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.~~d.~~ The sale, purchase, trade, or other transfer of a prescription drug from or for any federal, state, or local government agency or any entity eligible to purchase prescription drugs at public health services prices pursuant to Pub. L. No. 102-585, s. 602 to a contract provider or its subcontractor for eligible patients of the agency or entity under the following conditions:

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

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

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

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

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

administered by patient identifier, which must be submitted to the agency or entity quarterly.

f.~~(VI)~~ 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-~~ sub-subparagraph e.~~(V)~~.

g.~~(VII)~~ 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 sub-subparagraph shall be subject to inspection by the agency or entity. All records relating to prescription drugs of a manufacturer under this sub-subparagraph shall be subject to audit by the manufacturer of those drugs, without identifying individual patient information.

(b)~~2.~~ 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.~~a.~~ The sale, purchase, or trade of a prescription drug among federal, state, or local government health care entities that are under common control and are authorized to purchase such prescription drug.

2.~~b.~~ The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug for

emergency medical reasons. For purposes of this ~~sub-~~subparagraph, the term "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.

3.~~c.~~ The transfer of a prescription drug acquired by a medical director on behalf of a licensed emergency medical services provider to that emergency medical services provider and its transport vehicles for use in accordance with the provider's license under chapter 401.

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

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

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

7.~~g.~~ The transfer of a prescription drug by a hospital or other health care entity to a person licensed under this chapter to repackage prescription drugs for the purpose of repackaging the prescription drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the prescription drugs remains with the

hospital or other health care entity at all times. In addition to the recordkeeping requirements of s. 499.0121(6), the hospital or health care entity that transfers prescription drugs pursuant to this ~~sub-~~subparagraph must reconcile all drugs transferred and returned and resolve any discrepancies in a timely manner.

(c)~~3.~~ The distribution of prescription drug samples by manufacturers' representatives or distributors' representatives conducted in accordance with s. 499.028.

(d)~~4.~~ The sale, purchase, or trade of blood and blood components intended for transfusion. As used in this subparagraph, the term "blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing, and the term "blood components" means that part of the blood separated by physical or mechanical means.

(e)~~5.~~ The lawful dispensing of a prescription drug in accordance with chapter 465.

(f)~~6.~~ The sale, purchase, or trade of a prescription drug between pharmacies as a result of a sale, transfer, merger, or consolidation of all or part of the business of the pharmacies from or with another pharmacy, whether accomplished as a purchase and sale of stock or of business assets.

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

Section 3. Section 499.005, Florida Statutes, is 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:

(1) The manufacture, repackaging, sale, delivery, or holding or offering for sale of any drug, device, or cosmetic that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use.

(2) The adulteration or misbranding of any drug, device, or cosmetic.

(3) The receipt of any drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery of such drug, device, or cosmetic, for pay or otherwise.

(4) The sale, distribution, purchase, trade, holding, or offering of any drug, device, or cosmetic in violation of this part ~~ss. 499.001-499.081~~.

(5) The dissemination of any false or misleading advertisement of a drug, device, or cosmetic.

(6) The refusal or constructive refusal:

(a) To allow the department to enter or inspect an establishment in which drugs, devices, or cosmetics are manufactured, processed, repackaged, sold, brokered, or held;

(b) To allow inspection of any record of that establishment;

(c) To allow the department to enter and inspect any vehicle that is being used to transport drugs, devices, or cosmetics; or

(d) To allow the department to take samples of any drug, device, or cosmetic.

(7) The purchase or sale of prescription drugs for wholesale distribution in exchange for currency, as defined in s. 560.103(6).

(8) Committing any act that causes a drug, device, or cosmetic to be a counterfeit drug, device, or cosmetic; or selling, dispensing, or holding for sale a counterfeit drug, device, or cosmetic.

(9) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of a drug, device, or cosmetic, or the doing of any other act with respect to a drug, device, or cosmetic, if the act is done while the drug, device, or cosmetic is held for sale and the act results in the drug, device, or cosmetic being misbranded.

(10) Forging; counterfeiting; simulating; falsely representing any drug, device, or cosmetic; or, without the authority of the manufacturer, using any mark, stamp, tag, label, or other identification device authorized or required by rules adopted under this part ~~ss. 499.001-499.081~~.

(11) The use, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application of the drug is effective when it is not or that the drug complies with this part ~~ss. 499.001-499.081~~ when it does not.

(12) The possession of any drug in violation of this part ~~ss. 499.001-499.081~~.

(13) The sale, delivery, holding, or offering for sale of any self-testing kits designed to tell persons their status

concerning human immunodeficiency virus or acquired immune deficiency syndrome or related disorders or conditions. This prohibition shall not apply to home access HIV test kits approved for distribution and sale by the United States Food and Drug Administration.

(14) The purchase or receipt of a prescription ~~legend~~ drug from a person that is not authorized under this chapter to distribute prescription ~~legend~~ drugs to that purchaser or recipient.

(15) The sale or transfer of a prescription ~~legend~~ drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug to purchase or possess prescription ~~legend~~ drugs from the person selling or transferring the prescription ~~legend~~ drug.

(16) The purchase or receipt of a compressed medical gas from a person that is not authorized under this chapter to distribute compressed medical gases.

(17) The sale, purchase, or trade, or the offer to sell, purchase, or trade, a drug sample as defined in s. 499.028; the distribution of a drug sample in violation of s. 499.028; or the failure to otherwise comply with s. 499.028.

(18) Failure to maintain records as required by this part ~~ss. 499.001-499.081~~ and rules adopted under those sections.

(19) Providing the department with false or fraudulent records, or making false or fraudulent statements, regarding any matter within the provisions of this chapter.

(20) The importation of a prescription ~~legend~~ drug except as provided by s. 801(d) of the Federal Food, Drug, and Cosmetic Act.

(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.

(22) Failure to obtain a permit or registration, or operating without a valid permit when a permit or registration is required by this part ~~ss. 499.001 499.081~~ for that activity.

(23) Obtaining or attempting to obtain a prescription drug or device by fraud, deceit, misrepresentation or subterfuge, or engaging in misrepresentation or fraud in the distribution of a drug or device.

(24) The distribution of a prescription ~~legend~~ device to the patient or ultimate consumer without a prescription or order from a practitioner licensed by law to use or prescribe the device.

(25) Charging a dispensing fee for dispensing, administering, or distributing a prescription drug sample.

(26) Removing a pharmacy's dispensing label from a dispensed prescription drug with the intent to further distribute the prescription drug.

(27) Distributing a prescription drug that was previously dispensed by a licensed pharmacy, unless such distribution was authorized in chapter 465 or the rules adopted under chapter 465.

(28) Failure to acquire ~~obtain~~ or deliver ~~pass on~~ a pedigree paper where required under this part.

(29) The receipt of a prescription drug pursuant to a wholesale distribution without previously or simultaneously

~~either first~~ receiving a pedigree paper that was attested to as accurate and complete by the wholesale distributor, where required under this part ~~or complying with the provisions of s. 499.0121(6)(d)5~~.

Section 4. Section 499.0051, Florida Statutes, is amended, section 499.0052, Florida Statutes, is renumbered as subsection (7) of that section and amended, section 499.00535, Florida Statutes, is renumbered as subsection (9) of that section and amended, section 499.00545, Florida Statutes, is renumbered as subsection (10) of that section and amended, section 499.069, Florida Statutes, is renumbered as subsection (11) of that section and amended, and section 499.0691, Florida Statutes, is renumbered as subsections (12)-(15) of that section and amended, to read:

499.0051 Criminal acts ~~involving contraband or adulterated drugs~~.--

(1) FAILURE TO MAINTAIN OR DELIVER PEDIGREE PAPERS.--

(a) A person, other than a manufacturer, engaged in the wholesale distribution of prescription ~~legend~~ drugs who fails to deliver to another person complete and accurate pedigree papers concerning a prescription ~~legend~~ drug or contraband prescription ~~legend~~ drug prior to, or simultaneous with, the transfer of, ~~transferring~~ the prescription ~~legend~~ drug or contraband prescription ~~legend~~ 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 ~~legend~~ drugs who fails to acquire complete and accurate pedigree papers concerning a prescription ~~legend~~ drug or

contraband prescription ~~legend~~ drug prior to, or simultaneous with, the receipt of ~~obtaining~~ the prescription ~~legend~~ drug or contraband prescription ~~legend~~ 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 complete and accurate pedigree papers concerning any prescription ~~legend~~ drug or contraband prescription ~~legend~~ drug 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 ~~legend~~ drugs who is in possession of pedigree papers concerning prescription ~~legend~~ drugs or contraband prescription ~~legend~~ drugs and who fails to authenticate the matters contained in the pedigree papers and who nevertheless attempts to further distribute prescription ~~legend~~ drugs or contraband prescription ~~legend~~ 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 ~~legend~~ drugs or contraband prescription ~~legend~~ 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.

(3) KNOWING FORGERY OF PEDIGREE PAPERS.--A person who knowingly forges, counterfeits, or falsely creates any pedigree

paper; who falsely represents any factual matter contained on any pedigree paper; or who knowingly omits to record material information required to be recorded in a pedigree paper, commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(4) KNOWING PURCHASE OR RECEIPT OF PRESCRIPTION ~~LEGEND~~ DRUG FROM UNAUTHORIZED PERSON.--A person who knowingly purchases or receives from a person not authorized to distribute prescription ~~legend~~ drugs under this chapter a prescription ~~legend~~ drug in a wholesale distribution transaction commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(5) KNOWING SALE OR TRANSFER OF PRESCRIPTION ~~LEGEND~~ DRUG TO UNAUTHORIZED PERSON.--A person who knowingly sells or transfers to a person not authorized to purchase or possess prescription ~~legend~~ drugs, under the law of the jurisdiction in which the person receives the drug, a prescription ~~legend~~ drug in a wholesale distribution transaction commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(6) KNOWING SALE OR DELIVERY, OR POSSESSION WITH INTENT TO SELL, CONTRABAND PRESCRIPTION ~~LEGEND~~ DRUGS.--A person who is knowingly in actual or constructive possession of any amount of contraband prescription ~~legend~~ drugs, who knowingly sells or delivers, or who possesses with intent to sell or deliver any amount of contraband prescription ~~legend~~ drugs, commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(7) KNOWING ~~499.0052~~ TRAFFICKING IN CONTRABAND PRESCRIPTION ~~legend~~ DRUGS.--A person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of any amount of contraband prescription ~~legend~~ drugs valued at $25,000 or more commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(a) Upon conviction, each defendant shall be ordered to pay a mandatory fine according to the following schedule:

1.~~(1)~~ If the value of contraband prescription ~~legend~~ drugs involved is $25,000 or more, but less than $100,000, the defendant shall pay a mandatory fine of $25,000. If the defendant is a corporation or other person that is not a natural person, it shall pay a mandatory fine of $75,000.

2.~~(2)~~ If the value of contraband prescription ~~legend~~ drugs involved is $100,000 or more, but less than $250,000, the defendant shall pay a mandatory fine of $100,000. If the defendant is a corporation or other person that is not a natural person, it shall pay a mandatory fine of $300,000.

3.~~(3)~~ If the value of contraband prescription ~~legend~~ drugs involved is $250,000 or more, the defendant shall pay a mandatory fine of $200,000. If the defendant is a corporation or other person that is not a natural person, it shall pay a mandatory fine of $600,000.

(b) As used in this subsection, the term "value" means the market value of the property at the time and place of the offense or, if such cannot be satisfactorily ascertained, the cost of replacement of the property within a reasonable time after the offense. Amounts of value of separate contraband prescription

~~legend~~ drugs involved in distinct transactions for the distribution of the contraband prescription ~~legend~~ drugs committed pursuant to one scheme or course of conduct, whether involving the same person or several persons, may be aggregated in determining the punishment of the offense.

(8)~~(7)~~ KNOWING FORGERY OF PRESCRIPTION OR PRESCRIPTION ~~LEGEND~~ DRUG LABELS.--A person who knowingly forges, counterfeits, or falsely creates any prescription label or prescription ~~legend~~ drug label, or who falsely represents any factual matter contained on any prescription label or prescription ~~legend~~ drug label, commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(9) KNOWING ~~499.00535~~ SALE OR PURCHASE OF CONTRABAND PRESCRIPTION ~~LEGEND~~ DRUGS RESULTING IN GREAT BODILY HARM.-- A person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of any amount of contraband prescription ~~legend~~ drugs, and whose acts in violation of this section result in great bodily harm to a person, commits a felony of the first degree, as provided in s. 775.082, s. 775.083, or s. 775.084.

(10) KNOWING ~~499.00545~~ SALE OR PURCHASE OF CONTRABAND PRESCRIPTION ~~LEGEND~~ DRUGS RESULTING IN DEATH.-- A person who knowingly manufactures, sells, purchases, delivers, or brings into this state, or who is knowingly in actual or constructive possession of any amount of contraband prescription ~~legend~~ drugs, and whose acts in violation of this section result in the death of a person, commits a felony of the first degree, punishable by a term of years not exceeding life, as provided in s. 775.082, s. 775.083, or s. 775.084.

(11)~~499.069 Criminal punishment FOR~~ VIOLATIONS OF S. 499.005 RELATED TO DEVICES AND COSMETICS; DISSEMINATION OF FALSE ADVERTISEMENT.--Any person who violates any of the provisions of s. 499.005 with respect to a device or cosmetic 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 section has become final, such person is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083 or as otherwise provided in this part, except that any person who violates subsection (8) or subsection (10) of s. 499.005 with respect to a device or cosmetic 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 ~~ss. 499.001-499.081~~.

~~(2)~~ A publisher, radio broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, wholesaler, or seller of the article to which a false advertisement relates, is not liable under this subsection by reason of the dissemination by him or her of such false advertisement, unless he or she has refused, on the request of the department, to furnish to the department the name and post office address of the manufacturer, wholesaler, seller, or advertising agency that asked him or her to disseminate such advertisement.

(12) ADULTERATED AND MISBRANDED DRUGS; FALSE ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS~~499.0691 Criminal punishment for violations related to drugs; dissemination of false advertisement~~.--

~~(1)~~ 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 section 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 ~~ss. 499.001-499.081~~:

(a) The manufacture, repackaging, sale, delivery, or holding or offering for sale of any drug that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use.

(b) The adulteration or misbranding of any drug intended for further distribution.

(c) The receipt of any drug that is adulterated or misbranded, and the delivery or proffered delivery of such drug, for pay or otherwise.

(d) The dissemination of any false or misleading advertisement of a drug.

(e) The use, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application of the drug is effective when it is not or that the drug complies with this part ~~ss. 499.001-499.081~~ when it does not.

(f) The purchase or receipt of a compressed medical gas from a person that is not authorized under this chapter to distribute compressed medical gases.

(g) Charging a dispensing fee for dispensing, administering, or distributing a prescription drug sample.

(h) The failure to maintain records related to a drug as required by this part ~~ss. 499.001-499.081~~ and rules adopted under those sections, except for pedigree papers, invoices, or shipping documents related to prescription ~~legend~~ drugs.

(i) The possession of any drug in violation of this part ~~ss. 499.001-499.081~~, except if the violation relates to a deficiency in pedigree papers.

(13) REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING, OR TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO PRESCRIPTION DRUGS.--~~(2)~~ 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: ~~ss. 499.001-499.081.~~

(a) The refusal or constructive refusal to allow:

1. The department to enter or inspect an establishment in which drugs are manufactured, processed, repackaged, sold, brokered, or held;

2. Inspection of any record of that establishment;

3. The department to enter and inspect any vehicle that is being used to transport drugs; or

4. The department to take samples of any drug.

(b) The sale, purchase, or trade, or the offer to sell, purchase, or trade, a drug sample as defined in s. 499.028; the distribution of a drug sample in violation of s. 499.028; or the failure to otherwise comply with s. 499.028.

(c) Providing the department with false or fraudulent records, or making false or fraudulent statements, regarding any matter within the provisions of this chapter related to a drug.

(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 ~~legend~~ drug.

(e) The importation of a prescription ~~legend~~ drug for wholesale distribution, except as provided by s. 801(d) of the Federal Food, Drug, and Cosmetic Act.

(f) The wholesale distribution of a~~ny~~ prescription drug that was:

1. Purchased by a public or private hospital or other health care entity; or

2. Donated or supplied at a reduced price to a charitable organization.

(g) The failure to obtain a permit as a prescription drug wholesale distributor ~~wholesaler~~ when a permit is required by this part for that activity.

(h) Knowingly possessing any adulterated or misbranded prescription ~~legend~~ drug outside of a designated quarantine area.

(i) The purchase or sale of a prescription drug~~s~~ for wholesale distribution in exchange for currency, as defined in s. 560.103(6).

(14) OTHER VIOLATIONS.--~~(3)~~ Any person who violates any of the following provisions commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in this part: ~~ss. 499.001-499.081.~~

(a) Knowingly manufacturing, repackaging, selling, delivering, or holding or offering for sale any drug that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use.

(b) Knowingly adulterating a drug that is intended for further distribution.

(c) Knowingly receiving a drug that is adulterated and delivering or proffering delivery of such drug for pay or otherwise.

(d) Committing any act that causes a drug to be a counterfeit drug, or selling, dispensing, or knowingly holding for sale a counterfeit drug.

(e) Forging, counterfeiting, simulating, or falsely representing any drug, or, without the authority of the manufacturer, using any mark, stamp, tag, label, or other identification device authorized or required by rules adopted under this part ~~ss. 499.001-499.081~~.

(f) Knowingly obtaining or attempting to obtain a prescription drug for wholesale distribution by fraud, deceit, misrepresentation, or subterfuge, or engaging in misrepresentation or fraud in the distribution of a drug.

(g) Removing a pharmacy's dispensing label from a dispensed prescription drug with the intent to further distribute the prescription drug.

(h) Knowingly distributing a prescription drug that was previously dispensed by a licensed pharmacy, unless such distribution was authorized in chapter 465 or the rules adopted under chapter 465.

(15) FALSE ADVERTISEMENT.--~~(4)~~ A publisher, radio broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, repackager, wholesale distributor, or seller of the article to which a false advertisement relates, is not liable under subsections (12),

(13), or (14) ~~this section~~ by reason of the dissemination by him or her of such false advertisement, unless he or she has refused, on the request of the department, to furnish to the department the name and post office address of the manufacturer, repackager, wholesale distributor, seller, or advertising agency that asked him or her to disseminate such advertisement.

Section 5. Section 499.0054, Florida Statutes, is amended, section 499.0055, Florida Statutes, is renumbered as subsection (2) of that section and amended, and section 499.0057, Florida Statutes, is renumbered as subsection (3) of that section and amended, to read:

499.0054 Advertising and labeling of drugs, devices, and cosmetics; exemptions.~~—~~

(1) It is a violation of the Florida Drug and Cosmetic Act to perform or cause the performance of any of the following acts:

(a) ~~(1)~~ The dissemination of any false advertisement of any drug, device, or cosmetic. An advertisement is false if it is false or misleading in any way.

(b) ~~(2)~~ The distribution in commerce of any drug, device, or cosmetic, if its labeling or advertising is in violation of this part ~~ss. 499.001-499.081~~.

(c) ~~(3)~~ The manufacturing, repackaging, packaging, selling, delivery, holding, or offering for sale of any drug, device, or cosmetic for which the advertising or labeling is false or misleading.

(d) ~~(4)~~ The advertising of any drug, device, or cosmetic that is adulterated or misbranded.

(e) ~~(5)~~ The receiving in commerce of any drug, device, or cosmetic that is falsely advertised or labeled or the delivering or proffering for delivery of any such drug, device, or cosmetic.

(f) ~~(6)~~ The advertising or labeling of any product containing ephedrine, a salt of ephedrine, an isomer of ephedrine, or a salt of an isomer of ephedrine, for the indication of stimulation, mental alertness, weight loss, appetite control, energy, or other indications not approved by the pertinent United States Food and Drug Administration Over-the-Counter Final or Tentative Final Monograph or approved new drug application under the federal act. In determining compliance with this requirement, the department may consider the following factors:

1. ~~(a)~~ The packaging of the product.

2. ~~(b)~~ The name and labeling of the product.

3. ~~(c)~~ The manner of distribution, advertising, and promotion of the product, including verbal representations at the point of sale.

4. ~~(d)~~ The duration, scope, and significance of abuse of the particular product.

(g) ~~(7)~~ The advertising of any drug or device represented to have any effect in any of the following conditions, disorders, diseases, or processes:

1. ~~(a)~~ Blood disorders.

2. ~~(b)~~ Bone or joint diseases.

3. ~~(c)~~ Kidney diseases or disorders.

4. ~~(d)~~ Cancer.

5. ~~(e)~~ Diabetes.

6. ~~(f)~~ Gall bladder diseases or disorders.

7. ~~(g)~~ Heart and vascular diseases.

8. ~~(h)~~ High blood pressure.

9. ~~(i)~~ Diseases or disorders of the ear or auditory apparatus, including hearing loss or deafness.

10. ~~(j)~~ Mental disease or mental retardation.

11. ~~(k)~~ Paralysis.

12. ~~(l)~~ Prostate gland disorders.

13. ~~(m)~~ Conditions of the scalp affecting hair loss.

14. ~~(n)~~ Baldness.

15. ~~(o)~~ Endocrine disorders.

16. ~~(p)~~ Sexual impotence.

17. ~~(q)~~ Tumors.

18. ~~(r)~~ Venereal diseases.

19. ~~(s)~~ Varicose ulcers.

20. ~~(t)~~ Breast enlargement.

21. ~~(u)~~ Purifying blood.

22. ~~(v)~~ Metabolic disorders.

23. ~~(w)~~ Immune system disorders or conditions affecting the immune system.

24. ~~(x)~~ Extension of life expectancy.

25. ~~(y)~~ Stress and tension.

26. ~~(z)~~ Brain stimulation or performance.

27. ~~(aa)~~ The body's natural defense mechanisms.

28. ~~(bb)~~ Blood flow.

29. ~~(cc)~~ Depression.

30. ~~(dd)~~ Human immunodeficiency virus or acquired immune deficiency syndrome or related disorders or conditions.

(h) ~~(8)~~ The representation or suggestion in labeling or advertising that an article is approved under this part ~~ss. 499.001-499.081~~, when such is not the case.

(2) ~~499.0055 False or misleading advertisement.--~~In determining whether an advertisement is false or misleading, the department shall review the representations made or suggested by statement, word, design, device, sound, or any combination thereof within the advertisement and the extent to which the advertisement fails to reveal material facts with respect to consequences that can result from the use of the drug, device, or cosmetic to which the advertisement relates under the conditions of use prescribed in the labeling or advertisement.

(3)(a) ~~499.0057 Advertisement exemptions.-~~

~~(1)~~ An advertisement that is not prohibited under paragraph (1)(a) ~~s. 499.0054(1)~~ is not prohibited under paragraph (1)(g) ~~s. 499.0054(7)~~ if it is disseminated:

1. To the public solely to advertise the product for those indications that are safe and effective indications and the product is safe and effective for self-medication, as established by the United States Food and Drug Administration; or

2. ~~if it is disseminated~~ Only to members of the medical, dental, pharmaceutical, or veterinary professions or appears only in the scientific periodicals of these professions.

(b) ~~(2)~~ Compliance with this part ~~ss. 499.001-499.081~~ and the rules adopted under those sections creates no legal presumption that a drug or device is safe or effective.

Section 6. Section 499.006, Florida Statutes, is amended to read:

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

(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance;

(2) If it has been produced, prepared, packed, or held under conditions whereby it could have been contaminated with filth or rendered injurious to health;

(3) If it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, current good manufacturing practices to assure that the drug meets the requirements of this part ~~ss. 499.001-499.081~~ and that the drug has the identity and strength, and meets the standard of quality and purity, which it purports or is represented to possess;

(4) If it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which could render the contents injurious to health;

(5) If it is a drug and it bears or contains, for the purpose of coloring only, a color additive that is unsafe within the meaning of the federal act; or, if it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, and it is unsafe within the meaning of the federal act;

(6) If it purports to be, or is represented as, a drug the name of which is recognized in the official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. The determination as to strength, quality, or purity must be made in accordance with the

tests or methods of assay set forth in such compendium, or, when such tests or methods of assay are absent or inadequate, in accordance with those tests or methods of assay prescribed under authority of the federal act. A drug defined in the official compendium is not adulterated under this subsection merely because it differs from the standard of strength, quality, or purity set forth for that drug in such compendium if its difference in strength, quality, or purity from such standard is plainly stated on its label;

(7) If it is not subject to subsection (6) and its strength differs from, or its purity or quality falls below the standard of, that which it purports or is represented to possess;

(8) If it is a drug:

(a) With which any substance has been mixed or packed so as to reduce the quality or strength of the drug; or

(b) For which any substance has been substituted wholly or in part;

(9) If it is a drug or device for which the expiration date has passed;

(10) If it is a prescription ~~legend~~ drug for which the required pedigree paper is nonexistent, fraudulent, or incomplete under the requirements of this part ~~ss. 499.001 499.081~~ 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

(11) If it is a 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 to a limited prescription drug veterinary wholesaler.

Section 7. Section 499.007, Florida Statutes, is amended to read:

499.007 Misbranded drug or device.--A drug or device is misbranded:

(1) If its labeling is in any way false or misleading.

(2) ~~Unless,~~ If in package form, it does not bear ~~bears~~ a label containing:

(a) The name and place of business of the manufacturer, repackager, or distributor of the finished dosage form of the drug. For the purpose of this paragraph, the finished dosage form of a prescription ~~medicinal~~ drug is that form of the drug which is, or is intended to be, dispensed or administered to the patient and requires no further manufacturing or processing other than packaging, reconstitution, and labeling; and

(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.~~;~~ However, under this section, reasonable variations are permitted, and the department shall establish by rule exemptions for small packages.

(3) If it is an active pharmaceutical ingredient in bulk form, and does not bear a label containing:

(a) the name and place of business of the manufacturer, repackager or distributor; and

(b) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

(4)~~(3)~~ If any word, statement, or other information required by or under this part ~~ss. 499.001-499.081~~ to appear on the label or labeling is not prominently placed thereon with such conspicuousness as compared with other words, statements, designs, or devices in the labeling, and in such terms, as to

render the word, statement, or other information likely to be read and understood under customary conditions of purchase and use.

(5)~~(4)~~ If it is a drug and is not designated solely by a name recognized in an official compendium and ~~, unless~~ its label does not bear ~~bears~~:

(a) The common or usual name of the drug, if any; and

(b) In case it is fabricated from two or more ingredients, the common or usual name and quantity of each active ingredient.

(6)~~(5)~~ If ~~Unless~~ its labeling does not bear ~~bears~~:

(a) Adequate directions for use; and

(b) Adequate warnings against use in those pathological conditions in which its use may be dangerous to health or against use by children if its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.

(7)~~(6)~~ If it purports to be a drug the name of which is recognized in the official compendium and it ~~, unless it~~ is not packaged and labeled as prescribed therein.~~,~~ However, the method of packaging may be modified with the consent of the department.

(8)~~(7)~~ If it has been found by the department to be a drug liable to deterioration and it ~~, unless it~~ is not packaged in such form and manner, and its label bears a statement of such precautions, as the department by rule requires as necessary to protect the public health. Such rule may not be established for any drug recognized in an official compendium until the department has informed the appropriate body charged with the revision of such compendium of the need for such packaging or

labeling requirements and that body has failed within a reasonable time to prescribe such requirements.

(9)~~(8)~~ If it is:

(a) A drug and its container or finished dosage form is so made, formed, or filled as to be misleading;

(b) An imitation of another drug; or

(c) Offered for sale under the name of another drug.

(10)~~(9)~~ If it is dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling of the drug.

(11)~~(10)~~ If it is, purports to be, or is represented as a drug composed wholly or partly of insulin and it ~~, unless:~~

~~(a) It~~ is not from a batch with respect to which a certificate has been issued pursuant to s. 506 of the federal act, which ~~; and~~

~~(b) The~~ certificate is in effect with respect to the drug.

(12)~~(11)~~ If it is, purports to be, or is represented as a drug composed wholly or partly of any kind of antibiotic requiring certification under the federal act and ~~unless:~~

~~(a)~~ it is not from a batch with respect to which a certificate has been issued pursuant to s. 507 of the federal act, which ~~; and~~

~~(b) The~~ certificate is in effect with respect to the drug. ~~;~~

However, this subsection does not apply to any drug or class of drugs exempted by regulations adopted under s. 507(c) or (d) of the federal act.

(13) ~~(12)~~ If it is a drug intended for use by humans which is a habit-forming drug or which, because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drugs, ~~;~~ or which is limited by an effective application under s. 505 of the federal act to use under the professional supervision of a practitioner licensed by law to prescribe such drug, if ~~unless~~ it is not dispensed only:

(a) Upon the written prescription of a practitioner licensed by law to prescribe such drug;

(b) Upon an oral prescription of such practitioner, which is reduced promptly to writing and filled by the pharmacist; or

(c) By refilling any such written or oral prescription, if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filled by the pharmacist.

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.

(14) ~~(13)~~ If it is a drug that is subject to paragraph (13) ~~(12)~~(a), and if, at any time before it is dispensed, its label does not ~~fails to~~ bear the statement:

(a) "Caution: Federal Law Prohibits Dispensing Without Prescription";

(b) "Rx Only";

(c) The prescription symbol followed by the word "Only"; or

(d) "Caution: State Law Prohibits Dispensing Without Prescription."

(15) ~~(14)~~ If it is a drug that is not subject to paragraph (13) ~~(12)~~(a), if at any time before it is dispensed its label bears the statement of caution required in subsection (14) ~~(13)~~.

(16) ~~(15)~~ If it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only and ~~,~~ ~~unless~~ its packaging and labeling are not in conformity with the packaging and labeling requirements that apply to such color additive and are prescribed under the federal act.

(17) A drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to prescribe such drug is exempt from the requirements of this section, except subsections (1), (9) ~~(8)~~, (11) ~~(10)~~, and (12) ~~(11)~~ and the packaging requirements of subsections (7) ~~(6)~~ and (8) ~~(7)~~, if the drug bears a label that contains the name and address of the dispenser or seller, the prescription number and the date the prescription was written or filled, the name of the prescriber and the name of the patient, and the directions for use and cautionary statements. This exemption does not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail or to any drug dispensed in violation of subsection (13) ~~(12)~~. The department may, by rule, exempt drugs subject to ss. 499.062-499.064 from subsection (13) ~~(12)~~ if compliance with that subsection is not necessary to protect the public health, safety, and welfare.

Section 8. Section 499.008, Florida Statutes, is amended to read:

499.008 Adulterated cosmetics.--A cosmetic is adulterated:

(1) If it bears or contains any poisonous or deleterious substance that is injurious to users under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual. ~~;~~ However, this subsection does not apply to coal-tar hair dye:

(a) The label of which bears the following legend conspicuously displayed thereon: "Caution: This product contains ingredients which may cause skin irritation on certain individuals, and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness"; and

(b) The labeling of which bears adequate directions for such preliminary testing.

~~For the purposes of this subsection and subsection (4), the term "hair dye" does not include eyelash dyes or eyebrow dyes.~~

(2) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(3) If it has been produced, prepared, packed, or held under conditions whereby it could have become contaminated with filth or whereby it could have been rendered injurious to health.

(4) If it is not a hair dye and it is, or it bears or contains, a color additive that is unsafe within the meaning of the federal act.

(5) For the purposes of subsections (1) and (4), the term "hair dye" does not include eyelash dyes or eyebrow dyes.

Section 9. Section 499.009, Florida Statutes, is amended to read:

499.009 Misbranded cosmetics.--A cosmetic is misbranded:

(1) If its labeling is false or misleading in any particular.

(2) ~~Unless,~~ If in package form, it does not bear ~~bears~~ a label containing:

(a) The name and place of business of the manufacturer, packer, or distributor;

(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; however, under this paragraph reasonable variations are permitted, and the department shall establish by rule exemptions for small packages; and

(c) A declaration of ingredients in descending order of predominance, or as otherwise required by federal law.

(3) If any word, statement, or other information required by or under authority of this part ~~ss. 499.001 499.081~~ to appear on the label or labeling is not prominently placed thereon with such conspicuousness as compared with other words, statements, designs, or devices in the labeling, and in such terms, as to render the word, statement, or other information likely to be read and understood by an individual under customary conditions of purchase and use.

(4) If its container is so made, formed, or filled as to be misleading.

(5) ~~Unless,~~ If it is a color additive, its packaging and labeling are not in conformity with the packaging and labeling requirements applicable to that color additive prescribed under the federal act. This subsection does not apply to packages of

color additives that, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes.

Section 10. Section 499.01, Florida Statutes, is amended, subsection (2) and paragraphs (2)(a)-(h) of section 499.012, Florida Statutes, are renumbered as subsection (2) and paragraphs (2)(d), (n), (e), (f), (c), (i), (k), and (l) of that section and amended, paragraphs (2)(b)-(e) of section 499.013, Florida Statutes, are renumbered as paragraphs (2)(f), (o), (q), and (r) of that section and amended, and section 499.014, Florida Statutes, is renumbered as paragraph (2)(g) of that section and amended, to read:

499.01 Permits~~; applications; renewal; general requirements~~.--

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

(a) A prescription drug manufacturer;

(b) A prescription drug repackager;

(c) A nonresident prescription drug manufacturer;

(d) A prescription drug wholesale distributor;

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

(f) A retail pharmacy drug wholesale distributor;

(g) A restricted prescription drug distributor;

(h) A complimentary drug distributor;

(i) A freight forwarder;

(j) A veterinary prescription drug retail establishment;

(k) A veterinary prescription drug wholesale distributor;

(l) A limited prescription drug veterinary wholesale distributor;

(m) A medical oxygen retail establishment;

(n) A compressed medical gas wholesale distributor;

(o) A compressed medical gas manufacturer;

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

~~(d) A compressed medical gas manufacturer;~~

(q) ~~(e)~~ A device manufacturer; or

(r) ~~(f)~~ A cosmetic manufacturer. ~~;~~

~~(g) A prescription drug wholesaler;~~

~~(h) A veterinary prescription drug wholesaler;~~

~~(i) A compressed medical gas wholesaler;~~

~~(j) An out-of-state prescription drug wholesaler;~~

~~(k) A nonresident prescription drug manufacturer;~~

~~(l) A freight forwarder;~~

~~(m) A retail pharmacy drug wholesaler;~~

~~(n) A veterinary legend drug retail establishment;~~

~~(o) A medical oxygen retail establishment;~~

~~(p) A complimentary drug distributor;~~

~~(q) A restricted prescription drug distributor; or~~

~~(r) A limited prescription drug veterinary wholesaler.~~

(2) The following ~~types of wholesaler~~ permits are established:

(a) Prescription drug manufacturer permit.--A prescription drug manufacturer permit is required for any person that manufactures a prescription drug in this state.

1. A person that operates an establishment permitted as a prescription drug manufacturer may engage in wholesale distribution of prescription drugs manufactured at that establishment and must comply with all the provisions of this

part and the rules adopted under those sections that apply to a wholesale distributor.

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

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

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

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

(c) ~~(e)~~ Nonresident prescription drug manufacturer permit.--A nonresident prescription drug manufacturer permit is required for any person that is a manufacturer of prescription drugs, or the distribution point for a manufacturer of prescription drugs, and located outside of this state, or that is an entity to whom an approved new drug application has been issued by the United States Food and Drug Administration, or the contracted manufacturer of the approved new drug application holder, and located outside the United States, which engages in the wholesale distribution in this state of the prescription drugs it manufactures or is responsible for manufacturing. Each such manufacturer or entity must be permitted by the department and comply with all the provisions required of a wholesale distributor under this part ~~ss. 499.001-499.081~~, except s. 499.01211~~(6)(d)~~.

1. A person that distributes prescription drugs that it did not manufacture must also obtain an out-of-state prescription drug wholesale distributor ~~wholesaler~~ permit pursuant to this section to engage in the wholesale distribution of the prescription drugs manufactured by another person and comply with the requirements of an out-of-state prescription drug wholesale distributor ~~wholesaler~~.

2. Any such person must comply with the licensing or permitting requirements of the jurisdiction in which the establishment is located and the federal act, and any product wholesaled into this state must comply with this part ~~ss. 499.001-499.081~~. 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) ~~(a)~~ A prescription drug wholesale distributor ~~wholesaler's~~ permit.--A prescription drug wholesale distributor ~~wholesaler~~ is a wholesale distributor that may engage in the wholesale distribution of prescription drugs. A prescription drug wholesale distributor ~~wholesaler~~ that applies to the department for a new permit or the renewal of a permit must submit a bond of $100,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the

department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part that involves the permittee is concluded, including any appeal, whichever occurs later. The department may adopt rules for issuing a prescription drug wholesale distributor ~~wholesaler~~ broker permit to a person who engages in the wholesale distribution of prescription drugs and does not take physical possession of any prescription drugs.

(e) ~~(c)~~ An out-of-state prescription drug wholesale distributor ~~wholesaler's~~ permit.--An out-of-state prescription drug wholesale distributor ~~wholesaler~~ is a wholesale distributor located outside this state which engages in the wholesale distribution of prescription drugs into this state and which must be permitted by the department and comply with all the provisions required of a wholesale distributor under this part ~~ss. 499.001-499.081~~. An out-of-state prescription drug wholesale distributor ~~wholesaler~~ that applies to the department for a new permit or the renewal of a permit must submit a bond of $100,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs

become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part that involves the permittee is concluded, including any appeal, whichever occurs later.

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

2. An out-of-state prescription drug wholesale distributor ~~wholesaler's~~ 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 ~~wholesaler~~, in its state of residence, to a licensed prescription drug wholesale distributor ~~wholesaler~~ in this state, if both wholesale distributor ~~wholesalers~~ conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of ss. ~~s.~~ 499.0121(6) and 499.012111 must be followed for this transaction.

(f)~~(d)~~ A retail pharmacy wholesale distributor ~~wholesaler's~~ permit.--A retail pharmacy wholesale distributor ~~wholesaler~~ 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 wholesale distributor ~~wholesaler's~~ permit pursuant to this part ~~ss. 499.001-499.081~~ and the rules adopted under those sections.

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 ~~wholesaler's~~ 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 ~~ss. 499.001-499.081~~.

(g) Restricted prescription drug distributor permit.-- ~~499.014 Distribution of legend drugs by hospitals, health care entities, charitable organizations, and return or destruction companies; permits, general requirements.~~

~~(1)~~ A restricted prescription drug distributor permit is required for any person that engages in the distribution of a prescription ~~legend~~ drug, which distribution is not considered "wholesale distribution" under s. 499.003(55)(a)~~012(1)(a)1~~.

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

2.~~(3)~~ Storage, handling, and recordkeeping of these distributions must comply with the requirements for wholesale distributors under s. 499.0121, except those set forth in s. 499.012111~~(6)(d)~~.

3.~~(4)~~ 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.~~(5)~~ The department ~~may issue permits to restricted prescription drug distributors and~~ may adopt rules regarding the distribution of prescription drugs by hospitals, health care entities, charitable organizations, or other persons not involved in wholesale distribution, which rules are necessary for the protection of the public health, safety, and welfare.

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

(i)~~(f)~~ Freight forwarder permit.--A freight forwarder permit is required for any person that engages in the distribution of a prescription ~~legend~~ 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, except those set forth in s. 499.012111~~(6)(d)~~. A freight forwarder must provide the source of the prescription ~~legend~~ drugs with a validated airway bill, bill of lading, or other appropriate documentation to evidence the exportation of the product.

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

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

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

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

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

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

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

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

(k) ~~(g)~~ A veterinary prescription drug wholesale distributor ~~wholesaler~~ permit.--A veterinary prescription drug wholesale distributor ~~wholesaler~~ 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 ~~wholesaler~~ 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 ~~wholesaler~~, an out-of-state prescription drug wholesale distributor ~~wholesaler~~, or a limited prescription drug veterinary wholesale distributor ~~wholesaler~~ in lieu of the veterinary prescription drug wholesale distributor ~~wholesaler~~ permit. A veterinary prescription drug wholesale distributor ~~wholesaler~~ must comply with the requirements for wholesale distributors under s. 499.0121, except those set forth in s. 499.012111~~(6)(d)~~.

(l)~~(h)~~ Limited prescription drug veterinary wholesale distributor ~~wholesaler~~ permit.--Unless engaging in the activities of and permitted as a prescription drug manufacturer, nonresident prescription drug manufacturer, prescription drug wholesale distributor ~~wholesaler~~, or out-of-state prescription drug wholesale distributor ~~wholesaler~~, a limited prescription drug veterinary wholesale distributor ~~wholesaler~~ 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 ~~is not permitted, licensed, or otherwise authorized~~ in any jurisdiction ~~state to wholesale~~ 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 ~~wholesaler~~ that applies to the department for a new permit or the renewal of a permit must submit a bond of $20,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine

or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part that ~~ss. 499.001-499.081 which~~ involves the permittee is concluded, including any appeal, whichever occurs later.

5. A limited prescription drug veterinary wholesale distributor ~~wholesaler~~ 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 ~~wholesaler~~ must comply with the requirements for wholesale distributors under s. 499.0121, except that a limited prescription drug veterinary wholesale distributor ~~wholesaler~~ is not required to provide a pedigree paper as required by s. 499.01211~~(6)(d)~~ upon the wholesale distribution of a prescription drug to a veterinarian.

7. A limited prescription drug veterinary wholesale distributor ~~wholesaler~~ 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. ~~An out-of-state prescription drug wholesaler's permit or~~ A limited prescription drug veterinary wholesale distributor ~~wholesaler~~ 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 ~~wholesaler~~ in this state if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of ss. ~~s.~~ 499.0121(6) and 499.012111 must be followed for this transaction.

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

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

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

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

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

(n) ~~(b)~~ A compressed medical gas wholesale distributor ~~wholesaler's~~ permit.--A compressed medical gas wholesale distributor ~~wholesaler~~ is a wholesale distributor that is limited to the wholesale distribution of compressed medical gases to

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

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

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

2. A compressed medical gas manufacturer ~~permittee~~ may engage in wholesale distribution of compressed medical gases manufactured at that establishment and must comply with all the provisions of this part ~~ss. 499.001-499.081~~ and the rules adopted under those sections that apply to a wholesale distributor.

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

(p) Over-the-counter drug manufacturer permit. ~~(b)~~ An over-the-counter drug manufacturer ~~manufacturer's~~ 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 ~~permittee~~ may not possess or purchase prescription drugs.

2. A pharmacy is exempt from obtaining an over-the-counter drug manufacturer~~'s~~ 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 ~~permittee~~ must comply with all appropriate state and federal good manufacturing practices.

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

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

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

(r) Cosmetic manufacturer permit. ~~(e)~~ A cosmetic manufacturer ~~manufacturer's~~ 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.

Section 11. Section 499.012, Florida Statutes, is amended and subsections (2)-(8) of section 499.01, Florida States, are renumbered as subsections (1)-(7) of that section and amended to read:

499.012 Permit application ~~Wholesale distribution; definitions; permits; applications; general~~ requirements.--

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

~~(2)~~(a) A permit issued pursuant to this part ~~ss. 499.001-499.081~~ 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 ~~ss. 499.001-499.081~~.

(c) A person that applies for or renews a permit to manufacture or distribute prescription ~~legend~~ 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 ~~wholesaler~~ 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 ~~wholesaler~~, limited prescription drug veterinary wholesale distributor ~~wholesaler~~, or retail pharmacy wholesale distributor ~~wholesaler~~ may not be issued to the address of a health care entity or to a pharmacy licensed under chapter 465, except as provided in this paragraph. The department may issue a prescription drug manufacturer permit to an applicant at the same address as a licensed nuclear pharmacy, which is a health care entity, for the purpose of manufacturing prescription drugs used in positron emission tomography or other radiopharmaceuticals, as listed in a rule adopted by the department pursuant to this paragraph. The purpose of this exemption is to assure availability of state-of-the-art pharmaceuticals that would pose a significant danger to the public health if manufactured at a separate establishment address from the nuclear pharmacy from which the prescription drugs are dispensed. The department may also issue a retail pharmacy wholesale distributor ~~wholesaler~~ permit to the address of a community pharmacy licensed under chapter 465 which does not meet the definition of a closed pharmacy in s. 499.003.

(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 ~~ss. 499.001-499.081~~, 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 ~~ss. 499.001-499.081~~.

(2)~~(3)~~ Notwithstanding subsection (6)~~(7)~~, 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 ~~wholesaler~~, an out-of-state prescription drug wholesale distributor ~~wholesaler~~, or a retail pharmacy drug wholesale distributor ~~wholesaler~~ 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)~~(4)~~ 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.

(4)~~(5)~~(a) Except for a permit for a prescription drug wholesale distributor ~~wholesaler~~ or an out-of-state prescription drug wholesale distributor ~~wholesaler~~, 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 ~~ss. 499.001 499.081~~ and rules adopted under those sections.

(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 ~~ss. 499.001-499.081~~:

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 ~~ss. 499.001-499.081~~.

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) ~~(6)~~ Except for a permit ~~permits~~ for a prescription drug wholesale distributor ~~wholesalers~~ or an out-of-state prescription drug wholesale distributor ~~wholesalers~~:

(a) The department shall adopt rules for the biennial renewal of permits.

(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 ~~ss. 499.001-499.081~~ and the rules adopted under those sections.

(c) 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. A permit issued under this part ~~ss. 499.001-499.081~~ 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 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.

(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 section has expired and cannot be renewed, before an establishment may engage in activities that

require a permit under this part ~~ss. 499.001-499.081~~, 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)~~(7)~~ 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 ~~ss. 499.001-499.081~~ 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 ~~legend~~ 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 ~~legend~~ drugs.

(c) If an establishment permitted under this part ~~ss. 499.001-499.081~~ 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 ~~legend~~ 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 ~~ss. 499.001-499.081~~. Transfer of ownership of prescription drugs may be made only to persons authorized to possess prescription ~~legend~~ drugs under this part ~~ss. 499.001 499.081~~.

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

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

(8)~~(3)~~ An application for a permit or to renew a permit for a prescription drug wholesale distributor ~~wholesaler~~ or an out-of-state prescription drug wholesale distributor ~~wholesaler~~ 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 member of the affiliated group of which the applicant is a member.

(g)1. 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)~~(4)~~ for each of such persons.

(l) The name of each of the applicant's designated representatives as required by subsection (16)~~(11)~~, together with the personal information statement and fingerprints required pursuant to subsection (9)~~(4)~~ for each such person.

(m) For an applicant that is a secondary wholesaler, each of the following:

1. A personal background information statement containing the background information and fingerprints required pursuant to subsection (9)~~(4)~~ 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) 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 wholesaler or a secondary wholesaler.

(9) ~~(4)~~ (a) Each person required by subsection (8) ~~(3)~~ 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, either 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 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 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 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.

(10) ~~(5)~~ The department may deny an application for a permit or refuse to renew a permit for a prescription drug wholesale distributor ~~wholesaler~~ or an out-of-state prescription drug wholesale distributor ~~wholesaler~~ 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 ~~ss. 499.001 499.081~~ or chapter 465, chapter 501, or chapter 893, any rules adopted under any of those sections or 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 paragraph (1)(d) ~~(2)(a)~~ or paragraph (1)(e) ~~(2)(c)~~ of s. 499.01 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 paragraph (1)(d) ~~(2)(a)~~ or paragraph (1)(e) ~~(2)(c)~~ of s. 499.01 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 ~~ss. 499.001-499.081~~, similar federal laws, similar laws in other states, or the rules adopted under such laws.

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

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

(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 ~~wholesaler~~ or out-of-state prescription drug wholesale distributor ~~wholesaler~~ 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 ~~ss. 499.001-499.081~~, 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.

(13) ~~(8)~~ 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 ~~wholesaler~~ 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 ~~wholesaler~~ 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 ~~wholesaler~~, which has no legal authority to dispense prescription drugs, complies with all wholesale distribution requirements of s. 499.0121 and 499.012111 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 ~~wholesaler~~. 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 wholesaler 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 ~~wholesaler~~, permitted under this chapter, in accordance with a written consignment agreement between the pharmacy and that wholesale distributor ~~wholesaler~~ if~~:~~ the permitted pharmacy and the permitted prescription drug wholesale distributor ~~wholesaler~~ 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 ~~wholesaler~~ may not use the pharmacy as a wholesale distributor through which it distributes the prescription ~~legend~~ drugs to other pharmacies. Nothing in this section is intended to prevent a wholesale ~~drug~~ distributor

from obtaining this inventory in the event of nonpayment by the pharmacy.

(c) The department shall require information from each wholesale distributor as part of the permit and renewal of such permit, as required under ~~s. 499.01 or~~ this section.

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

(15) ~~(10)~~ The name of a permittee or establishment on a prescription drug wholesale distributor ~~wholesaler~~ permit or an out-of-state prescription drug wholesale distributor ~~wholesaler~~ 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.

(16) ~~(11)~~(a) Each establishment that is issued an initial or renewal permit as a prescription drug wholesale distributor ~~wholesaler~~ or an out-of-state prescription drug wholesale distributor ~~wholesaler~~ must designate in writing to the department at least one natural person to serve as the designated representative of the wholesale distributor ~~wholesaler~~. 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 not less than 2 years of verifiable full-time 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, or have not less than 2 years of verifiable full-time managerial experience with a prescription drug wholesale distributor ~~wholesaler~~ licensed in this state or in another state;

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 ~~ss. 499.001-499.081~~ 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; and

5. Provide the department with a personal information statement and fingerprints pursuant to subsection (9)~~(4)~~.

(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 ~~wholesaler~~ permit or an out-of-state prescription drug wholesale distributor ~~wholesaler~~ 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 12. 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 provisions of law to the contrary, the Agency for Health Care Administration may not:

(1) Review or use any violation or alleged violation of ss. 499.0121(6) or 499.012111, or any rules adopted under those

sections ~~that section~~, 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 ss. 499.0121(6) or 499.012111, or any rules adopted under those sections ~~that section~~, as the subject of any audit of Medicaid-related records held by a pharmacy licensed under chapter 465.

Section 13. Section 499.0121, Florida Statutes, is amended and subsection (4) of section 499.013, Florida Statutes, is renumbered as paragraph (6)(d) of that section and 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.

(1) ESTABLISHMENTS.--An establishment at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed must:

(a) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(b) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(c) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or

adulterated, or that are in immediate or sealed, secondary containers that have been opened;

(d) Be maintained in a clean and orderly condition; and

(e) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(2) SECURITY.--

(a) An establishment that is used for wholesale drug distribution must be secure from unauthorized entry.

1. Access from outside the premises must be kept to a minimum and be well-controlled.

2. The outside perimeter of the premises must be well-lighted.

3. Entry into areas where prescription drugs are held must be limited to authorized personnel.

(b) An establishment that is used for wholesale drug distribution must be equipped with:

1. An alarm system to detect entry after hours; however, the department may exempt by rule establishments that only hold a permit as prescription drug wholesale distributor ~~wholesaler~~-brokers and establishments that only handle medical oxygen; and

2. A security system that will provide suitable protection against theft and diversion. When appropriate, the security system must provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(c) Any vehicle that contains prescription drugs must be secure from unauthorized access to the prescription drugs in the vehicle.

(3) STORAGE.--All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the official compendium.

(a) If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in the official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(b) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs must be used to document proper storage of prescription drugs.

(c) The recordkeeping requirements in subsection (6) must be followed for all stored prescription drugs.

(4) EXAMINATION OF MATERIALS AND RECORDS.--

(a) Upon receipt, each outside shipping container must be visually examined for identity and to prevent the acceptance of contaminated prescription drugs that are otherwise unfit for distribution. This examination must be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(b) Each outgoing shipment must be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have expired or been damaged in storage or held under improper conditions.

(c) The recordkeeping requirements in subsection (6) must be followed for all incoming and outgoing prescription drugs.

(d) Upon receipt, a wholesale distributor ~~wholesaler~~ 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) ~~499.001(31)~~.

(5) RETURNED, DAMAGED, OR OUTDATED PRESCRIPTION DRUGS.--

(a)1. Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier. A quarantine section must be separate and apart from other sections where prescription drugs are stored so that prescription drugs in this section are not confused with usable prescription drugs.

2. Prescription drugs must be examined at least every 12 months, and drugs for which the expiration date has passed must be removed and quarantined.

(b) Any prescription drugs of which the immediate or sealed outer containers or sealed secondary containers have been opened or used must be identified as such and must be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(c) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug must be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or

purity, the wholesale ~~drug~~ distributor must consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the conditions of the drug and its container, carton, or labeling, as a result of storage or shipping.

(d) The recordkeeping requirements in subsection (6) must be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(6) RECORDKEEPING.--The department shall adopt rules that require keeping such records of prescription drugs as are necessary for the protection of the public health.

(a) Wholesale ~~drug~~ distributors must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. 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 drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

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

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

4. The dates of receipt and distribution or other disposition of the drugs; 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 ~~ss. 499.001 499.081~~ 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) A wholesale distributor must maintain pedigree papers separate and distinct from other records required under this chapter.

~~(d)1. Effective July 1, 2006, each person who is engaged in the wholesale distribution of a prescription drug and who is not~~

~~the manufacturer of that drug must, before each wholesale distribution of such drug, provide to the person who receives the drug a pedigree paper as defined in s. 499.003(31).~~

~~2. A repackager must comply with this paragraph.~~

~~3. The pedigree paper requirements in this paragraph do not apply to compressed medical gases or veterinary legend drugs.~~

~~4. Each wholesale distributor of prescription drugs must maintain separate and distinct from other required records all statements that are required under subparagraph 1.~~

~~5. Subparagraph 1. is satisfied when a wholesale distributor takes title to, but not possession of, a prescription drug and the prescription drug's manufacturer ships the prescription drug directly to a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug, as defined in s. 465.003, or a member of an affiliated group, as described in paragraph (f), with the exception of a repackager.~~

~~a. The wholesale distributor must deliver to the recipient of the prescription drug, within 14 days after the shipment notification from the manufacturer, an invoice and the following sworn statement: "This wholesale distributor purchased the specific unit of the prescription drug listed on the invoice directly from the manufacturer, and the specific unit of prescription drug was shipped by the manufacturer directly to a person authorized by law to administer or dispense the legend drug, as defined in s. 465.003, Florida Statutes, or a member of an affiliated group, as described in s. 499.0121(6)(f), Florida Statutes, with the exception of a repackager." The invoice must~~

~~contain a unique cross-reference to the shipping document sent by the manufacturer to the recipient of the prescription drug.~~

~~b. The manufacturer of the prescription drug shipped directly to the recipient under this section must provide and the recipient of the prescription drug must acquire, within 14 days after receipt of the prescription drug, a shipping document from the manufacturer that contains, at a minimum:~~

~~(I) The name and address of the manufacturer, including the point of origin of the shipment, and the names and addresses of the wholesaler and the purchaser.~~

~~(II) The name of the prescription drug as it appears on the label.~~

~~(III) The quantity, dosage form, and strength of the prescription drug.~~

~~(IV) The date of the shipment from the manufacturer.~~

~~c. The wholesale distributor must also maintain and make available to the department, upon request, the lot number of such drug if not contained in the shipping document acquired by the recipient.~~

~~6. Failure of the manufacturer to provide, the recipient to acquire, or the wholesale distributor to deliver, the documentation required under subparagraph 5. shall constitute failure to acquire or deliver a pedigree paper under s. 499.0051. Forgery by the manufacturer, the recipient, or the wholesale distributor of the documentation required to be acquired or delivered under subparagraph 5. shall constitute forgery of a pedigree paper under s. 499.0051. 7. The department may, by rule, specify alternatives to compliance with subparagraph 1. for a prescription drug in the inventory of a permitted prescription~~

~~drug wholesaler 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.~~

(7)~~(e)~~ Each wholesale distributor, except for a manufacturer, shall annually provide the department with a written list of all wholesale distributors and manufacturers from whom the wholesale distributor purchases prescription drugs. A wholesale distributor, except a manufacturer, shall notify the department not later than 10 days after any change to either list. 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.

~~(f)1. This paragraph applies only to 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, if the affiliated group:~~

~~a. Discloses to the department the names of all its members; and~~

~~b. Agrees in writing to provide records on prescription drug purchases by members of the affiliated group not later than 48 hours after the department requests such records, regardless of the location where the records are stored.~~

~~2. Each warehouse within the affiliated group must comply with all applicable federal and state drug wholesale permit requirements and must purchase, receive, hold, and distribute prescription drugs only to a retail pharmacy or warehouse within the affiliated group. Such a warehouse is exempt from providing a~~

~~pedigree paper in accordance with paragraph (d) to its affiliated group member warehouse or retail pharmacy, provided that:~~

~~a. Any affiliated group member that purchases or receives a prescription drug from outside the affiliated group must receive a pedigree paper if the prescription drug is distributed in or into this state and a pedigree paper is required under this section and must authenticate the documentation as required in subsection (4), regardless of whether the affiliated group member is directly subject to regulation under this chapter; and~~

~~b. The affiliated group makes available to the department on request all records related to the purchase or acquisition of prescription drugs by members of the affiliated group, regardless of the location where the records are stored, if the prescription drugs were distributed in or into this state.~~

~~3. If a repackager repackages prescription drugs solely for distribution to its affiliated group members for the exclusive distribution to and among retail pharmacies that are members of the affiliated group to which the repackager is a member:~~

~~a. The repackager must:~~

~~(I) In lieu of the written statement required by paragraph (d), for all repackaged prescription drugs distributed in or into this state, state in writing under oath with each distribution of a repackaged prescription drug to an affiliated group member warehouse or repackager: "All repackaged prescription drugs are purchased by the affiliated group directly from the manufacturer or from a prescription drug wholesaler that purchased the prescription drugs directly from the manufacturer.";~~

~~(II) Purchase all prescription drugs it repackages:~~

~~(A) Directly from the manufacturer; or~~

~~(B) From a prescription drug wholesaler that purchased the prescription drugs directly from the manufacturer; and~~

~~(III) Maintain records in accordance with this section to document that it purchased the prescription drugs directly from the manufacturer or that its prescription drug wholesale supplier purchased the prescription drugs directly from the manufacturer.~~

~~b. All members of the affiliated group must provide to agents of the department on request records of purchases by all members of the affiliated group of prescription drugs that have been repackaged, regardless of the location where the records are stored or where the repackager is located.~~

(8) ~~(7)~~ WRITTEN POLICIES AND PROCEDURES.--Wholesale ~~drug~~ distributors must establish, maintain, and adhere to written policies and procedures, which must be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale ~~drug~~ distributors must include in their written policies and procedures:

(a) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if the deviation is temporary and appropriate.

(b) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure must be adequate to deal with recalls and withdrawals due to:

1. Any action initiated at the request of the Food and Drug Administration or any other federal, state, or local law enforcement or other government agency, including the department.

2. Any voluntary action by the manufacturer or repackager to remove defective or potentially defective drugs from the market; or

3. Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

(c) A procedure to ensure that wholesale ~~drug~~ distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility if a strike, fire, flood, or other natural disaster, or a local, state, or national emergency, occurs.

(d) A procedure to ensure that any outdated prescription drugs are segregated from other drugs and either returned to the manufacturer or repackager or destroyed. This procedure must provide for written documentation of the disposition of outdated prescription drugs. This documentation must be maintained for 2 years after disposition of the outdated drugs.

(9) ~~(8)~~ RESPONSIBLE PERSONS.--Wholesale ~~drug~~ distributors must establish and maintain lists of officers, directors, managers, designated representatives, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(10) ~~(9)~~ COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAW.--A wholesale ~~drug~~ distributor must operate in compliance with applicable federal, state, and local laws and regulations.

(a) A wholesale ~~drug~~ distributor must allow the department and authorized federal, state, and local officials to enter and inspect its premises and delivery vehicles, and to audit its records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(b) A wholesale ~~drug~~ distributor that deals in controlled substances must register with the Drug Enforcement Administration and must comply with all applicable state, local, and federal laws. A wholesale ~~drug~~ distributor that distributes any substance controlled under chapter 893 must notify the department when registering with the Drug Enforcement Administration pursuant to that chapter and must provide the department with its DEA number.

(11) ~~(10)~~ SALVAGING AND REPROCESSING.--A wholesale ~~drug~~ distributor is subject to any applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing.

(12) ~~(11)~~ SHIPPING AND TRANSPORTATION.--The person responsible for shipment and transportation of a prescription drug in a wholesale distribution may use a common carrier; its own vehicle or employee acting within the scope of employment if authorized under s. 499.03 for the possession of prescription drugs in this state; or, in the case of a prescription drug intended for domestic distribution, an independent contractor who must be the agent of the authorized seller or recipient responsible for shipping and transportation as set forth in a written contract between the parties. A person selling a prescription drug for export must obtain documentation, such as a validated airway bill, bill of lading, or other appropriate documentation that the prescription drug was exported. A person

responsible for shipping or transporting prescription drugs is not required to maintain documentation from a common carrier that the designated recipient received the prescription drugs; however, the person must obtain such documentation from the common carrier and make it available to the department upon request of the department.

(13) ~~(12)~~ DUE DILIGENCE OF SUPPLIERS.--Prior to purchasing any prescription drugs from another wholesale ~~drug~~ distributor, a prescription drug wholesale distributor ~~wholesaler~~, an out-of-state prescription drug wholesale distributor ~~wholesaler~~, or a prescription drug repackager must:

(a) Enter an agreement with the selling wholesale ~~drug~~ distributor by which the selling wholesale ~~drug~~ distributor will indemnify the purchasing wholesale ~~drug~~ distributor for any loss caused to the purchasing wholesale ~~drug~~ distributor related to the purchase of drugs from the selling wholesale ~~drug~~ distributor which are determined to be counterfeit or to have been distributed in violation of any federal or state law governing the distribution of drugs.

(b) Determine that the selling wholesale ~~drug~~ distributor has insurance coverage of not less than the greater of 1 percent of the amount of total dollar volume of the prescription drug sales reported to the department under s. 499.012(8) ~~(3)~~(g) or $500,000; however the coverage need not exceed $2 million.

(c) Obtain information from the selling wholesale ~~drug~~ distributor, including the length of time the selling wholesale ~~drug~~ distributor has been licensed in this state, a copy of the selling wholesale ~~drug~~ distributor's licenses or permits, and background information concerning the ownership of the selling

wholesale ~~drug~~ distributor, including the experience of the wholesale distributor in the wholesale distribution of prescription drugs.

(d) Verify that the selling wholesale ~~drug~~ distributor's Florida permit is valid.

(e) Inspect the selling wholesale ~~drug~~ distributor's licensed establishment to document that it has a policies and procedures manual relating to the distribution of drugs, the appropriate temperature controlled environment for drugs requiring temperature control, an alarm system, appropriate access restrictions, and procedures to ensure that records related to the wholesale distribution of prescription drugs are maintained as required by law:

1. Before purchasing any drug from the wholesale ~~drug~~ distributor, and at least once each subsequent year; or

2. Before purchasing any drug from the wholesale ~~drug~~ distributor, and each subsequent year obtain a complete copy of the most recent inspection report for the establishment which was prepared by the department or the regulatory authority responsible for wholesale ~~drug~~ distributors in the state in which the establishment is located.

Section 14. Section 499.012111, Florida Statutes, is created to read:

499.012111 Pedigree Paper.—

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

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

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

1. The following statement: "This wholesale distributor purchased the specific unit of the prescription drug directly from the manufacturer."

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

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

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

The wholesale distributor must also maintain and make available to the department, upon request, the point of origin of the prescription drugs, including intracompany transfers; the date of the shipment from the manufacturer to the wholesale distributor; the lot numbers of such drugs; and the invoice numbers from the manufacturer.

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

1. Quantity, dosage form, and strength of the prescription drugs.

2. Lot numbers of the prescription drugs.

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

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

5. An invoice number, a shipping document number, or another number uniquely identifying the transaction.

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

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

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

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

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

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

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

(d) A drop shipment, provided that:

1. The wholesale distributor delivers to the recipient of the prescription drug, within 14 days after the shipment notification from the manufacturer, an invoice and the following sworn statement: "This wholesale distributor purchased the specific unit of the prescription drug listed on the invoice directly from the manufacturer, and the specific unit of prescription drug was shipped by the manufacturer directly to a person authorized by law administer or dispense the legend drug, as defined in s. 465.003, Florida Statutes, or a member of an

affiliated group, Florida Statutes, with the exception of a repackager." The invoice must contain a unique cross-reference to the shipping document sent by the manufacturer to the recipient of the prescription drug.

2. The manufacturer of the prescription drug shipped directly to the recipient provides and the recipient of the prescription drug acquires, within 14 days after receipt of the prescription drug, a shipping document from the manufacturer that contains, at a minimum:

a. The name and address of the manufacturer, including the point of origin of the shipment, and the names and addresses of the wholesaler and the purchaser.

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

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

d. The date of the shipment from the manufacturer.

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

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

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

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

1. Any affiliated group member that purchases or receives a prescription drug from outside the affiliated group must receive a pedigree paper if the prescription drug is distributed in or into this state and a pedigree paper is required under this section and must authenticate the documentation as required in subsection (4) of s. 499.0121, regardless of whether the affiliated group member is directly subject to regulation under this chapter; and

2. The affiliated group makes available, within 48 hours, to the department on request to one or more of its members all records related to the purchase or acquisition of prescription drugs by members of the affiliated group, regardless of the location where the records are stored, if the prescription drugs were distributed in or into this state.

(f) The repackaging of prescription drugs by a repackager solely for distribution to its affiliated group members for the exclusive distribution to and among retail pharmacies that are members of the affiliated group to which the repackager is a member.

1. The repackager must:

a. For all repackaged prescription drugs distributed in or into this state, state in writing under oath with each

distribution of a repackaged prescription drug to an affiliated group member warehouse or repackager: "All repackaged prescription drugs are purchased by the affiliated group directly from the manufacturer or from a prescription drug wholesale distributor that purchased the prescription drugs directly from the manufacturer.";

b. Purchase all prescription drugs it repackages:

(I) Directly from the manufacturer; or

(II) From a prescription drug wholesaler that purchased the prescription drugs directly from the manufacturer; and

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

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

Section 15. Section 499.0122, Florida Statutes, is repealed.

Section 16. Section 499.013, Florida Statutes, is repealed.

Section 17. Section 499.015, Florida Statutes, is 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(32) ~~(28)~~, any person who

manufactures, packages, repackages, labels, or relabels a drug, device, or cosmetic in this state must register such drug, 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, device, or cosmetic at the time of registration.

(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.

(2) The department may require the submission of a catalog and specimens of labels at the time of application for registration of drugs, devices, and cosmetics packaged and prepared in compliance with the federal act, which submission constitutes a satisfactory compliance for registration of the products. With respect to all other drugs, devices, and cosmetics, the department may require the submission of a catalog and specimens of labels at the time of application for registration, but the registration will not become effective until the department has examined and approved the label of the drug, device, or cosmetic product. This approval or denial must include written notification to the manufacturer.

(3) Except for those persons exempted from the definition of manufacturer in s. 499.003(32) ~~(28)~~, 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,

device, or cosmetic product to seizure and condemnation as provided in ss. 499.062-499.064, and subjects such person to the penalties and remedies provided in this part ~~ss. 499.001-499.081~~.

(4) Unless a registration is renewed, it expires 2 years after the last day of the month in which it was issued. 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 ~~ss. 499.001-499.081~~ until he or she complies with the requirements of this section.

(5) A product regulated under this section which is not included in the biennial registration may not be sold until it is registered and complies with this section.

(6) The department may issue a certificate of free sale for any product that is required to be registered under this part ~~ss. 499.001-499.081~~.

(7) A product registration is valid only for the company named on the registration and located at the address on the registration. A person whose product is registered by the department under this section must notify the department before any change in the name or address of the establishment to which the product is registered. If a person whose product is registered ceases conducting business, the person must notify the department before closing the business.

(8) Notwithstanding any requirements set forth in this part ~~ss. 499.001-499.081~~, a manufacturer of medical devices that is

registered with the federal Food and Drug Administration is exempt from this section and s. 499.041(6) if:

(a) The manufacturer's medical devices are approved for marketing by, or listed with the federal Food and Drug Administration in accordance with federal law for commercial distribution; or

(b) The manufacturer subcontracts with a manufacturer of medical devices to manufacture components of such devices.

(9) However, the manufacturer must submit evidence of such registration, listing, or approval with its initial application for a permit to do business in this state, as required in s. 499.013 and any changes to such information previously submitted at the time of renewal of the permit. Evidence of approval, listing, and registration by the federal Food and Drug Administration must include:

(a) For Class II devices, a copy of the pre-market notification letter (510K);

(b) For Class III devices, a Federal Drug Administration pre-market approval number;

(c) For a manufacturer who subcontracts with a manufacturer of medical devices to manufacture components of such devices, a Federal Drug Administration registration number; or

(d) For a manufacturer of medical devices whose devices are exempt from pre-market approval by the Federal Drug Administration, a Federal Drug Administration registration number.

Section 18. Section 499.023, Florida Statutes, is amended to read:

499.023 New drugs; sale, manufacture, repackaging, distribution.--A person may not sell, offer for sale, hold for sale, manufacture, repackage, distribute, or give away any new drug unless an approved application has become effective under s. 505 of the federal act or unless otherwise permitted by the Secretary of the United States Department of Health and Human Services for shipment in interstate commerce.

Section 19. Section 499.024, Florida Statutes, is amended to read:

499.024 Drug product classification.--The State Surgeon General shall adopt rules to classify drug products intended for use by humans which the United States Food and Drug Administration has not classified in the federal act or the Code of Federal Regulations.

(1) Drug products must be classified as proprietary, prescription, or investigational drugs.

(2) If a product is distributed without required labeling, it is misbranded while held for sale.

(3) Any product that falls under the definition of drug in ~~definition,~~ s. 499.003(19) ~~(17),~~ may be classified under the authority of this section. This section does not subject portable emergency oxygen inhalators to classification; however, this section does not exempt any person from ss. 499.01 and 499.015.

(4) Any product classified under the authority of this section reverts to the federal classification, if different, upon the federal regulation or act becoming effective.

(5) The department may by rule reclassify drugs subject to this part ~~ss. 499.001-499.081~~ when such classification action is necessary to protect the public health.

(6) The department may adopt rules that exempt from any labeling or packaging requirements of this part ~~ss. 499.001-499.081~~ drugs classified under this section if those requirements are not necessary to protect the public health.

Section 20. Section 499.025, Florida Statutes, is amended to read:

499.025 Drug products in finished, solid, oral dosage form; identification requirements.--

(1) A drug product in finished, solid, oral dosage form for which a prescription is required by federal or state law may not be manufactured or distributed within this state unless it is clearly and prominently marked or imprinted with an individual symbol, number, company name, words, letters, marking, or national drug code, or any combination thereof, that identifies the drug product and the manufacturer or distributor of the drug product which has the ability to respond to requests for information regarding the drug product.

(2) A manufacturer or distributor must make available to the department on request descriptive material that identifies each current imprint used by the manufacturer.

(3) The department, upon application by a manufacturer, may exempt a particular drug product from the requirements of subsection (1) on the ground that imprinting is not feasible because of the size, texture, or other unique characteristic of the drug product.

(4) This section does not apply to drug products compounded by a pharmacist licensed under chapter 465 in a pharmacy operating under a permit issued by the Board of Pharmacy.

(5) The department shall adopt rules for implementing this section.

Section 21. Section 499.028, Florida Statutes, is amended to read:

499.028 Drug samples or complimentary drugs; starter packs; permits to distribute.--

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

(a) "Drug sample," or "complimentary drug," means a human prescription drug that is labeled "sample," "not to be sold," "complimentary," or other words to that effect, that is provided as a courtesy, that is not intended to be sold, and that is intended to promote the sale of the drug.

(b) "Starter packs," also known as "stock samples," "trade packages," "initial dose packs," or "starter stocks," means human prescription drugs that are generally distributed without charge by manufacturers or distributors to pharmacies to be placed in stock and sold at retail. Although starter packs are generally given without charge to the pharmacy, they are not intended to be a free sample to the consumer nor are they labeled as such. Starter packs are subject to regulation as prescription drugs under the Florida Drug and Cosmetic Act in the same manner as stock shipments of prescription drugs. Starter packs are not drug samples.

(2) A person may not sell, purchase, or trade or offer to sell, purchase, or trade any drug sample. An officer or executive of a drug manufacturer or distributor is not subject to criminal liability solely because of a sale, purchase, trade, or offer to sell, purchase, or trade of a drug sample in violation of this subsection by other employees of the manufacturer or distributor.

(3) Except as provided in this section, a representative of a drug manufacturer or distributor may not distribute any drug sample.

(a) The manufacturer or distributor of a human prescription drug may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed to prescribe such drugs or, at the request of a licensed practitioner, to pharmacies of hospitals or to pharmacies of other health care entities. Such a distribution of drug samples may only be made:

1. In response to a written request for drug samples made on a form that meets the requirements of paragraph (b); and

2. Under a system that requires the recipient of the drug sample to execute a written receipt for the drug sample upon its delivery and to return the receipt to the manufacturer or distributor.

(b) A written request for a drug sample that is required by this section must contain:

1. The name, address, professional designation, and signature of the practitioner who makes the request;

2. The name, strength, and dosage form of the drug sample requested and the quantity requested;

3. The name of the manufacturer of the drug sample requested; and

4. The date of the request.

(c) Each drug manufacturer or distributor that makes distributions by mail or common carrier under this paragraph must maintain, for a period of 3 years, the request forms submitted for such distributions and the receipts submitted for such

distributions and must maintain a record of distributions of drug samples which identifies the drugs distributed and the recipients of the distributions. Forms, receipts, and records required to be maintained under this paragraph must be made available by the drug manufacturer or distributor to the department for its review and inspection.

(d) The manufacturer or distributor of a drug subject to paragraph (1)(a) may, by means other than mail or common carrier, distribute drug samples only if the manufacturer or distributor makes the distributions in accordance with paragraph (e) and carries out the activities described in subsections (4)-(9).

(e) Drug samples may only be distributed:

1. To a practitioner authorized by law to prescribe such drugs if the practitioner makes a written request for the drug samples; or

2. At the written request of such a practitioner, to pharmacies of hospitals or to pharmacies of other health care entities. The written request for drug samples must be made on a form that contains the practitioner's name, address, and professional designation, the name, strength, and dosage form of the drug sample requested, the quantity of drug samples requested, the name of the manufacturer or distributor of the drug sample, the date of the request, and the signature of the practitioner that makes the request.

(4) A drug manufacturer or distributor must store drug samples under the conditions described on their labels that will maintain the stability, integrity, and effectiveness of the drug samples and will assure that the drug samples remain free of contamination, deterioration, and adulteration.

(5) A drug manufacturer or distributor must conduct, at least annually, a complete and accurate inventory of all drug samples in the possession of representatives of the manufacturer or distributor. A drug manufacturer or distributor must maintain lists of the names and addresses of each of its representatives who distribute drug samples and of the sites where drug samples are stored. A drug manufacturer or distributor must maintain for at least 3 years records of all drug samples distributed, destroyed, or returned to the manufacturer or distributor, of all inventories maintained under this subsection, of all thefts or significant losses of drug samples, and of all requests made under subparagraph 1. for drug samples. The drug manufacturer or distributor must make available to the department upon request any record or list maintained under this subsection. The department shall provide to the Department of Business and Professional Regulation the names of those practitioners who have received an excessive or inappropriate quantity of such drugs.

(6) A drug manufacturer or distributor must notify the department of any significant loss of drug samples and any known theft of drug samples.

(7) A drug manufacturer or distributor must report to the department any conviction of itself or of its assigns, agents, employees, or representatives for a violation of s. 503(c)(1) of the federal act or of this part ~~ss. 499.001-499.081~~ because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample.

(8) Drug manufacturers or distributors must provide to the department the name and telephone number of the individual

responsible for responding to a request for information regarding drug samples.

(9) All out-of-date drug samples must be returned to the manufacturer or distributor of that drug sample.

(10) A manufacturer or distributor may not directly or through its agents, employees, or independent contractors, hold, distribute, or otherwise dispose of any complimentary drugs or drug samples in this state without first obtaining a complimentary drug distributor permit pursuant to this section.

(11)(a) Application for a permit by a manufacturer or distributor to hold, distribute, or otherwise dispose of drugs pursuant to this section must be made on a form prescribed by the department and must be accompanied by an application fee in an amount not exceeding $250 per year, as is determined by the department.

(b) A permit issued under this section expires 2 years after the date of issuance, unless sooner suspended or revoked.

(c) A permit is renewable biennially upon the filing of an application for renewal and the payment of a renewal fee of not more than $250 per year, as determined by the department, if the applicant meets the requirements established by this section and the rules adopted under this section.

(12) The department may suspend or revoke a permit issued under this section, after giving notice and an opportunity to be heard pursuant to chapter 120, when:

(a) Such permit was obtained by misrepresentation or fraud or through a mistake of the department.

(b) The holder of the permit has distributed or disposed of any prescription ~~legend~~ drug, directly or through its agents,

employees, or independent contractors, to any person not authorized to possess such drug.

(c) The holder of the permit, or its agents, employees, or independent contractors, has distributed or possessed any prescription ~~legend~~ drug except in the usual course of its business.

(d) The holder of the permit, or its agents, employees, or independent contractors, has distributed any prescription ~~legend~~ drug that is misbranded or adulterated under this part ~~ss. 499.001-499.081~~.

(e) The holder of the permit, or its agents, employees, or independent contractors, has distributed any prescription ~~legend~~ drug without written request, when a written request is required by this section.

(f) The holder of the permit has in its employ, or uses as agent or independent contractor for the purpose of distributing or disposing of drugs, any person who has:

1. Violated the requirements of this section or any rule adopted under this section.

2. Been convicted in any of the courts of this state, the United States, or any other state of a felony or any other crime involving moral turpitude or involving those drugs named or described in chapter 893.

(13) The department may, pursuant to chapter 120, impose an administrative fine, not to exceed $5,000 per violation per day, for the violation of this section or rules adopted under this section. Each day such violation continues constitutes a separate violation, and each such separate violation is subject to a separate fine. All amounts collected under this section shall be

deposited into the Drug, Device, and Cosmetic Trust Fund. In determining the amount of fine to be levied for a violation, the following factors must be considered:

(a) The severity of the violation.

(b) Any actions taken by the permittee to correct the violation or to remedy complaints.

(c) Any previous violations.

(14) Chapter 893 applies to all drug samples that are controlled substances.

(15) A person may not possess a prescription drug sample unless:

(a) The drug sample was prescribed to her or him as evidenced by the label required in s. 465.0276(5).

(b) She or he is the employee of a complimentary drug distributor that holds a permit issued under this part ~~ss. 499.001-499.081~~.

(c) She or he is a person to whom prescription drug samples may be distributed pursuant to this section.

(d) He or she is an officer or employee of a federal, state, or local government acting within the scope of his or her employment.

Section 22. Section 499.029, Florida Statutes, is amended to read:

499.029 Cancer Drug Donation Program.--

(1) This section may be cited as the "Cancer Drug Donation Program Act."

(2) There is created a Cancer Drug Donation Program within the department ~~of Health~~ for the purpose of authorizing and

facilitating the donation of cancer drugs and supplies to eligible patients.

(3) As used in this section:

(a) "Cancer drug" means a prescription drug that has been approved under s. 505 of the federal Food, Drug, and Cosmetic Act and is used to treat cancer or its side effects or is used to treat the side effects of a prescription drug used to treat cancer or its side effects. "Cancer drug" does not include a substance listed in Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03.

(b) "Closed drug delivery system" means a system in which the actual control of the unit-dose medication package is maintained by the facility rather than by the individual patient.

~~(c) "Department" means the Department of Health.~~

(c) ~~(d)~~ "Donor" means a patient or patient representative who donates cancer drugs or supplies needed to administer cancer drugs that have been maintained within a closed drug delivery system; health care facilities, nursing homes, hospices, or hospitals with closed drug delivery systems; or pharmacies, drug manufacturers, medical device manufacturers or suppliers, or wholesalers of drugs or supplies, in accordance with this section. "Donor" includes a physician licensed under chapter 458 or chapter 459 who receives cancer drugs or supplies directly from a drug manufacturer, drug wholesaler, or pharmacy.

(d) ~~(e)~~ "Eligible patient" means a person who the department determines is eligible to receive cancer drugs from the program.

(e) ~~(k)~~ "Participant facility" means a class II hospital pharmacy that has elected to participate in the program and that

accepts donated cancer drugs and supplies under the rules adopted by the department for the program.

~~(o) "Prescription drug" means a drug as defined in s. 465.003(8).~~

(f) ~~(p)~~ "Program" means the Cancer Drug Donation Program created by this section.

(g) ~~(q)~~ "Supplies" means any supplies used in the administration of a cancer drug.

(4) Any donor may donate cancer drugs or supplies to a participant facility that elects to participate in the program and meets criteria established by the department for such participation. Cancer drugs or supplies may not be donated to a specific cancer patient, and donated drugs or supplies may not be resold by the program. Cancer drugs billed to and paid for by Medicaid in long-term care facilities that are eligible for return to stock under federal Medicaid regulations shall be credited to Medicaid and are not eligible for donation under the program. A participant facility may provide dispensing and consulting services to individuals who are not patients of the hospital.

(5) The cancer drugs or supplies donated to the program may be prescribed only by a prescribing practitioner for use by an eligible patient and may be dispensed only by a pharmacist.

(6)(a) A cancer drug may only be accepted or dispensed under the program if the drug is in its original, unopened, sealed container, or in a tamper-evident unit-dose packaging, except that a cancer drug packaged in single-unit doses may be accepted and dispensed if the outside packaging is opened but the

single-unit-dose packaging is unopened with tamper-resistant packaging intact.

(b) A cancer drug may not be accepted or dispensed under the program if the drug bears an expiration date that is less than 6 months after the date the drug was donated or if the drug appears to have been tampered with or mislabeled as determined in paragraph (c).

(c) Prior to being dispensed to an eligible patient, the cancer drug or supplies donated under the program shall be inspected by a pharmacist to determine that the drug and supplies do not appear to have been tampered with or mislabeled.

(d) A dispenser of donated cancer drugs or supplies may not submit a claim or otherwise seek reimbursement from any public or private third-party payor for donated cancer drugs or supplies dispensed to any patient under the program, and a public or private third-party payor is not required to provide reimbursement to a dispenser for donated cancer drugs or supplies dispensed to any patient under the program.

(7)(a) A donation of cancer drugs or supplies shall be made only at a participant facility. A participant facility may decline to accept a donation. A participant facility that accepts donated cancer drugs or supplies under the program shall comply with all applicable provisions of state and federal law relating to the storage and dispensing of the donated cancer drugs or supplies.

(b) A participant facility that voluntarily takes part in the program may charge a handling fee sufficient to cover the cost of preparation and dispensing of cancer drugs or supplies

under the program. The fee shall be established in rules adopted by the department.

(8) The department, upon the recommendation of the Board of Pharmacy, shall adopt rules to carry out the provisions of this section. Initial rules under this section shall be adopted no later than 90 days after the effective date of this act. The rules shall include, but not be limited to:

(a) Eligibility criteria, including a method to determine priority of eligible patients under the program.

(b) Standards and procedures for participant facilities that accept, store, distribute, or dispense donated cancer drugs or supplies.

(c) Necessary forms for administration of the program, including, but not limited to, forms for use by entities that donate, accept, distribute, or dispense cancer drugs or supplies under the program.

(d) The maximum handling fee that may be charged by a participant facility that accepts and distributes or dispenses donated cancer drugs or supplies.

(e) Categories of cancer drugs and supplies that the program will accept for dispensing; however, the department may exclude any drug based on its therapeutic effectiveness or high potential for abuse or diversion.

(f) Maintenance and distribution of the participant facility registry established in subsection (10).

(9) A person who is eligible to receive cancer drugs or supplies under the state Medicaid program or under any other prescription drug program funded in whole or in part by the state, by any other prescription drug program funded in whole or

in part by the Federal Government, or by any other prescription drug program offered by a third-party insurer, unless benefits have been exhausted, or a certain cancer drug or supply is not covered by the prescription drug program, is ineligible to participate in the program created under this section.

(10) The department shall establish and maintain a participant facility registry for the program. The participant facility registry shall include the participant facility's name, address, and telephone number. The department shall make the participant facility registry available on the department's website to any donor wishing to donate cancer drugs or supplies to the program. The department's website shall also contain links to cancer drug manufacturers that offer drug assistance programs or free medication.

(11) Any donor of cancer drugs or supplies, or any participant in the program, who exercises reasonable care in donating, accepting, distributing, or dispensing cancer drugs or supplies under the program and the rules adopted under this section shall be immune from civil or criminal liability and from professional disciplinary action of any kind for any injury, death, or loss to person or property relating to such activities.

(12) A pharmaceutical manufacturer is not liable for any claim or injury arising from the transfer of any cancer drug under this section, including, but not limited to, liability for failure to transfer or communicate product or consumer information regarding the transferred drug, as well as the expiration date of the transferred drug.

(13) If any conflict exists between the provisions in this section and the provisions in this chapter or chapter 465, the

provisions in this section shall control the operation of the Cancer Drug Donation Program.

Section 23. 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(33) ~~(29)~~, or prescription ~~legend~~ drug as defined in s. 499.003(44) ~~(25)~~, 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 ~~legend~~ 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 ~~legend~~ 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 that ~~ss. 499.001-499.081 which~~ authorizes that person to possess prescription drugs.

(2) The possession of a drug under subsection (1) by any person not exempted under this section, which drug is not properly labeled to indicate that possession is by a valid prescription of a practitioner licensed by law to prescribe such drug, is prima facie evidence that such possession is unlawful.

(3) Violation of subsection (1) is a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083, except that possession with the intent to sell, dispense, or deliver is a third degree felony, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(4) The department may adopt rules regarding persons engaged in lawful teaching, research, or testing who possess prescription drugs and may issue letters of exemption to facilitate the lawful possession of prescription drugs under this section.

Section 24. Section 499.032, Florida Statutes, is amended to read:

499.032 Phenylalanine; prescription required.--

Phenylalanine restricted formula is declared to be a prescription ~~legend~~ drug and may be dispensed only upon the prescription of a

practitioner authorized by law to prescribe prescription ~~medicinal~~ drugs.

Section 25. Section 499.033, Florida Statutes, is amended to read:

499.033 Ephedrine; prescription required.--Ephedrine is declared to be a prescription drug.

(1) Except as provided in subsection (2), any product that contains any quantity of ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine may be dispensed only upon the prescription of a duly licensed practitioner authorized by the laws of the state to prescribe prescription ~~medicinal~~ drugs.

(2) A product containing ephedrine described in paragraphs (a)-(e) is exempt from subsection (1) if it may lawfully be sold over the counter without a prescription under the federal act; is labeled and marketed in a manner consistent with the pertinent United States Food and Drug Administration Over-the-Counter Tentative Final or Final Monograph; and is manufactured and distributed for legitimate medicinal use in a manner that reduces or eliminates the likelihood of abuse, when considered in the context with: the package sizes and the manner of packaging of the drug product; the name and labeling of the product; the manner of distribution, advertising, and promotion of the product; the duration, scope, health significance, and societal cost of abuse of the particular product; the need to provide medically important ephedrine-containing therapies to the public for United States Food and Drug Administration approved indications on an unrestricted, over-the-counter basis; and other

facts as may be relevant to and consistent with public health and safety.

(a) Solid oral dosage forms that combine active ingredients in the following ranges for each dosage unit:

1. Theophylline (100-130mg), ephedrine (12.5-24mg).

2. Theophylline (60-100mg), ephedrine (12.5-24mg), guaifenesin (200-400mg).

3. Ephedrine (12.5-25mg), guaifenesin (200-400mg).

4. Phenobarbital (not greater than 8mg) in combination with the ingredients of subparagraph 1. or subparagraph 2.

(b) Liquid oral dosage forms that combine active ingredients in the following ranges for each (5ml) dose:

1. Theophylline (not greater than 45mg), ephedrine (not greater than 36mg), guaifenesin (not greater than 100mg), phenobarbital (not greater than 12mg).

2. Phenylephrine (not greater than 5mg), ephedrine (not greater than 5mg), chlorpheniramine (not greater than 2mg), dextromethorphan (not greater than 10mg), ammonium chloride (not greater than 40mg), ipecac fluid extract (not greater than 0.005ml).

(c) Anorectal preparations containing less than 5 percent ephedrine.

(d) Nasal decongestant compounds, mixtures, or preparations containing 0.5 percent or less ephedrine.

(e) Any drug product containing ephedrine that is marketed pursuant to an approved new drug application or legal equivalent under the federal act.

(3) The department may implement this section by rule.

Section 26. Section 499.035, Florida Statutes, is amended to read:

499.035 Dimethyl sulfoxide (DMSO); labeling and advertising.--

(1) Dimethyl sulfoxide (DMSO) not approved for drug use must be clearly marked in at least 12-point boldfaced type: "May be unsafe. Not approved for human use."

(2) All advertisements for the sale of dimethyl sulfoxide (DMSO) not approved for drug use must contain, within the advertisement and in bold lettering, the following statement: "Warning. May be unsafe. Not approved for human use."

Section 27. Section 499.039, Florida Statutes, is amended to read:

499.039 Sale, distribution, or transfer of harmful chemical substances; penalties; authority for enforcement.--It is unlawful for a person to sell, deliver, or give to a person under the age of 18 years any compound, liquid, or chemical containing toluol, hexane, trichloroethylene, acetone, toluene, ethyl acetate, methyl ethyl ketone, trichloroethane, isopropanol, methyl isobutyl ketone, ethylene glycol monomethyl ether acetate, cyclohexanone, nitrous oxide, diethyl ether, alkyl nitrites (butyl nitrite), or any similar substance for the purpose of inducing by breathing, inhaling, or ingesting a condition of intoxication or which is intended to distort or disturb the auditory, visual, or other physical or mental processes.

(1) On the first violation of this section, the department may issue a warning according to s. 499.071, if the violation has not caused temporary or permanent physical or mental injury to the user.

(2) If any violation of this section has caused temporary or permanent physical or mental injury to the user, the department may, pursuant to chapter 120, impose fines according to s. 499.066 and may report any violation to the appropriate state attorney for prosecution.

(3) The department ~~of Health~~ shall adopt rules to implement this section.

Section 28. Section 499.04, Florida Statutes, is amended to read:

499.04 Fee authority.--The department may collect fees for all drug, device, and cosmetic applications, permits, product registrations, and free-sale certificates. The total amount of fees collected from all permits, applications, product registrations, and free-sale certificates must be adequate to fund the expenses incurred by the department in carrying out this part ~~ss. 499.001-499.081~~. The department shall, by rule, establish a schedule of fees that are within the ranges provided in this section and shall adjust those fees from time to time based on the costs associated with administering this part ~~ss. 499.001-499.081~~. The fees are payable to the department to be deposited into the Florida Drug, Device, and Cosmetic Trust Fund for the sole purpose of carrying out the provisions of this part ~~ss. 499.001-499.081~~.

Section 29. Section 499.041, Florida Statutes, is amended to read:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(5) In addition to the fee charged for a permit required by this part ~~ss. 499.001-499.081~~, the department shall assess applicants an initial application fee of $150 for each new permit issued by the department which requires an onsite inspection.

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

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

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

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

(10) The department shall assess other fees as provided in this part ~~ss. 499.001-499.081~~.

Section 30. Section 499.05, Florida Statutes, is amended, subsection (3) of section 499.013, Florida Statutes, is renumbered as paragraph (1)(k) of that section and amended, paragraph (2)(b) of section 499.0122, Florida Statutes, is renumbered as paragraph (1)(l) of that section and amended, and subsection (12) of section 499.012, Florida Statutes, is renumbered as subsection (1)(m) of that section and amended, to read:

499.05 Rules.--

(1) The department shall adopt rules to implement and enforce this part ~~ss. 499.001-499.081~~ with respect to:

(a) The definition of terms used in this part ~~ss. 499.001-499.081~~, and used in the rules adopted under this part ~~ss. 499.001-499.081~~, when the use of the term is not its usual and ordinary meaning.

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

(c) The establishment of fees authorized in this part ~~ss. 499.001-499.081~~.

(d) The identification of permits that require an initial application and onsite inspection or other prerequisites for permitting which demonstrate that the establishment and person are in compliance with the requirements of this part ~~ss. 499.001-499.081~~.

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

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

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

(h) The establishment of a range of penalties, as provided in s. 499.066 ~~499.006~~; requirements for notifying persons of the potential impact of a violation of this part ~~ss. 499.001-499.081~~; and a process for the uncontested settlement of alleged violations.

(i) Additional conditions that qualify as an emergency medical reason under s. 499.003(55)(b)2. ~~499.012(1)(a)2.b.~~

(j) Procedures and forms relating to the pedigree paper requirement of s. 499.012111.

(k) ~~(3) The department may adopt such rules as are necessary for~~ The protection of the public health, safety, and welfare regarding good manufacturing practices that manufacturers and repackagers must follow to ensure the safety of the products.

(l) ~~(b) The department shall adopt rules relating to~~ Information required from each retail establishment pursuant to s. 499.012(3) ~~499.01(4)~~, including requirements for prescriptions or orders.

(m) ~~(12) The department may adopt rules governing~~ The recordkeeping, storage, and handling with respect to each of the distributions of prescription drugs specified in ~~sub~~paragraphs (55)(a)-(d) of s. 499.003 ~~(1)(a)1.-4~~.

(n) Alternatives to compliance with s. 499.012111 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.

(2) With respect to products in interstate commerce, those rules must not be inconsistent with rules and regulations of federal agencies unless specifically otherwise directed by the Legislature.

(3) The department shall adopt rules regulating recordkeeping for and the storage, handling, and distribution of medical devices and over-the-counter drugs to protect the public from adulterated products.

Section 31. Section 499.051, Florida Statutes, is amended to read:

499.051 Inspections and investigations.--

(1) The agents of the department ~~of Health~~ and of the Department of Law Enforcement, after they present proper identification, may inspect, monitor, and investigate any establishment permitted pursuant to this part ~~ss. 499.001-499.081~~ during business hours for the purpose of enforcing this part ~~ss. 499.001-499.081~~, chapters 465, 501, and 893, and the rules of the department that protect the public health, safety, and welfare.

(2) In addition to the authority set forth in subsection (1), the department and any duly designated officer or employee of the department may enter and inspect any other establishment for the purpose of determining compliance with this part ~~ss. 499.001-499.081~~ and rules adopted under those sections regarding any drug, device, or cosmetic product.

(3) Any application for a permit or product registration or for renewal of such permit or registration made pursuant to this part ~~ss. 499.001-499.081~~ and rules adopted under those sections

constitutes permission for any entry or inspection of the premises in order to verify compliance with those sections and rules; to discover, investigate, and determine the existence of compliance; or to elicit, receive, respond to, and resolve complaints and violations.

(4) Any application for a permit made pursuant to ~~ss.~~ ~~499.01 and~~ 499.012 and rules adopted under those sections constitutes permission for agents of the department ~~of Health~~ and the Department of Law Enforcement, after presenting proper identification, to inspect, review, and copy any financial document or record related to the manufacture, repackaging, or distribution of a drug as is necessary to verify compliance with this part ~~ss. 499.001-499.081~~ and the rules adopted by the department to administer those sections, in order to discover, investigate, and determine the existence of compliance, or to elicit, receive, respond to, and resolve complaints and violations.

(5) The authority to inspect under this section includes the authority to access, review, and copy any and all financial documents related to the activity of manufacturing, repackaging, or distributing prescription drugs.

(6) The authority to inspect under this section includes the authority to secure:

(a) Samples or specimens of any drug, device, or cosmetic; or

(b) Such other evidence as is needed for any action to enforce this part ~~ss. 499.001-499.081~~ and the rules adopted under those sections.

(7) The complaint and all information obtained pursuant to the investigation by the department are confidential and exempt from the provisions of 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. 499.012111~~(6)(d)~~, and the pedigree papers required in that subsection shall not be deemed a trade secret.

Section 32. Section 499.052, Florida Statutes, is amended to read:

499.052 Records of interstate shipment.--For the purpose of enforcing this part ~~ss. 499.001-499.081~~, carriers engaged in interstate commerce and persons receiving drugs, devices, or cosmetics in interstate commerce must, upon the request, in the manner set out below, by an officer or employee duly designated by the department, permit the officer or employee to have access to and to copy all records showing the movement in interstate commerce of any drug, device, or cosmetic, and the quantity, shipper, and consignee thereof.

Section 33. Section 499.055, Florida Statutes, is amended to read:

499.055 Reports and dissemination of information by department.--

(1) The department may cause to be published from time to time reports summarizing all judgments, decrees, and court orders that have been rendered under ss. 499.001-499.79, including the nature of any charges and the dispositions of the charges.

(2) The department may also cause to be disseminated such information regarding drugs, devices, and cosmetics as considered necessary in the interest of public health and the protection of consumers against fraud.

(3) This section does not prohibit the department from collecting, reporting, and illustrating the results of its investigations.

(4) The department shall publish on the department's website and update at least monthly:

(a) A list of the prescription drug wholesale distributors ~~wholesalers~~, out-of-state prescription drug wholesale distributors ~~wholesalers~~, and retail pharmacy drug wholesale distributors ~~wholesalers~~ against whom the department has initiated enforcement action pursuant to this part ~~ss. 499.001-499.081~~ to suspend or revoke a permit, seek an injunction, or otherwise file an administrative complaint and the permit number of each such wholesaler.

(b) A list of the prescription drug wholesale distributors ~~wholesalers~~, out-of-state prescription drug wholesale distributors ~~wholesalers~~, and retail pharmacy drug wholesale

distributors ~~wholesalers~~ to which the department has issued a permit, including the date on which each permit will expire.

(c) A list of the prescription drug wholesale distributors ~~wholesalers~~, out-of-state prescription drug wholesale distributors ~~wholesalers~~, and retail pharmacy drug wholesale distributors ~~wholesalers~~ permits that have been returned to the department, were suspended, were revoked, have expired, or were not renewed in the previous year.

Section 34. Section 499.057, Florida Statutes, is amended to read:

499.057 Expenses and salaries.--All expenses and salaries shall be paid out of the special fund hereby created in the office of the Chief Financial Officer, which fund is to be known as the "Florida Drug, Device, and Cosmetic Trust Fund."

Section 35. Section 499.06, Florida Statutes, is amended to read:

499.06 Embargoing, detaining, or destroying article or processing equipment which is in violation of law or rule.--

(1) When a duly authorized agent of the department finds, or has probable cause to believe, that any drug, device, or cosmetic is in violation of any provision of this part ~~ss. 499.001-499.081~~ or any rule adopted under such sections so as to be dangerous, unwholesome, or fraudulent within the meaning of this part ~~ss. 499.001-499.081~~, she or he may issue and enforce a stop-sale, stop-use, removal, or hold order, which order gives notice that such article or processing equipment is, or is suspected of being, in violation and has been detained or embargoed, and which order warns all persons not to remove, use, or dispose of such article or processing equipment by sale or

otherwise until permission for removal, use, or disposal is given by such agent or the court. It is unlawful for any person to remove, use, or dispose of such detained or embargoed article or processing equipment by sale or otherwise without such permission; and such act is a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(2) When an article or processing equipment detained or embargoed under subsection (1) has been found by such agent to be in violation of law or rule, she or he shall, within 90 days after the issuance of such notice, petition the circuit court, in the jurisdiction of which the article or processing equipment is detained or embargoed, for an order for condemnation of such article or processing equipment. When such agent has found that an article or processing equipment so detained or embargoed is not in violation, she or he shall rescind the stop-sale, stop-use, removal, or hold order.

(3) If the court finds that the detained or embargoed article or processing equipment is in violation, such article or processing equipment shall, after entry of the court order, be destroyed or made sanitary at the expense of the claimant thereof, under the supervision of such agent; and all court costs, fees, and storage and other proper expenses shall be taxed against the claimant of such article or processing equipment or her or his agent. However, when the violation can be corrected by proper labeling of the article or sanitizing of the processing equipment, and after such costs, fees, and expenses have been paid and a good and sufficient bond, conditioned that such article be so labeled or processed or such processing equipment be so sanitized, has been executed, the court may by order direct

that such article or processing equipment be delivered to the claimant thereof for such labeling, processing, or sanitizing, under the supervision of an agent of the department. The expense of such supervision shall be paid by the claimant. Such bond shall be returned to the claimant of the article or processing equipment upon representation to the court by the department that the article or processing equipment is no longer in violation of this part ~~ss. 499.001-499.081~~ and that the expenses of such supervision have been paid.

(4) When the department or any of its authorized agents finds in any room, building, vehicle of transportation, or other structure any perishable articles that are unsound or contain any filthy, decomposed, or putrid substances, or which may be poisonous or deleterious to health or otherwise unsafe, the same being hereby declared to be a nuisance, the department, or its authorized agent, shall forthwith condemn or destroy such articles or in any other manner render such articles unsalable.

Section 36. Section 499.062, Florida Statutes, is amended, section 499.063, Florida Statutes, is renumbered as section (2) of that section and amended, and section 499.064, Florida Statutes, is renumbered as paragraphs (2)(a) and (b) of that section and amended, to read:

499.062 ~~Cause for~~ Seizure and condemnation of drugs, devices, or cosmetics.--

(1) Any article of any drug, device, or cosmetic that is adulterated or misbranded under this part ~~ss. 499.001-499.081~~ is subject to seizure and condemnation by the department or by its duly authorized agents designated for that purpose in regard to drugs, devices, or cosmetics.

(2) ~~499.063 Seizure; procedure; prohibition on sale or disposal of article; penalty.~~ Whenever a duly authorized officer or employee of the department finds cause, or has probable cause to believe that cause exists, for the seizure of any drug, device, or cosmetic, as set out in this part ~~ss. 499.001-499.081~~, he or she shall affix to the article a tag, stamp, or other appropriate marking, giving notice that the article is, or is suspected of being, subject to seizure under this part ~~ss. 499.001 499.081~~ and that the article has been detained and seized by the department. Such officer or employee shall also warn all persons not to remove or dispose of the article, by sale or otherwise, until permission is given by the department or the court. Any person who violates this subsection is guilty of a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(a) ~~499.064 Condemnation and sale; release of seized article.~~

~~(1)~~ When any article detained or seized under this subsection ~~s.499.063~~ has been found by the department to be subject to seizure and condemnation ~~under s. 499.063~~, the department shall petition the court for an order of condemnation or sale, as the court directs. The proceeds of the sale of drugs, devices, and cosmetics, less the legal costs and charges, shall be deposited into the Florida Drug, Device, and Cosmetic Trust Fund.

(b) ~~(2)~~ If the department finds that any article seized under this subsection ~~s. 499.063~~ was not subject to seizure, the department or the designated officer or employee shall remove the tag or marking.

Section 37. Section 499.065, Florida Statutes, is amended to read:

499.065 Inspections; imminent danger.--

(1) Notwithstanding s. 499.051, the department shall inspect each prescription drug wholesale distributor establishment, prescription drug repackager establishment, veterinary prescription drug wholesale distributor establishment, limited prescription drug veterinary wholesale distributor ~~wholesaler~~ establishment, and retail pharmacy drug wholesale distributor ~~wholesaler~~ establishment that is required to be permitted under this part ~~chapter~~ as often as necessary to ensure compliance with applicable laws and rules. The department shall have the right of entry and access to these facilities at any reasonable time.

(2) To protect the public from prescription drugs that are adulterated or otherwise unfit for human or animal consumption, the department may examine, sample, seize, and stop the sale or use of prescription drugs to determine the condition of those drugs. The department may immediately seize and remove any prescription drugs if the State Surgeon General or his or her designee determines that the prescription drugs represent a threat to the public health. The owner of any property seized under this section may, within 10 days after the seizure, apply to a court of competent jurisdiction for whatever relief is appropriate. At any time after 10 days, the department may destroy the drugs as contraband.

(3) The department may determine that a prescription drug wholesale distributor establishment, prescription drug repackager establishment, veterinary prescription drug wholesale distributor

establishment, limited prescription drug veterinary wholesale distributor ~~wholesaler~~ establishment, or retail pharmacy drug wholesale distributor ~~wholesaler~~ establishment that is required to be permitted under this part ~~chapter~~ is an imminent danger to the public health and shall require its immediate closure if the establishment fails to comply with applicable laws and rules and, because of the failure, presents an imminent threat to the public's health, safety, or welfare. Any establishment so deemed and closed shall remain closed until allowed by the department or by judicial order to reopen.

(4) For purposes of this section, a refusal to allow entry to the department for inspection at reasonable times, or a failure or refusal to provide the department with required documentation for purposes of inspection, constitutes an imminent danger to the public health.

Section 38. Section 499.066, Florida Statutes, is amended to read:

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

(1) The department may institute such suits or other legal proceedings as are required to enforce any provision of this part ~~ss. 499.001-499.081~~. If it appears that a person has violated any provision of this part ~~ss. 499.001-499.081~~ for which criminal prosecution is provided, the department may provide the appropriate state attorney or other prosecuting agency having jurisdiction with respect to such prosecution with the relevant information in the department's possession.

(2) If any person engaged in any activity covered by this part ~~ss. 499.001-499.081~~ violates any provision of those

sections, any rule adopted under those sections, or a cease and desist order as provided by those sections, the department may obtain an injunction in the circuit court of the county in which the violation occurred or in which the person resides or has its principal place of business, and may apply in that court for such temporary and permanent orders as the department considers necessary to restrain the person from engaging in any such activities until the person complies with this part ~~ss. 499.001-499.081~~, the rules adopted under those sections, and the orders of the department authorized by those sections or to mandate compliance with this part ~~ss. 499.001-499.081~~, the rules adopted under those sections, and any order or permit issued by the department under those sections.

(3) The department may impose an administrative fine, not to exceed $5,000 per violation per day, for the violation of any provision of this part ~~ss. 499.001 499.081~~ or rules adopted under those sections. Each day a violation continues constitutes a separate violation, and each separate violation is subject to a separate fine. All amounts collected pursuant to this section shall be deposited into the Florida Drug, Device, and Cosmetic Trust Fund and are appropriated for the use of the department in administering this part ~~ss. 499.001 499.081~~. In determining the amount of the fine to be levied for a violation, the department shall consider:

(a) The severity of the violation;

(b) Any actions taken by the person to correct the violation or to remedy complaints; and

(c) Any previous violations.

(4) The department shall deposit any rewards, fines, or collections that are due the department and which derive from joint enforcement activities with other state and federal agencies which relate to this part ~~ss. 499.001-499.081~~, chapter 893, or the federal act, into the Florida Drug, Device, and Cosmetic Trust Fund. The proceeds of those rewards, fines, and collections are appropriated for the use of the department in administering this part ~~ss. 499.001-499.081~~.

(5) The department may issue an emergency order immediately suspending or revoking a permit if it determines that any condition in the establishment presents a danger to the public health, safety, and welfare.

(6) The department may issue an emergency order to immediately remove from commerce and public access any drug, device, or cosmetic, if the department determines that the drug, device, or cosmetic presents a clear and present danger to the public health, safety, and welfare.

(7) Resignation or termination of an affiliated party does not affect the department's jurisdiction or discretion to proceed with action to suspend or revoke a permit or to impose other penalties or enforcement actions authorized by law.

Section 39. Section 499.0661, Florida Statutes, is amended to read:

499.0661 Cease and desist orders; removal of certain persons.--

(1)~~(2)~~ CEASE AND DESIST ORDERS.--

(a) In addition to any authority otherwise provided in this chapter, the department may issue and serve a complaint stating charges upon any permittee or upon any affiliated party, whenever

the department has reasonable cause to believe that the person or individual named therein is engaging in or has engaged in conduct that is:

1. An act that demonstrates a lack of fitness or trustworthiness to engage in the business authorized under the permit issued pursuant to this part ~~ss. 499.001 499.081~~, is hazardous to the public health, or constitutes business operations that are a detriment to the public health;

2. A violation of any provision of this part ~~ss. 499.001 499.081~~;

3. A violation of any rule of the department;

4. A violation of any order of the department; or

5. A breach of any written agreement with the department.

(b) The complaint must contain a statement of facts and notice of opportunity for a hearing pursuant to ss. 120.569 and 120.57.

(c) If a hearing is not requested within the time allowed by ss. 120.569 and 120.57, or if a hearing is held and the department finds that any of the charges are proven, the department may enter an order directing the permittee or the affiliated party named in the complaint to cease and desist from engaging in the conduct complained of and take corrective action to remedy the effects of past improper conduct and assure future compliance.

(d) A contested or default cease and desist order is effective when reduced to writing and served upon the permittee or affiliated party named therein. An uncontested cease and desist order is effective as agreed.

(e) Whenever the department finds that conduct described in paragraph (a) is likely to cause an immediate threat to the public health, it may issue an emergency cease and desist order requiring the permittee or any affiliated party to immediately cease and desist from engaging in the conduct complained of and to take corrective and remedial action. The emergency order is effective immediately upon service of a copy of the order upon the permittee or affiliated party named therein and remains effective for 90 days. If the department begins nonemergency cease and desist proceedings under this subsection, the emergency order remains effective until the conclusion of the proceedings under ss. 120.569 and 120.57.

(2)~~(3)~~ REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.--

(a) The department may issue and serve a complaint stating charges upon any affiliated party and upon the permittee involved whenever the department has reason to believe that an affiliated party is engaging in or has engaged in conduct that constitutes:

1. An act that demonstrates a lack of fitness or trustworthiness to engage in the business authorized under the permit issued pursuant to this part ~~ss. 499.001-499.081~~, is hazardous to the public health, or constitutes business operations that are a detriment to the public health;

2. A willful violation of this part ~~ss. 499.001-499.081~~; however, if the violation constitutes a misdemeanor, a complaint may not be served as provided in this section until the affiliated party is notified in writing of the matter of the violation and has been afforded a reasonable period of time, as set forth in the notice, to correct the violation and has failed to do so;

3. A violation of any other law involving fraud or moral turpitude which constitutes a felony;

4. A willful violation of any rule of the department;

5. A willful violation of any order of the department; or

6. A material misrepresentation of fact, made knowingly and willfully or made with reckless disregard for the truth of the matter.

(b) The complaint must contain a statement of facts and notice of opportunity for a hearing pursuant to ss. 120.569 and 120.57.

(c) If a hearing is not requested within the time allotted by ss. 120.569 and 120.57, or if a hearing is held and the department finds that any of the charges in the complaint are proven true, the department may enter an order removing the affiliated party or restricting or prohibiting participation by the person in the affairs of that permittee or of any other permittee.

(d) A contested or default order of removal, restriction, or prohibition is effective when reduced to writing and served on the permittee and the affiliated party. An uncontested order of removal, restriction, or prohibition is effective as agreed.

(e)1. The chief executive officer, designated representative, or the person holding the equivalent office, of a permittee shall promptly notify the department if she or he has actual knowledge that any affiliated party is charged with a felony in a state or federal court.

2. Whenever any affiliated party is charged with a felony in a state or federal court or with the equivalent of a felony in the courts of any foreign country with which the United States

maintains diplomatic relations, and the charge alleges violation of any law involving prescription drugs, pharmaceuticals, fraud, theft, or moral turpitude, the department may enter an emergency order suspending the affiliated party or restricting or prohibiting participation by the affiliated party in the affairs of the particular permittee or of any other permittee upon service of the order upon the permittee and the affiliated party charged. The order must contain notice of opportunity for a hearing pursuant to ss. 120.569 and 120.57, where the affiliated party may request a postsuspension hearing to show that continued service to or participation in the affairs of the permittee does not pose a threat to the public health or the interests of the permittee and does not threaten to impair public confidence in the permittee. In accordance with applicable departmental rules, the department shall notify the affiliated party whether the order suspending or prohibiting the person from participation in the affairs of a permittee will be rescinded or otherwise modified. The emergency order remains in effect, unless otherwise modified by the department, until the criminal charge is disposed of. The acquittal of the person charged, or the final, unappealed dismissal of all charges against the person, dissolves the emergency order but does not prohibit the department from instituting proceedings under paragraph (a). If the person charged is convicted or pleads guilty or nolo contendere, whether or not an adjudication of guilt is entered by the court, the emergency order shall become final.

(f) Any affiliated party removed pursuant to this section is not eligible for reemployment by the permittee or to be an affiliated party of any permittee except upon the written consent

of the department. Any affiliated party who is removed, restricted, or prohibited from participating in the affairs of a permittee pursuant to this section may petition the department for modification or termination of the removal, restriction, or prohibition.

Section 40. Section 499.067, Florida Statutes, is amended to read:

499.067 Denial, suspension, or revocation of permit, certification, or registration.--

(1)(a) The department may deny, suspend, or revoke a permit if it finds that there has been a substantial failure to comply with this part ~~ss. 499.001-499.081~~ or chapter 465, chapter 501, or chapter 893, the rules adopted under any of those sections or chapters, any final order of the department, or applicable federal laws or regulations or other state laws or rules governing drugs, devices, or cosmetics.

(b) The department may deny an application for a permit or certification, or suspend or revoke a permit or certification, if the department finds that:

1. The applicant is not of good moral character or that it would be a danger or not in the best interest of the public health, safety, and welfare if the applicant were issued a permit or certification.

2. The applicant has not met the requirements for the permit or certification.

3. The applicant is not eligible for a permit or certification for any of the reasons enumerated in s. 499.012 ~~499.01 or s. 499.012(5)~~.

4. The applicant, permittee, or person certified under s. 499.012(16) ~~(11)~~ demonstrates any of the conditions enumerated in s. 499.012 ~~499.01 or s. 499.012(5)~~.

5. The applicant, permittee, or person certified under s. 499.012(16) ~~(11)~~ has committed any violation of ss. 499.005-499.0054.

(2) The department may deny, suspend, or revoke any registration required by the provisions of this part ~~ss. 499.001-499.081~~ for the violation of any provision of this part ~~ss. 499.001-499.081~~ or of any rules adopted under those sections.

(3) The department may revoke or suspend a permit:

(a) If the permit was obtained by misrepresentation or fraud or through a mistake of the department;

(b) If the permit was procured, or attempted to be procured, for any other person by making or causing to be made any false representation; or

(c) If the permittee has violated any provision of this part ~~ss. 499.001 499.081~~ or rules adopted under those sections.

(4) If any permit issued under this part ~~ss. 499.001-499.081~~ is revoked or suspended, the owner, manager, operator, or proprietor of the establishment shall cease to operate as the permit authorized, from the effective date of the suspension or revocation until the person is again registered with the department and possesses the required permit. If a permit is revoked or suspended, the owner, manager, or proprietor shall remove all signs and symbols that identify the operation as premises permitted as a drug wholesaling establishment; drug, device, or cosmetic manufacturing establishment; or retail establishment. The department shall determine the length of time

for which the permit is to be suspended. If a permit is revoked, the person that owns or operates the establishment may not apply for any permit under this part ~~ss. 499.001-499.081~~ for a period of 1 year after the date of the revocation. A revocation of a permit may be permanent if the department considers that to be in the best interest of the public health.

(5) The department may deny, suspend, or revoke a permit issued under this part ~~ss. 499.001-499.081~~ which authorizes the permittee to purchase prescription drugs, if any owner, officer, employee, or other person who participates in administering or operating the establishment has been found guilty of any violation of this part ~~ss. 499.001-499.081~~ or chapter 465, chapter 501, or chapter 893, any rules adopted under any of those sections or chapters, or any federal or state drug law, regardless of whether the person has been pardoned, had her or his civil rights restored, or had adjudication withheld.

(6) The department shall deny, suspend, or revoke the permit of any person or establishment if the assignment, sale, transfer, or lease of an establishment permitted under this part ~~ss. 499.001-499.081~~ will avoid an administrative penalty, civil action, or criminal prosecution.

(7) Notwithstanding s. 120.60(5), if a permittee fails to comply with s. 499.012(6) ~~499.01(7)~~, the department may revoke the permit of the permittee and shall provide notice of the intended agency action by posting a notice at the department's headquarters and by mailing a copy of the notice of intended agency action by certified mail to the most recent mailing address on record with the department and, if the permittee is

not a natural person, to the permittee's registered agent on file with the Department of State.

Section 41. This act shall take effect July 1, 2008.