By the Committee on Health, Aging, and Long-Term Care; and Senator Peaden

317-2253-03

A bill to be entitled

An act relating to the distribution of prescription drugs; providing a short title; providing legislative findings and intent with respect to a report by the Seventeenth Statewide Grand Jury; amending s. 499.003, F.S.; defining additional terms; amending s. 499.005, F.S.; prohibiting the purchase or sale of prescription drugs in wholesale distribution in exchange for currency; clarifying provisions prohibiting the transfer of legend drugs from or to any person not authorized to possess such drugs; prohibiting additional acts concerning the distribution of prescription drugs; creating s. 499.0051, F.S.; providing that failure to maintain or deliver pedigree papers, failure to authenticate pedigree papers, forgery of pedigree papers, purchase of legend drugs from an unlicensed person, sale of legend drugs to an unlicensed person, possession or sale of contraband legend drugs and possession with intent to sell or deliver contraband legend drugs, and forgery of prescription labels or legend drug labels are felony offenses; providing penalties; creating s. 499.0052, F.S.; providing that trafficking in contraband legend drugs is a felony offense; providing penalties; providing enhanced penalties if the defendant is a corporation or not a natural person; creating s. 499.0053, F.S.; providing that the sale or purchase of a

contraband legend drug resulting in great bodily harm is a first-degree felony; creating s. 499.0054, F.S.; providing that the sale or purchase of a contraband legend drug resulting in death is a first-degree felony; amending s. 499.006, F.S.; providing that a legend drug that is unaccompanied by a proper pedigree paper or that has been in the possession of an unauthorized person is an adulterated drug; amending s. 499.007, F.S.; revising labeling requirements to conform to federal law; amending s. 499.01, F.S.; requiring that prescription drug repackagers, nonresident prescription drug manufacturers, and freight forwarders obtain a permit from the Department of Health in order to do business; prohibiting a county or municipality from issuing an occupational license prior to an establishment obtaining a permit required under ch. 499, F.S., under specified circumstances; providing for early expiration of certain permits; amending s. 499.012, F.S.; excluding the transfer of prescription drugs within a hospital from the definition of wholesale distribution; providing bond requirements for prescription drug wholesalers; deleting provisions authorizing the department to grant out-of-state wholesalers reciprocity; requiring freight forwarders and nonresident prescription drug manufacturers to obtain a permit; providing requirements for permit applications;

providing definitions; providing requirements for the permitting of prescription drug wholesalers and out-of-state prescription drug wholesalers; providing criteria for permit denials; requiring prescription drug wholesalers to designate a representative; providing criteria for designation as a representative; amending s. 499.0121, F.S.; requiring record review; requiring pedigree papers for the transfer and sale of legend drugs; providing exemptions; providing documentation requirements for the shipment of prescription drugs; providing requirements for wholesale drug distributors with respect to the exercise of due diligence; providing rulemaking authority; creating s. 499.01211, F.S.; creating the Drug Wholesaler Advisory Council within the Department of Health; providing for membership of the council and terms of office; requiring the council to review rules and make recommendations to the secretary of the department; amending s. 499.013, F.S.; providing requirements for repackagers of drugs, devices, and cosmetics; requiring that a repackager obtain a permit from the department; providing labeling requirements; amending s. 499.014, F.S.; specifying that certain restricted distributors are exempt from the requirements concerning pedigree papers; amending s. 499.041, F.S.; revising the schedule of fees for permits; amending s.

499.051, F.S.; revising the authority of the Department of Health to inspect pharmacies and pharmacy wholesalers; authorizing the department and the Department of Law Enforcement to inspect certain financial documents and records; amending s. 499.055, F.S.; requiring the Department of Health to establish a website listing all permitholders and pending enforcement actions; creating s. 499.065, F.S.; authorizing the department to enter and inspect all permitted facilities at any reasonable time; authorizing the department to seize and destroy prescription drugs representing a threat to public health; authorizing the department to close facilities that represent an imminent danger to public health; amending s. 499.066, F.S.; providing for administrative actions by the department; creating s. 499.0661, F.S.; providing for the department to issue cease and desist orders; providing for the department to order the removal of certain persons from involvement with certain drug wholesalers; providing penalties; amending s. 499.067, F.S.; specifying additional grounds for denial of a permit or certification; amending s. 499.069, F.S.; revising certain penalty provisions; creating s. 499.0691, F.S.; providing criminal penalties for violations related to drugs or false advertisement; amending s. 921.0022, F.S., relating to the offense severity ranking

chart of the Criminal Punishment Code; conforming provisions to changes made by the act; amending s. 895.02, F.S.; including certain violations of part I of ch. 499, F.S., within the definition of racketeering activity; amending ss. 16.56 and 905.34, F.S.; authorizing criminal violations of part I of ch. 499, F.S., to be prosecuted by the Office of Statewide Prosecution and heard by the Statewide Grand Jury; providing for severability; providing an appropriation; providing an effective date.

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

Section 1. This act may be cited as the "Prescription Drug Protection Act."

Section 2. Legislative findings and intent.--Based on the report of the Seventeenth Statewide Grand Jury in its First Interim Report the Legislature finds that prescription drugs brought into the state by wholesalers are being relabeled and falsely represented as being of a higher dosage by other wholesalers in order to charge higher prices for those drugs and that counterfeit substances labeled as genuine pharmaceuticals are being distributed, thereby causing an extreme danger that persons eventually receiving the drugs by prescription are receiving ineffective drugs in nontherapeutic doses, or even receiving dangerous or unwholesome substances, with the result that the health and well-being of the public is at risk. The Statewide Grand Jury also found that the lack of an effective pedigree paper requirement has resulted in the

inability of prescription drug users to have confidence in the purity and efficacy of the drugs they use. The Statewide Grand Jury further noted that present laws do not allow effective criminal prosecution of persons involved in such false representations. It is the intent of the Legislature that the statutory changes and recommendations outlined in the Statewide Grand Jury's report be implemented as provided by this act.

Section 3. Section 499.003, Florida Statutes, is amended to read:

499.003 Definitions of terms used in ss. 499.001-499.081.--As used in 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 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(4) or is required to be identified in an application for a permit or to renew a permit pursuant to s. 499.012(3); or

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

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

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

(5)~~(2)~~ "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.

(6)~~(3)~~ "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.

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

(8)~~(5)~~ "Color additive" means 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.

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

(10) "Contraband legend drug" means any adulterated drug, as defined in s. 499.006, any counterfeit drug, as defined in this section, and also means any 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.

(11)~~(7)~~ "Cosmetic" means an article 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.

(12)~~(8)~~ "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.

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

(14)~~(10)~~ "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 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.

(15)~~(11)~~ "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.

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

(17)~~(12)~~ "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.

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

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

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

(21)~~(15)~~ "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.

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

(23)~~(17)~~ "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 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.

(24)~~(18)~~ "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)~~(19)~~ "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.

(27)~~(20)~~ "Manufacture" means the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any drug, device, or cosmetic. ~~The term includes repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of the drug, device, or cosmetic.~~

(28)~~(21)~~ "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.

(29)~~(22)~~ "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.

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

(31) "Pedigree paper" means:

(a) A document required pursuant to s. 499.0121(6)(d) or (e); or

(b) Effective March 1, 2005, a document in a form approved by the Department of Health and containing information that records each distribution of any given 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 a legend drug's pedigree paper 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, and a certification that the recipient has authenticated the pedigree papers. 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. The department shall adopt rules and a form relating to the requirements of this paragraph no later than 90 days after the effective date of this act.

(32)~~(24)~~ "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.

(33)~~(25)~~ "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.

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

(35)~~(26)~~ "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.

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

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

(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.

(39)~~(28)~~ "Veterinary prescription drug" means a 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."

Section 4. 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 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) <u>The purchase or sale of prescription drugs for wholesale distribution in exchange for currency, as defined in s. 560.103(6).</u> ~~The giving of a false guaranty or false undertaking with respect to a drug, device, or cosmetic, except by a person who relied on a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in this state from whom she or he received in good faith the drug, device, or cosmetic.~~

(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 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 ss. 499.001-499.081 when it does not.

(12) The possession of any drug in violation of 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 legend drug from a person that is not authorized under this chapter to distribute legend drugs to that purchaser or recipient.

(15) The sale or transfer of a 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 legend drugs from the person selling or transferring the 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 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 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 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 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 obtain or pass on a pedigree paper.

(29) The receipt of a prescription drug pursuant to a wholesale distribution without first receiving a pedigree paper that was attested to as accurate and complete by the wholesale distributor.

Section 5. Section 499.0051, Florida Statutes, is created 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 legend drugs who fails to deliver to another person complete and accurate pedigree papers concerning a legend drug or contraband legend drug prior to transferring the legend drug or contraband 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 legend drugs who fails to acquire complete and accurate pedigree papers concerning a legend drug or contraband legend drug prior to obtaining the legend drug or contraband 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 legend drug or contraband 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.--

(a)1. A person engaged in the wholesale distribution of legend drugs who is in possession of documents required under s. 499.0121(6)(e) and who fails to authenticate the matters contained in the documents and who nevertheless attempts to further distribute legend drugs or contraband legend drugs commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

2. A person in possession of documents required under s. 499.0121(6)(e) who falsely swears or certifies that he or

she has authenticated the matters contained in the documents commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

3. This paragraph expires March 1, 2005.

(b) Effective March 1, 2005:

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

2. A person in possession of pedigree papers concerning legend drugs or contraband 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) 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) PURCHASE OR RECEIPT OF LEGEND DRUG FROM UNAUTHORIZED PERSON.--A person who knowingly purchases or receives from a person not authorized to distribute legend drugs under this chapter a 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) SALE OR TRANSFER OF LEGEND DRUG TO UNAUTHORIZED PERSON.--A person who knowingly sells or transfers to a person not authorized to purchase or possess legend drugs, under the law of the jurisdiction in which the person receives the drug, a 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) SALE OR DELIVERY, OR POSSESSION WITH INTENT TO SELL, CONTRABAND LEGEND DRUGS.--A person who is knowingly in actual or constructive possession of any amount of contraband legend drugs, who knowingly sells or delivers, or who possesses with intent to sell or deliver any amount of contraband legend drugs, commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

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

Section 6. Section 499.0052, Florida Statutes, is created to read:

499.0052 Trafficking in contraband 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 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. Upon conviction, each defendant shall be ordered to pay a mandatory fine according to the following schedule:

(1) If the value of contraband 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) If the value of contraband 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) If the value of contraband 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.

As used in this section, 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 legend drugs involved in distinct transactions for the distribution of the contraband 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.

Section 7. Section 499.0053, Florida Statutes, is created, to read:

499.0053 Sale or purchase of contraband 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 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.

Section 8. Section 499.0054, Florida Statutes, is created to read:

499.0054 Sale or purchase of contraband 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 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.

Section 9. 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 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; ~~or~~

(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; or ~~.~~

(10) If it is a legend drug for which the required pedigree paper is nonexistent, fraudulent, or incomplete under the requirements of 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.

Section 10. Subsection (2) of section 499.007, Florida Statutes, is amended to read:

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

(2) Unless, if in package form, it bears a label containing:

(a) The name and place of business of the manufacturer, repackager, or distributor ~~; in addition, for a medicinal drug, as defined in s. 499.003, the label must contain the name and place of business of the manufacturer~~ of the finished dosage form of the drug. For the purpose of this paragraph, the finished dosage form of a 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.

Section 11. Subsections (1) and (3) of section 499.01, Florida Statutes, are amended to read:

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

(1) Any person that is required under ss. 499.001-499.081 to have a permit must apply to the department on forms furnished by the department.

(a) A permit issued pursuant to ss. 499.001-499.081 may be issued only to a natural person ~~an individual~~ 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 ~~a corporation that is registered pursuant to chapter 607 or chapter 617 and each officer of which~~ 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 ss. 499.001-499.081.

(c) A person that applies for or renews a permit to manufacture or distribute 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 wholesaler will be issued a permit in the name of its retail pharmacy permit.

(d) A permit is required for each establishment that operates as a:

1. Prescription drug manufacturer;
2. Over-the-counter drug manufacturer;
3. Compressed medical gas manufacturer;
4. Device manufacturer;
5. Cosmetic manufacturer;
6. Prescription drug wholesaler;
7. Compressed medical gas wholesaler;
8. Out-of-state prescription drug wholesaler;
9. Retail pharmacy drug wholesaler;
10. Veterinary legend drug retail establishment;
11. Medical oxygen retail establishment;
12. Complimentary drug distributor; or
13. Restricted prescription drug distributor.

(e) A permit for a prescription drug manufacturer, prescription drug wholesaler, or retail pharmacy wholesaler may not be issued to the address of a health care entity <u>or to a pharmacy licensed under chapter 465, except as provided in this paragraph</u>. <u>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</u>

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 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.

(f) 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 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 ss. 499.001-499.081.

(g)~~(f)~~ Notwithstanding subsection (4), 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 wholesaler and an out-of-state prescription drug 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 ~~biennial~~ fee for the new permit is less than the fee that was paid original permit ~~for which a fee was paid~~.

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

(a) The department shall renew a permit upon receipt of the renewal application and renewal fee if the applicant meets the requirements established under ss. 499.001-499.081 and the rules adopted under those sections.

(b) 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; except that a prescription drug wholesaler permit or an out-of-state prescription drug wholesaler permit issued from July 1, 2003, through December 31, 2003, shall expire 1 year after the last day of the anniversary month in which the permit was issued. Any valid prescription drug wholesaler or out-of-state prescription drug wholesaler permit issued by the department on or before June 30, 2003, with an expiration date between January 1, 2005, and June 30, 2005, shall automatically expire 1 year prior to the expiration date stated on the permit. A permittee that submits a renewal application for a permit with a stated expiration date between January 1, 2005, and June 30, 2005, shall receive a credit of one-half of the permit fee paid when the application for the expiring permit was submitted. Any valid prescription drug wholesaler or out-of-state prescription drug wholesaler permit issued by the department on or before June 30, 2003, with an expiration date between July 1, 2004, and December 31, 2004, shall automatically expire 6 months prior to the expiration

date stated on the permit. A permittee that submits a renewal application for a permit with a stated expiration date between July 1, 2004, and December 31, 2004, shall receive a credit of one-fourth of the permit fee paid when the application for the expiring permit was submitted. A permittee whose permit expiration date was accelerated in this paragraph may request a pro rata refund equivalent to the credit available for submission of a renewal application if the permittee does not submit a renewal application.A permit issued under ss. 499.001-499.081 may ~~must~~ 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 ~~not~~ submitted and postmarked after ~~by~~ the expiration date of the permit, the permit may be renewed ~~reinstated~~ only upon payment of a late renewal delinquent fee of $100, plus the required renewal fee, not later than ~~within~~ 60 days after the expiration date.

(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 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.~~Continuing to engage in activities that require a permit under ss. 499.001-499.081 requires a new permit application and payment of an application fee, initial permit fee, and applicable penalties.~~

Section 12. Effective January 1, 2004, section 499.01, Florida Statutes, as amended by this act, is 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) An over-the-counter drug manufacturer;

(d) A compressed medical gas manufacturer;

(e) A device manufacturer;

(f) A cosmetic manufacturer;

(g) A prescription drug wholesaler;

(h) A compressed medical gas wholesaler;

(i) An out-of-state prescription drug wholesaler;

(j) A nonresident prescription drug manufacturer;

(k) A freight forwarder;

(l) A retail pharmacy drug wholesaler;

(m) A veterinary legend drug retail establishment;

(n) A medical oxygen retail establishment;

(o) A complimentary drug distributor; or

(p) A restricted prescription drug distributor.

~~(1) Any person that is required under ss. 499.001-499.081 to have a permit must apply to the department on forms furnished by the department.~~

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

(c) A person that applies for or renews a permit to manufacture or distribute 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 wholesaler will be issued a permit in the name of its retail pharmacy permit.

~~(d) A permit is required for each establishment that operates as a:~~

~~1. Prescription drug manufacturer;~~

~~2. Over-the-counter drug manufacturer;~~

~~3. Compressed medical gas manufacturer;~~

~~4. Device manufacturer;~~

~~5. Cosmetic manufacturer;~~

~~6. Prescription drug wholesaler;~~

~~7. Compressed medical gas wholesaler;~~

~~8. Out-of-state prescription drug wholesaler;~~

~~9. Retail pharmacy drug wholesaler;~~

~~10. Veterinary legend drug retail establishment;~~

~~11. Medical oxygen retail establishment;~~

~~12. Complimentary drug distributor; or~~

~~13. Restricted prescription drug distributor.~~

(d)~~(e)~~ A permit for a prescription drug manufacturer, prescription drug repackager, prescription drug wholesaler, or retail pharmacy 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 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)~~(f)~~ 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 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 ss. 499.001-499.081.

(3)~~(g)~~ Notwithstanding subsection (7)~~(4)~~, 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 wholesaler, an out-of-state prescription drug wholesaler, or a retail pharmacy drug 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 original permit.

(4)~~(2)~~ 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.

(5)~~(a)~~ Except for a permit for a prescription drug wholesaler or an out-of-state prescription drug wholesaler, an application for a permit must include ~~Information that an applicant must provide includes, but need not be limited to~~:

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; ~~and~~

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.~~e.~~ 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 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 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 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.

(6) Except for permits for prescription drug wholesalers or out-of-state prescription drug wholesalers:

(a)~~(3)~~ The department shall adopt rules for the biennial renewal of permits.

(b)~~(a)~~ The department shall renew a permit upon receipt of the renewal application and renewal fee if the

applicant meets the requirements established under ss. 499.001-499.081 and the rules adopted under those sections.

(c)~~(b)~~ 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~~;~~ ~~except that a prescription drug wholesaler permit and an out-of-state prescription drug wholesaler permit, issued from July 1, 2003, through December 31, 2003, shall expire 1 year after the last day of the anniversary month in which the permit was issued~~. ~~Any valid prescription drug wholesaler or out-of-state prescription drug wholesaler permit issued by the department on or before June 30, 2003, with an expiration date between January 1, 2005, and June 30, 2005, shall automatically expire 1 year prior to the expiration date stated on the permit. A permittee that submits a renewal application for a permit with a stated expiration date between January 1, 2005, and June 30, 2005, shall receive a credit of one-half of the permit fee paid when the application for the expiring permit was submitted. Any valid prescription drug wholesaler or out-of-state prescription drug wholesaler permit issued by the department on or before June 30, 2003, with an expiration date between July 1, 2004, and December 31, 2004, shall automatically expire 6 months prior to the expiration date stated on the permit. A permittee that submits a renewal application for a permit with a stated expiration date between July 1, 2004, and December 31, 2004, shall receive a credit of one-fourth of the permit fee paid when the application for the expiring permit was submitted. A permittee whose permit expiration date was accelerated in this paragraph may request a pro rata refund equivalent to the credit available for submission of a renewal application if the permittee does not

~~submit a renewal application.~~A permit issued under 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)~~(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 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.

(7)~~(4)~~ 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 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 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 legend drugs.

~~(c) 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 ss. 499.001-499.081 will avoid an administrative penalty, civil action, or criminal prosecution.~~

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

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

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

Section 13. Section 499.012, Florida Statutes, is amended to read:

499.012 Wholesale distribution; definitions; permits; applications;general requirements.--

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

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

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:

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.

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.

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.

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:

(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 Secretary of Health or his or her designee.

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

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

(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.

(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.

(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 (V).

(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.

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:

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.

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.

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.

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

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.

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.

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.

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

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.

5. The lawful dispensing of a prescription drug in accordance with chapter 465.

(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 ~~repackers~~; 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.

(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.

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

(a) A prescription drug wholesaler's permit. A prescription drug wholesaler is a wholesale distributor that may engage in the wholesale distribution of prescription drugs. A prescription drug wholesaler that applies to the department for a new permit or the renewal of a permit after July 1, 2003 ~~January 1, 1993~~, 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~~$200~~, 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 ss. 499.001-499.081 which involves the permittee is concluded, including any appeal, whichever occurs later.~~This bond will be refunded to the permittee when the permit is returned to the department and the permittee ceases to function as a business. A permittee that fails to notify the department before changing the address of the business, fails to notify the department before closing the business, or fails to notify the department before a change of ownership forfeits its bond.~~The department may adopt rules for issuing a prescription drug 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.

(b) A compressed medical gas wholesaler's permit. A compressed medical gas 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 wholesaler. A compressed medical gas 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.

(c) An out-of-state prescription drug wholesaler's permit. An out-of-state prescription drug 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 ss. 499.001-499.081. An out-of-state prescription drug wholesaler that applies to the department for a new permit or the renewal of a permit after July 1, 2003, 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 ss. 499.001-499.081 which involves the permittee is concluded, including any appeal, whichever occurs later.

1. The out-of-state drug 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 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 wholesaler, in its state of residence, to a licensed prescription drug wholesaler in this state, if both wholesalers conduct wholesale distributions of prescription drugs under the same business name ~~are under common control~~. The recordkeeping requirements of s. 499.0121(6) must be followed for this transaction.

~~3. The department may adopt rules that allow out-of-state drug wholesalers to obtain a drug wholesale permit on the basis of reciprocity to the extent that an out-of-state drug wholesaler:~~

~~a. Possesses a valid permit granted by another state that has requirements comparable to those that a drug wholesaler in this state must meet as prerequisites to obtaining a permit under the laws of this state.~~

~~b. Can show that the other state from which the wholesaler holds a permit would extend reciprocal treatment under its own laws to a drug wholesaler of this state.~~

(d) A retail pharmacy wholesaler's permit. A retail pharmacy 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 wholesaler's permit pursuant to 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 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 ss. 499.001-499.081.

(3) 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 wholesaler consigns a prescription drug to a pharmacy that is permitted under chapter 465 and located in this state, provided that:

1. The consignor 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 wholesaler, which has no legal authority to dispense prescription drugs, complies with all wholesale distribution requirements of s. 499.0121 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 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 wholesaler, permitted under this chapter, in accordance with a written consignment agreement between the pharmacy and that wholesaler if: the permitted pharmacy and the permitted prescription drug 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 wholesaler may not use the pharmacy as a wholesale distributor through which it distributes the 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.

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

(5) The department may adopt rules governing the recordkeeping, storage, and handling with respect to each of the distributions of prescription drugs specified in subparagraphs (1)(a)1.-4.

Section 14. Effective January 1, 2004, section 499.012, Florida Statutes, as amended by this act, is amended to read:

499.012 Wholesale distribution; definitions; permits; applications; general requirements.--

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

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

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:

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.

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.

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.

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:

(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 Secretary of Health or his or her designee.

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

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

(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.

(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.

(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 (V).

(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.

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:

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.

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.

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.

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

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.

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.

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(7), 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.

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

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.

5. The lawful dispensing of a prescription drug in accordance with chapter 465.

(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.

(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.

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

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

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

b. Has, or the affiliated group of which the wholesale distributor is a member has, not fewer than 250 employees.

(e) "Directly from 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 manufacturers in the previous year; or

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.

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

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

(a) A prescription drug wholesaler's permit. A prescription drug wholesaler is a wholesale distributor that may engage in the wholesale distribution of prescription drugs. A prescription drug wholesaler that applies to the department for a new permit or the renewal of a permit ~~after~~

~~July 1, 2003~~, 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 ss. 499.001-499.081 which involves the permittee is concluded, including any appeal, whichever occurs later. The department may adopt rules for issuing a prescription drug 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.

(b) A compressed medical gas wholesaler's permit. A compressed medical gas 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 wholesaler. A compressed medical gas 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.

(c) An out-of-state prescription drug wholesaler's permit. An out-of-state prescription drug 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 ss. 499.001-499.081. An out-of-state prescription drug wholesaler that applies to the department for a new permit or the renewal of a permit ~~after July 1, 2003~~, 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 ss. 499.001-499.081 which involves the permittee is concluded, including any appeal, whichever occurs later.

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

(d) A retail pharmacy wholesaler's permit. A retail pharmacy 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 wholesaler's permit pursuant to 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 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 ss. 499.001-499.081.

(e) 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 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 ss. 499.001-499.081, except s. 499.0121(6)(d), (e), or (f).

1. A person that distributes prescription drugs that it did not manufacture must also obtain an out-of-state prescription drug wholesaler permit pursuant 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 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 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.

(f) A freight forwarder permit is required for any person that engages in the distribution of a 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. 499.0121(6)(d), (e), or (f). A freight forwarder must provide the source of the legend drugs with a validated airway bill, bill of lading, or other appropriate documentation to evidence the exportation of the product.

(3) An application for a permit or to renew a permit for a prescription drug wholesaler or an out-of-state prescription drug 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 (4) for each of such persons.

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

(4)(a) Each person required by subsection (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 the issuance of an initial permit or the initial renewal of a permit of an applicant after January 1, 2004.

(5) The department may deny an application for a permit or refuse to renew a permit for a prescription drug wholesaler or an out-of-state prescription drug 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 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 (2)(a) or paragraph (2)(c) 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 (2)(a) or paragraph (2)(c) 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 ss. 499.001-499.081, similar federal laws, similar laws in other states, or the rules adopted under such laws.

(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.

(7) For permits for prescription drug wholesalers or out-of-state prescription drug 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 wholesaler or out-of-state prescription drug 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 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.

(8)~~(3)~~ 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 wholesaler consigns a prescription drug to a pharmacy that is permitted under chapter 465 and located in this state, provided that:

1. The consignor 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 wholesaler, which has no legal authority to dispense prescription drugs, complies with all wholesale distribution requirements of s. 499.0121 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 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 wholesaler, permitted under this chapter, in accordance with a written consignment agreement between the pharmacy and that wholesaler if: the permitted pharmacy and the permitted prescription drug 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 wholesaler may not use the pharmacy as a wholesale distributor through which it distributes the 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 s. 499.012.

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

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

(11)(a) Each establishment that is issued an initial or renewal permit as a prescription drug wholesaler or an out-of-state prescription drug wholesaler must designate in writing to the department at least one natural person to serve as the designated representative of the 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 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 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 (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 wholesaler permit or an out-of-state prescription drug 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.

(12)~~(5)~~ The department may adopt rules governing the recordkeeping, storage, and handling with respect to each of the distributions of prescription drugs specified in subparagraphs (1)(a)1.-4.

Section 15. Subsections (4), (6), (7), and (8) of section 499.0121, Florida Statutes, are amended, and subsection (11) is added to that section, to read:

499.0121 Storage and handling of prescription drugs; recordkeeping.--The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

(4) EXAMINATION OF MATERIALS AND RECORDS.--

(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 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. 499.001(31).

(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; ~~and~~

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 ss. 499.001-499.081 and must be readily available.

(d)1. Each person who is engaged in the wholesale distribution of a prescription drug, and who is not an authorized distributor of record for the drug manufacturer's products ~~of such drug~~, must provide to each wholesale distributor of such drug, before the sale is made to such wholesale distributor, a written statement under oath identifying each previous sale of the drug back to the last authorized distributor of record, the lot number of the drug, and the sales invoice number of the invoice evidencing the sale of the drug. The written statement ~~identifying all sales of such drug~~ must accompany the drug ~~for each subsequent wholesale distribution of the drug~~ to the next ~~a~~ wholesale distributor. The department shall adopt rules relating to the requirements of this written statement. This paragraph does not apply to a manufacturer unless the manufacturer is performing the manufacturing operation of repackaging prescription drugs.

2. Each wholesale distributor of prescription drugs must maintain separate and distinct from other required records all statements that are required under subparagraph 1. and paragraph (e).

3. Each manufacturer of a prescription drug sold in this state must maintain at its corporate offices a current list of authorized distributors and must make such list available to the department upon request.

4. For the purposes of this subsection, the term "authorized distributors of record" means a wholesale distributor ~~those distributors~~ with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products. Effective March 1, 2004, an ongoing relationship is deemed to exist when a wholesale distributor, including any affiliated group, as defined in s. 1504 of the Internal Revenue Code, of which the wholesale distributor is a member:

a. Is listed on the manufacturer's current list of authorized distributors.

b. Annually purchases not less than 90 percent of all of its purchases of a manufacturer's prescription drug products, based on dollar volume, directly from that manufacturer.

c. Has reported to the department pursuant to s. 499.012(2)(g)2. that the wholesale distributor has total annual prescription drug sales of $100 million or more, and has a verifiable account number issued by the manufacturer authorizing the wholesale distributor to purchase the manufacturer's drug products directly from that manufacturer and that wholesale distributor makes not fewer than twelve purchases of that manufacturer's drug products directly from

the manufacturer annually using said verifiable account number.

d. Meets other criteria for an ongoing relationship that the department may develop by rule.

Effective July 1, 2003, each manufacturer shall file a written list of all of the manufacturer's authorized distributors with the department. A manufacturer shall notify the department not later than 10 days after any change to the list. The department shall publish the list of all authorized distributors qualified pursuant to subparagraph (d)4. on its website.

5. If a prescription drug manufacturer fails to file a copy of its manufacturer's list of authorized distributors with the department or files a list of authorized distributors that contains fewer than five wholesale distributors that are permitted by the department, an ongoing relationship is deemed to exist if a wholesale distributor meets the following criteria. The wholesale distributor must request that the department publish its name on the list of authorized distributors with submission of documentation that the wholesale distributor:

a. Has a verifiable account number issued by the manufacturer which authorizes that whole distributor to purchase the manufacturer's products;

b. Made not fewer than 12 purchases of that manufacturer's prescription drug products directly from that manufacturer in the previous 12 months using the verifiable account number; and

c. Has total prescription drug sales of $100,000 or more annually.

6. This paragraph expires July 1, 2006.

(e)1. Notwithstanding paragraph (d), each person who is engaged in the wholesale distribution of a specified drug must provide to each wholesale distributor of such specified drug:

a. Upon any sale, a written statement that:

(I) If the establishment is not a member of an affiliated group: "This establishment purchased the specific unit of the specified drug directly from the manufacturer"; or

(II) If the establishment is a member of an affiliated group: "This establishment or a member of my affiliated group purchased the specific unit of the specified drug directly from the manufacturer"; or

b. Before the wholesale distribution, a written statement, under oath, that identifies each previous sale of the specific unit of the specified drug back to the manufacturer of the specified drug, the lot number of the specific unit of the specified prescription drug, and the sales invoice number of the invoice evidencing each previous sale of the specific unit of the specified drug. The written statement identifying all sales of such specific unit of the specified drug must accompany the specific unit of the specified drug for each subsequent wholesale distribution of the specific unit of the specified drug to a wholesale distributor.

The department shall adopt rules to administer the requirements of these written statements.

2. As used in this paragraph, the term "specified drug" means a specific prescription drug on the list of drugs adopted by the department by rule.

3.a. A drug may be placed on the list of specified drugs if the department has seized or issued a stop sale notice on the prescription drug because of the adulteration, counterfeiting, or diversion of the prescription drug from the legal channels of distribution for prescription drugs, or the United States Food and Drug Administration, a manufacturer, a wholesale distributor, a law enforcement agency, or a government agency responsible for regulating the sale or distribution of prescription drugs in another state has notified the department in writing or through a website operated by one of said entities that the prescription drug has been adulterated, counterfeit or diverted from the legal channels of distribution for prescription drugs; and the prescription drug satisfies one of the following criteria:

(I) The prescription drug is included among the top 150 prescription drugs for which the state has incurred the highest amount of Medicaid claims in the most recently ended state fiscal year;

(II) The prescription drug is available for normal prescription use in dosages or strengths that have a wholesale cost $200 or more;

(III) The prescription drug is used extensively for patients with human immunodeficiency virus, acquired immune deficiency syndrome, cancer, or other serious, life threatening conditions, where drug nonresponsiveness would not be considered to be medically unusual;

(IV) The prescription drug is an injectable drug;

(V) The prescription drug is subject to a special, limited distribution process and is not generally sold to wholesale distributors by the manufacturer of the prescription drug;

(VI) The department has found not less than five instances where statements required pursuant to paragraph (d) for the prescription drug were not passed on other than because of unintentional oversight, or have been passed on by or to a wholesale distributor and such statements were fraudulent; or

(VII) A shipment of a prescription drug has been reported to a law enforcement agency as having been stolen or as missing.

b. A prescription drug may be placed on the list of specified drugs if the prescription drug satisfies any three of the seven criteria set forth in sub-sub-subparagraphs (I)-(VII). However, a prescription drug may not be included on the list of specified drugs if the prescription drug is unlikely to be counterfeited or diverted from the legal channels of distribution for prescription drugs.

c. Before the department begins the rulemaking process to place a drug on the list of specified drugs, except when the department files a rule under the procedure specified in s. 499.0121(6)(e)3.e., the Drug Wholesaler Advisory Council created in s. 499.01211 shall consider whether a prescription drug should be included on or added to the list of specified drugs using the criteria enumerated in sub-subparagraph 3.a. or sub-subparagraph 3.b. and provide a written recommendation adopted by majority vote to the secretary of the department concerning each such drug. This paragraph does not apply to any list of prescription drugs on which the department has begun rulemaking prior to this paragraph becoming law.

d. When a prescription drug is added to the list of specified drugs, the requirements of this paragraph shall be effective as to the prescription drug beginning 60 days after

the effective date of the rule adding the prescription drug to the list, except when the department files a rule under the procedure specified in s. 499.0121(6)(e)3.e.

e.(I) Notwithstanding chapter 120, if the Attorney General or Statewide Prosecutor certifies to the secretary of the department that a prescription drug should be added to the list of specified drugs by emergency rule, the department may proceed to add such drug to the list of specified drugs and the emergency rule shall be effective for a period of one year from the date on which the emergency rule is filed, if the department begins the rulemaking process to adopt a permanent rule to place the drug on the list of specified drugs not later than 90 days after the date on which the emergency rule was filed. An emergency rule adding a drug to the list of specified drugs may not be renewed.

(II) A prescription drug may be placed on the list of specified drugs through the procedure provided in sub-subparagraph (e)3.e. when:

(A) The prescription drug satisfies any two of the criteria specified in sub-subparagraph (e)3.a. or sub-subparagraph (e)3.b.; or

(B) The prescription drug satisfies any one of the criteria specified in sub-subparagraph (e)3.a. or sub-subparagraph (e)3.b. if the prescription drug has not yet become available for wholesale distribution or has been available for wholesale distribution for not more than 60 days.

(III) Notwithstanding chapter 120, any emergency rule that places a prescription drug on the list of specified drugs may be challenged as being an invalid exercise of the delegated legislative authority only if the department lacks

any substantial competent evidence that the prescription drug satisfied the criteria required pursuant to sub-sub-subparagraph (I) or sub-sub-subparagraph (II). Not later than seven days after any request by any person, the department shall provide such person with the substantial competent evidence that justifies the department's adoption of an emergency rule placing a prescription drug on the list of specified drugs.

(IV) The department shall notify all prescription drug wholesalers and out-of-state-prescription drug wholesalers by electronic means, facsimile, or United States mail and on the bureau's website when any emergency rule is adopted which places a prescription drug on the list of specified drugs. Not later than seven days after the department adopts an emergency rule placing a prescription drug on the list of specified drugs, wholesalers shall provide the department with the lot numbers and quantities of such prescription drug which the wholesaler owns or has in transit on the date that the department adopted the emergency rule placing the prescription drug on the list of specified drugs.

(V) The requirements of subparagraph (e)1. do not apply to those lot numbers and quantities of a prescription drug which are included on a report filed pursuant to sub-sub-subparagraph (e)3.e.(IV), and paragraph (6)(d) shall apply to those lot numbers and quantities of the prescription drug. In addition to the requirements of paragraph (6)(d), any wholesale distributor selling a prescription drug included on a report filed pursuant to sub-sub-subparagraph (e)3.e.(IV) shall provide any wholesaler purchasing the prescription drugs with a statement under oath that the prescription drugs are among those included on a report filed pursuant to

sub-sub-subparagraph (e)3.e.(IV) and with a copy of the report filed by the wholesale distributor with the department for those prescription drugs.

f. Not less than annually, the council and department shall evaluate whether each prescription drug included on the list of specified drugs should remain on the list. In determining whether a prescription drug should remain on the list of specified drugs, the council and department must consider:

(I) The availability of generic forms of the drug.

(II) Changes in the price of the drug since the prescription drug was placed on the list.

(III) The current status of the drug that caused the department to place the prescription drug on the list of specified drugs.

The council shall provide a written recommendation adopted by majority vote to the secretary of the department concerning each drug that the council recommends be removed from the list of specified drugs.

4. This paragraph does not apply to a manufacturer; however, a repackager must comply with this paragraph.

5. This paragraph expires July 1, 2006.

(f)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. In order to verify compliance with paragraph (d)1., each manufacturer of a prescription drug sold in this state must make available upon request distribution documentation related to its sales of prescription drugs, regardless of whether the prescription drug was sold directly by the manufacturer to a person in Florida.

(g) 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.

(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.

(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.

(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.

Section 16. Effective January 1, 2004, subsection (12) is added to section 499.0121, Florida Statutes, 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.

(12) DUE DILIGENCE OF SUPPLIERS.--Prior to purchasing any prescription drugs from another wholesale drug distributor, a wholesale drug distributor 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 pursuant to s. 499.012(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 17. Section 499.01211, Florida Statutes, is created to read:

499.01211 Drug Wholesaler Advisory Council.--

(1) There is created the Drug Wholesaler Advisory Council within the department. The council shall meet at least once each calendar quarter. Staff for the council shall be provided by the department. The council shall consist of 11 members who shall serve without compensation. The council shall elect a chairperson and a vice chairperson annually.

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

(a) Three different persons each of whom is employed by a different prescription drug wholesaler licensed under this chapter which operates nationally and is a primary wholesaler, as defined in s. 499.012 (1)(d).

(b) One person employed by a prescription drug wholesaler licensed under this chapter which is a secondary wholesaler, as defined in s. 499.012(1)(f).

(c) One person employed by a retail pharmacy chain located in this state.

(d) One person who is a member of the Board of Pharmacy and is a pharmacist licensed under chapter 465.

(e) One person who is a physician licensed pursuant to chapter 458 or 459.

(f) One person who is an employee of a hospital licensed pursuant to chapter 395 and is a pharmacist licensed pursuant to chapter 465.

(g) One person who is an employee of a pharmaceutical manufacturer.

(3) The council shall review ss. 499.001-499.081 and the rules adopted to administer ss. 499.001-499.081 annually, provide input to the department regarding all proposed rules to administer ss. 499.001-499.081, make written recommendation to the secretary of the department regarding the listing of all specified drugs pursuant to s. 499.0121(6)(e), make recommendations to the department to improve the protection of the prescription drugs and public health, make recommendations to improve coordination with other states' regulatory agencies and the federal government concerning the wholesale distribution of drugs, and make recommendations to minimize the impact of regulation of the wholesale distribution industry while ensuring protection of the public health.

Section 18. Effective January 1, 2004, section 499.013, Florida Statutes, is amended to read:

499.013 Manufacturers and repackagers of drugs, devices, and cosmetics; definitions, permits, and general requirements.--

(1) As used in this section, the terms ~~term~~ "manufacture" and "repackage" have ~~has~~ the meaning as in ~~assigned to it under~~ s. 499.003. A pharmacy is exempt from these definitions ~~this definition~~ if it is operating in compliance with pharmacy practice standards as defined in chapter 465 and the rules adopted under that chapter.

(2) Any person that engages in the manufacture or repackaging of drugs, devices, or cosmetics in this state must first obtain one of the following permits and may engage only in the activity allowed under that permit:

(a) A prescription drug manufacturer's permit is required for any person that manufactures a prescription drug in this state. A prescription drug repackager's 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 manufacturer or prescription drug repackager may engage in wholesale distribution of prescription drugs manufactured or repackaged at that establishment and must comply with all the provisions of ss. 499.001-499.081 and the rules adopted under those sections that apply to a wholesale distributor.

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

(b) An over-the-counter drug 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.

(c) A compressed medical gas 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 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.

(d) A device 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.

(e) A cosmetic 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.

(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.

(4) 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.

Section 19. Subsection (3) of section 499.014, Florida Statutes, is amended to read:

499.014 Distribution of legend drugs by hospitals, health care entities, charitable organizations, and return or destruction companies; permits, general requirements.--

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

Section 20. 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's permit may not be less than $500 or more than $750~~$600~~ 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's permit may not be less than $250 or more than $400 annually.

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

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

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

(g)~~(f)~~ 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 wholesaler's permit may not be less than $300 or more than$800~~$400~~ annually.~~;~~

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

(c) The fee for an out-of-state prescription drug wholesaler's permit may not be less than$300~~$200~~ or more than$800~~$300~~ annually.~~;~~

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

(e)~~(d)~~ The fee for a retail pharmacy 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.

(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 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'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 ss. 499.001-499.081, ~~beginning January 1, 1993,~~ 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 wholesaler applicant or permittee an on-site 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 on-site 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)~~(8)~~ The department shall assess other fees as provided in ss. 499.001-499.081.

Section 21. Subsection (2) and present subsection (5) of section 499.051, Florida Statutes, are amended, present subsections (4) and (5) of that section are redesignated as subsections (6) and (7), respectively, and new subsections (4) and (5) are added to that section, to read:

499.051 Inspections and investigations.--

(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 ss. 499.001-499.081 and rules adopted under those sections regarding any drug, device, or cosmetic product. ~~The authority to enter and inspect does not extend to the practice of the profession of pharmacy, as defined in chapter 465 and the rules adopted under that chapter, in a pharmacy permitted under chapter 465. The Department of Business and Professional Regulation shall conduct routine inspections of retail pharmacy wholesalers at the time of the regular pharmacy permit inspection and shall send the inspection report regarding drug wholesale activity to the Department of Health.~~

(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 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.

(7)~~(5)~~ 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. 499.0121(6)(d), and the pedigree papers required in that subsection shall not be deemed a trade secret.

Section 22. Subsection (4) is added to section 499.055, Florida Statutes, to read:

499.055 Reports and dissemination of information by department.--

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

(a) A list of the prescription drug wholesalers, out-of-state prescription drug wholesalers, and retail pharmacy drug wholesalers against whom the department has initiated enforcement action pursuant to 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 wholesalers, out-of-state prescription drug wholesalers, and retail pharmacy drug 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 wholesalers, out-of-state prescription drug wholesalers, and retail pharmacy drug wholesalers' permits that have been returned to the department, were suspended, were revoked, have expired, or were not renewed in the previous year.

Section 23. Section 499.065, Florida Statutes, is created to read:

499.065 Imminent danger.--

(1) Notwithstanding s. 499.051, the department shall inspect each prescription drug wholesale establishment, prescription drug repackager establishment, and retail pharmacy drug wholesaler establishment that is required to be permitted under this 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 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 Secretary of Health or his or her designee determines that such 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 establishment, prescription drug repackager establishment, or retail pharmacy drug wholesaler establishment that is required to be permitted under this chapter is an imminent danger to the public health and require its immediate closure if such establishment fails to comply with applicable laws and rules and, because of such 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.

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 24. Subsection (1) of section 499.066, Florida Statutes, is amended, and subsection (7) is added to that section, 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 ss. 499.001-499.081. If it appears that a person has violated any provision of 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.~~When the department believes that any person has violated ss. 499.001-499.081 or any rules adopted pursuant to those sections, it may issue and deliver an order to cease and desist from such violation.~~

(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 25. Section 499.0661, Florida Statutes, is created to read:

499.0661 Cease and desist orders; removal of certain persons.--

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

(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 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 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.

(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 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 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 26. Effective January 1, 2004, subsection (1) of section 499.067, Florida Statutes, is amended, and subsections (6) and (7) are added to that section, 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 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 ~~it is shown~~ 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. 499.01 or s. 499.012(5).

4. The applicant, permittee, or person certified under s. 499.012(11) demonstrates any of the conditions enumerated in s. 499.01 or s. 499.012(5).

5. The applicant, permittee, or person certified under s. 499.012(11) has committed any violation of ss. 499.005-499.0054.

(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 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. 499.01(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 27. Section 499.069, Florida Statutes, is amended to read:

499.069 Criminal punishment for violations of s. 499.005 related to devices and cosmetics; dissemination of false advertisement.--

(1) Any person who violates any of the provisions of s. 499.005 with respect to a device or cosmetic commits ~~is guilty of~~ 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 ss. 499.001-499.081, except that any person who violates subsection (8), or

subsection (10)~~, subsection (14), subsection (15), or subsection (17)~~of s. 499.005 with respect to a device or cosmetic commits ~~is guilty of~~ 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 ss. 499.001-499.081.

~~(2) A person is not subject to the penalties of subsection (1) for having violated any of the provisions of s. 499.005 if he or she establishes a guaranty or undertaking, which guaranty or undertaking is signed by and contains the name and address of the person residing in the state, or the manufacturer, from whom he or she received the article in good faith, to the effect that such article is not adulterated or misbranded within the meaning of ss. 499.001-499.081, citing such sections.~~

(2)~~(3)~~ 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 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, wholesaler, seller, or advertising agency that asked him or her to disseminate such advertisement.

Section 28. Section 499.0691, Florida Statutes, is created to read:

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 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 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 ss. 499.001-499.081 and rules adopted under those sections, except for pedigree papers, invoices, or shipping documents related to legend drugs.

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

(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 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 legend drug.

(e) The importation of a 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 any 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 wholesaler when a permit is required by ss. 499.001-499.081 for that activity.

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

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

(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 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 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.

(4) A publisher, radio broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, repackager, wholesaler, or seller of the article to which a false advertisement relates, is not liable under 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, wholesaler, seller, or advertising agency that asked him or her to disseminate such advertisement.

Section 29. Paragraphs (d), (f), (h), (i), and (j) of subsection (3) of section 921.0022, Florida Statutes, are amended to read:

921.0022 Criminal Punishment Code; offense severity ranking chart.--

(3) OFFENSE SEVERITY RANKING CHART

Florida Statute	Felony Degree	Description
		(d) LEVEL 4
316.1935(3)	2nd	Driving at high speed or with wanton disregard for safety while fleeing or attempting to elude law enforcement officer who is in a marked patrol vehicle with siren and lights activated.
499.0051(1)	3rd	Failure to maintain or deliver pedigree papers.
499.0051(2)	3rd	Failure to authenticate pedigree papers.
499.0051(6)	2nd	Sale or delivery, or possession with intent to sell, contraband legend drugs.
784.07(2)(b)	3rd	Battery of law enforcement officer, firefighter, intake officer, etc.
784.074(1)(c)	3rd	Battery of sexually violent predators facility staff.
784.075	3rd	Battery on detention or commitment facility staff.
784.078	3rd	Battery of facility employee by throwing, tossing, or expelling certain fluids or materials.
784.08(2)(c)	3rd	Battery on a person 65 years of age or older.

784.081(3)	3rd	Battery on specified official or employee.
784.082(3)	3rd	Battery by detained person on visitor or other detainee.
784.083(3)	3rd	Battery on code inspector.
784.085	3rd	Battery of child by throwing, tossing, projecting, or expelling certain fluids or materials.
787.03(1)	3rd	Interference with custody; wrongly takes child from appointed guardian.
787.04(2)	3rd	Take, entice, or remove child beyond state limits with criminal intent pending custody proceedings.
787.04(3)	3rd	Carrying child beyond state lines with criminal intent to avoid producing child at custody hearing or delivering to designated person.
790.115(1)	3rd	Exhibiting firearm or weapon within 1,000 feet of a school.
790.115(2)(b)	3rd	Possessing electric weapon or device, destructive device, or other weapon on school property.
790.115(2)(c)	3rd	Possessing firearm on school property.
800.04(7)(d)	3rd	Lewd or lascivious exhibition; offender less than 18 years.

810.02(4)(a)	3rd	Burglary, or attempted burglary, of an unoccupied structure; unarmed; no assault or battery.
810.02(4)(b)	3rd	Burglary, or attempted burglary, of an unoccupied conveyance; unarmed; no assault or battery.
810.06	3rd	Burglary; possession of tools.
810.08(2)(c)	3rd	Trespass on property, armed with firearm or dangerous weapon.
812.014(2)(c)3.	3rd	Grand theft, 3rd degree $10,000 or more but less than $20,000.
812.014 (2)(c)4.-10.	3rd	Grand theft, 3rd degree, a will, firearm, motor vehicle, livestock, etc.
812.0195(2)	3rd	Dealing in stolen property by use of the Internet; property stolen $300 or more.
817.563(1)	3rd	Sell or deliver substance other than controlled substance agreed upon, excluding s. 893.03(5) drugs.
817.568(2)(a)	3rd	Fraudulent use of personal identification information.
817.625(2)(a)	3rd	Fraudulent use of scanning device or reencoder.
828.125(1)	2nd	Kill, maim, or cause great bodily harm or permanent breeding disability to any registered horse or cattle.
837.02(1)	3rd	Perjury in official proceedings.

837.021(1)	3rd	Make contradictory statements in official proceedings.
839.13(2)(a)	3rd	Falsifying records of an individual in the care and custody of a state agency.
839.13(2)(c)	3rd	Falsifying records of the Department of Children and Family Services.
843.021	3rd	Possession of a concealed handcuff key by a person in custody.
843.025	3rd	Deprive law enforcement, correctional, or correctional probation officer of means of protection or communication.
843.15(1)(a)	3rd	Failure to appear while on bail for felony (bond estreature or bond jumping).
874.05(1)	3rd	Encouraging or recruiting another to join a criminal street gang.
893.13(2)(a)1.	2nd	Purchase of cocaine (or other s. 893.03(1)(a), (b), or (d), (2)(a), (2)(b), or (2)(c)4. drugs).
914.14(2)	3rd	Witnesses accepting bribes.
914.22(1)	3rd	Force, threaten, etc., witness, victim, or informant.
914.23(2)	3rd	Retaliation against a witness, victim, or informant, no bodily injury.
918.12	3rd	Tampering with jurors.

934.215	3rd	Use of two-way communications device to facilitate commission of a crime.
		(f) LEVEL 6
316.027(1)(b)	2nd	Accident involving death, failure to stop; leaving scene.
316.193(2)(b)	3rd	Felony DUI, 4th or subsequent conviction.
499.0051(3)	2nd	Forgery of pedigree papers.
499.0051(4)	2nd	Purchase or receipt of legend drug from unauthorized person.
499.0051(5)	2nd	Sale of legend drug to unauthorized person.
775.0875(1)	3rd	Taking firearm from law enforcement officer.
775.21(10)	3rd	Sexual predators; failure to register; failure to renew driver's license or identification card.
784.021(1)(a)	3rd	Aggravated assault; deadly weapon without intent to kill.
784.021(1)(b)	3rd	Aggravated assault; intent to commit felony.
784.041	3rd	Felony battery.
784.048(3)	3rd	Aggravated stalking; credible threat.
784.048(5)	3rd	Aggravated stalking of person under 16.
784.07(2)(c)	2nd	Aggravated assault on law enforcement officer.

784.074(1)(b)	2nd	Aggravated assault on sexually violent predators facility staff.
784.08(2)(b)	2nd	Aggravated assault on a person 65 years of age or older.
784.081(2)	2nd	Aggravated assault on specified official or employee.
784.082(2)	2nd	Aggravated assault by detained person on visitor or other detainee.
784.083(2)	2nd	Aggravated assault on code inspector.
787.02(2)	3rd	False imprisonment; restraining with purpose other than those in s. 787.01.
790.115(2)(d)	2nd	Discharging firearm or weapon on school property.
790.161(2)	2nd	Make, possess, or throw destructive device with intent to do bodily harm or damage property.
790.164(1)	2nd	False report of deadly explosive, weapon of mass destruction, or act of arson or violence to state property.
790.19	2nd	Shooting or throwing deadly missiles into dwellings, vessels, or vehicles.
794.011(8)(a)	3rd	Solicitation of minor to participate in sexual activity by custodial adult.

794.05(1)	2nd	Unlawful sexual activity with specified minor.
800.04(5)(d)	3rd	Lewd or lascivious molestation; victim 12 years of age or older but less than 16 years; offender less than 18 years.
800.04(6)(b)	2nd	Lewd or lascivious conduct; offender 18 years of age or older.
806.031(2)	2nd	Arson resulting in great bodily harm to firefighter or any other person.
810.02(3)(c)	2nd	Burglary of occupied structure; unarmed; no assault or battery.
812.014(2)(b)1.	2nd	Property stolen $20,000 or more, but less than $100,000, grand theft in 2nd degree.
812.014(2)(b)2.	2nd	Property stolen; cargo valued at less than $50,000, grand theft in 2nd degree.
812.015(9)	2nd	Retail theft; property stolen $300 or more; second or subsequent conviction.
812.13(2)(c)	2nd	Robbery, no firearm or other weapon (strong-arm robbery).
817.034(4)(a)1.	1st	Communications fraud, value greater than $50,000.
817.4821(5)	2nd	Possess cloning paraphernalia with intent to create cloned cellular telephones.

825.102(1)	3rd	Abuse of an elderly person or disabled adult.
825.102(3)(c)	3rd	Neglect of an elderly person or disabled adult.
825.1025(3)	3rd	Lewd or lascivious molestation of an elderly person or disabled adult.
825.103(2)(c)	3rd	Exploiting an elderly person or disabled adult and property is valued at less than $20,000.
827.03(1)	3rd	Abuse of a child.
827.03(3)(c)	3rd	Neglect of a child.
827.071(2)&(3)	2nd	Use or induce a child in a sexual performance, or promote or direct such performance.
836.05	2nd	Threats; extortion.
836.10	2nd	Written threats to kill or do bodily injury.
843.12	3rd	Aids or assists person to escape.
847.0135(3)	3rd	Solicitation of a child, via a computer service, to commit an unlawful sex act.
914.23	2nd	Retaliation against a witness, victim, or informant, with bodily injury.
943.0435(9)	3rd	Sex offenders; failure to comply with reporting requirements.

944.35(3)(a)2.	3rd	Committing malicious battery upon or inflicting cruel or inhuman treatment on an inmate or offender on community supervision, resulting in great bodily harm.
944.40	2nd	Escapes.
944.46	3rd	Harboring, concealing, aiding escaped prisoners.
944.47(1)(a)5.	2nd	Introduction of contraband (firearm, weapon, or explosive) into correctional facility.
951.22(1)	3rd	Intoxicating drug, firearm, or weapon introduced into county facility.
		(h) LEVEL 8
316.193 (3)(c)3.a.	2nd	DUI manslaughter.
327.35(3)(c)3.	2nd	Vessel BUI manslaughter.
499.0051(7)	1st	Forgery of prescription or legend drug labels.
499.0052	1st	Trafficking in contraband legend drugs.
560.123(8)(b)2.	2nd	Failure to report currency or payment instruments totaling or exceeding $20,000, but less than $100,000 by money transmitter.

560.125(5)(b)	2nd	Money transmitter business by unauthorized person, currency or payment instruments totaling or exceeding $20,000, but less than $100,000.
655.50(10)(b)2.	2nd	Failure to report financial transactions totaling or exceeding $20,000, but less than $100,000 by financial institutions.
777.03(2)(a)	1st	Accessory after the fact, capital felony.
782.04(4)	2nd	Killing of human without design when engaged in act or attempt of any felony other than arson, sexual battery, robbery, burglary, kidnapping, aircraft piracy, or unlawfully discharging bomb.
782.051(2)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony not enumerated in s. 782.04(3).
782.071(1)(b)	1st	Committing vehicular homicide and failing to render aid or give information.
782.072(2)	1st	Committing vessel homicide and failing to render aid or give information.

790.161(3)	1st	Discharging a destructive device which results in bodily harm or property damage.
794.011(5)	2nd	Sexual battery, victim 12 years or over, offender does not use physical force likely to cause serious injury.
800.04(4)	2nd	Lewd or lascivious battery.
806.01(1)	1st	Maliciously damage dwelling or structure by fire or explosive, believing person in structure.
810.02(2)(a)	1st,PBL	Burglary with assault or battery.
810.02(2)(b)	1st,PBL	Burglary; armed with explosives or dangerous weapon.
810.02(2)(c)	1st	Burglary of a dwelling or structure causing structural damage or $1,000 or more property damage.
812.13(2)(b)	1st	Robbery with a weapon.
812.135(2)	1st	Home-invasion robbery.
825.102(2)	2nd	Aggravated abuse of an elderly person or disabled adult.
825.1025(2)	2nd	Lewd or lascivious battery upon an elderly person or disabled adult.
825.103(2)(a)	1st	Exploiting an elderly person or disabled adult and property is valued at $100,000 or more.
837.02(2)	2nd	Perjury in official proceedings relating to prosecution of a capital felony.

837.021(2)	2nd	Making contradictory statements in official proceedings relating to prosecution of a capital felony.
860.121(2)(c)	1st	Shooting at or throwing any object in path of railroad vehicle resulting in great bodily harm.
860.16	1st	Aircraft piracy.
893.13(1)(b)	1st	Sell or deliver in excess of 10 grams of any substance specified in s. 893.03(1)(a) or (b).
893.13(2)(b)	1st	Purchase in excess of 10 grams of any substance specified in s. 893.03(1)(a) or (b).
893.13(6)(c)	1st	Possess in excess of 10 grams of any substance specified in s. 893.03(1)(a) or (b).
893.135(1)(a)2.	1st	Trafficking in cannabis, more than 2,000 lbs., less than 10,000 lbs.
893.135 (1)(b)1.b.	1st	Trafficking in cocaine, more than 200 grams, less than 400 grams.
893.135 (1)(c)1.b.	1st	Trafficking in illegal drugs, more than 14 grams, less than 28 grams.

893.135 (1)(d)1.b.	1st	Trafficking in phencyclidine, more than 200 grams, less than 400 grams.
893.135 (1)(e)1.b.	1st	Trafficking in methaqualone, more than 5 kilograms, less than 25 kilograms.
893.135 (1)(f)1.b.	1st	Trafficking in amphetamine, more than 28 grams, less than 200 grams.
893.135 (1)(g)1.b.	1st	Trafficking in flunitrazepam, 14 grams or more, less than 28 grams.
893.135 (1)(h)1.b.	1st	Trafficking in gamma-hydroxybutyric acid (GHB), 5 kilograms or more, less than 10 kilograms.
893.135 (1)(j)1.b.	1st	Trafficking in 1,4-Butanediol, 5 kilograms or more, less than 10 kilograms.
893.135 (1)(k)2.b.	1st	Trafficking in Phenethylamines, 200 grams or more, less than 400 grams.

895.03(1)	1st	Use or invest proceeds derived from pattern of racketeering activity.
895.03(2)	1st	Acquire or maintain through racketeering activity any interest in or control of any enterprise or real property.
895.03(3)	1st	Conduct or participate in any enterprise through pattern of racketeering activity.
896.101(5)(b)	2nd	Money laundering, financial transactions totaling or exceeding $20,000, but less than $100,000.
896.104(4)(a)2.	2nd	Structuring transactions to evade reporting or registration requirements, financial transactions totaling or exceeding $20,000 but less than $100,000.
		(i) LEVEL 9
316.193 (3)(c)3.b.	1st	DUI manslaughter; failing to render aid or give information.
327.35(3)(c)3.b.	1st	BUI manslaughter; failing to render aid or give information.
<u>499.0053</u>	<u>1st</u>	<u>Sale or purchase of contraband legend drugs resulting in great bodily harm.</u>

560.123(8)(b)3.	1st	Failure to report currency or payment instruments totaling or exceeding $100,000 by money transmitter.
560.125(5)(c)	1st	Money transmitter business by unauthorized person, currency, or payment instruments totaling or exceeding $100,000.
655.50(10)(b)3.	1st	Failure to report financial transactions totaling or exceeding $100,000 by financial institution.
775.0844	1st	Aggravated white collar crime.
782.04(1)	1st	Attempt, conspire, or solicit to commit premeditated murder.
782.04(3)	1st,PBL	Accomplice to murder in connection with arson, sexual battery, robbery, burglary, and other specified felonies.
782.051(1)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony enumerated in s. 782.04(3).
782.07(2)	1st	Aggravated manslaughter of an elderly person or disabled adult.
787.01(1)(a)1.	1st,PBL	Kidnapping; hold for ransom or reward or as a shield or hostage.
787.01(1)(a)2.	1st,PBL	Kidnapping with intent to commit or facilitate commission of any felony.

787.01(1)(a)4.	1st,PBL	Kidnapping with intent to interfere with performance of any governmental or political function.
787.02(3)(a)	1st	False imprisonment; child under age 13; perpetrator also commits aggravated child abuse, sexual battery, or lewd or lascivious battery, molestation, conduct, or exhibition.
790.161	1st	Attempted capital destructive device offense.
790.166(2)	1st,PBL	Possessing, selling, using, or attempting to use a weapon of mass destruction.
794.011(2)	1st	Attempted sexual battery; victim less than 12 years of age.
794.011(2)	Life	Sexual battery; offender younger than 18 years and commits sexual battery on a person less than 12 years.
794.011(4)	1st	Sexual battery; victim 12 years or older, certain circumstances.
794.011(8)(b)	1st	Sexual battery; engage in sexual conduct with minor 12 to 18 years by person in familial or custodial authority.
800.04(5)(b)	1st	Lewd or lascivious molestation; victim less than 12 years; offender 18 years or older.

812.13(2)(a)	1st,PBL	Robbery with firearm or other deadly weapon.
812.133(2)(a)	1st,PBL	Carjacking; firearm or other deadly weapon.
827.03(2)	1st	Aggravated child abuse.
847.0145(1)	1st	Selling, or otherwise transferring custody or control, of a minor.
847.0145(2)	1st	Purchasing, or otherwise obtaining custody or control, of a minor.
859.01	1st	Poisoning or introducing bacteria, radioactive materials, viruses, or chemical compounds into food, drink, medicine, or water with intent to kill or injure another person.
893.135	1st	Attempted capital trafficking offense.
893.135(1)(a)3.	1st	Trafficking in cannabis, more than 10,000 lbs.
893.135 (1)(b)1.c.	1st	Trafficking in cocaine, more than 400 grams, less than 150 kilograms.
893.135 (1)(c)1.c.	1st	Trafficking in illegal drugs, more than 28 grams, less than 30 kilograms.

893.135		
(1)(d)1.c.	1st	Trafficking in phencyclidine, more than 400 grams.
893.135		
(1)(e)1.c.	1st	Trafficking in methaqualone, more than 25 kilograms.
893.135		
(1)(f)1.c.	1st	Trafficking in amphetamine, more than 200 grams.
893.135		
(1)(h)1.c.	1st	Trafficking in gamma-hydroxybutyric acid (GHB), 10 kilograms or more.
893.135		
(1)(j)1.c.	1st	Trafficking in 1,4-Butanediol, 10 kilograms or more.
893.135		
(1)(k)2.c.	1st	Trafficking in Phenethylamines, 400 grams or more.
896.101(5)(c)	1st	Money laundering, financial instruments totaling or exceeding $100,000.
896.104(4)(a)3.	1st	Structuring transactions to evade reporting or registration requirements, financial transactions totaling or exceeding $100,000.
		(j) LEVEL 10
499.0054	1st	Sale or purchase of contraband legend drugs resulting in death.

782.04(2)	1st,PBL	Unlawful killing of human; act is homicide, unpremeditated.
787.01(1)(a)3.	1st,PBL	Kidnapping; inflict bodily harm upon or terrorize victim.
787.01(3)(a)	Life	Kidnapping; child under age 13, perpetrator also commits aggravated child abuse, sexual battery, or lewd or lascivious battery, molestation, conduct, or exhibition.
782.07(3)	1st	Aggravated manslaughter of a child.
794.011(3)	Life	Sexual battery; victim 12 years or older, offender uses or threatens to use deadly weapon or physical force to cause serious injury.
876.32	1st	Treason against the state.

Section 30. Paragraph (a) of subsection (1) of section 16.56, Florida Statutes, is amended to read:

16.56 Office of Statewide Prosecution.--

(1) There is created in the Department of Legal Affairs an Office of Statewide Prosecution. The office shall be a separate "budget entity" as that term is defined in chapter 216. The office may:

(a) Investigate and prosecute the offenses of:

1. Bribery, burglary, criminal usury, extortion, gambling, kidnapping, larceny, murder, prostitution, perjury, robbery, carjacking, and home-invasion robbery;

2. Any crime involving narcotic or other dangerous drugs;

3. Any violation of the provisions of the Florida RICO (Racketeer Influenced and Corrupt Organization) Act, including any offense listed in the definition of racketeering activity in s. 895.02(1)(a), providing such listed offense is investigated in connection with a violation of s. 895.03 and is charged in a separate count of an information or indictment containing a count charging a violation of s. 895.03, the prosecution of which listed offense may continue independently if the prosecution of the violation of s. 895.03 is terminated for any reason;

4. Any violation of the provisions of the Florida Anti-Fencing Act;

5. Any violation of the provisions of the Florida Antitrust Act of 1980, as amended;

6. Any crime involving, or resulting in, fraud or deceit upon any person;

7. Any violation of s. 847.0135, relating to computer pornography and child exploitation prevention, or any offense related to a violation of s. 847.0135; ~~or~~

8. Any violation of the provisions of chapter 815; or

9. Any criminal violation of part I of chapter 499.

or any attempt, solicitation, or conspiracy to commit any of the crimes specifically enumerated above. The office shall have such power only when any such offense is occurring, or has occurred, in two or more judicial circuits as part of a related transaction, or when any such offense is connected with an organized criminal conspiracy affecting two or more judicial circuits.

Section 31. Paragraph (a) of subsection (1) of section 895.02, Florida Statutes, is amended to read:

895.02 Definitions.--As used in ss. 895.01-895.08, the term:

(1) "Racketeering activity" means to commit, to attempt to commit, to conspire to commit, or to solicit, coerce, or intimidate another person to commit:

(a) Any crime which is chargeable by indictment or information under the following provisions of the Florida Statutes:

1. Section 210.18, relating to evasion of payment of cigarette taxes.

2. Section 403.727(3)(b), relating to environmental control.

3. Section 414.39, relating to public assistance fraud.

4. Section 409.920, relating to Medicaid provider fraud.

5. Section 440.105 or s. 440.106, relating to workers' compensation.

6. Sections 499.0051, 499.0052, 499.0053, 499.0054, and 499.0691, relating to crimes involving contraband and adulterated drugs.

7.~~6.~~ Part IV of chapter 501, relating to telemarketing.

8.~~7.~~ Chapter 517, relating to sale of securities and investor protection.

9.~~8.~~ Section 550.235, s. 550.3551, or s. 550.3605, relating to dogracing and horseracing.

10.~~9.~~ Chapter 550, relating to jai alai frontons.

11.~~10.~~ Chapter 552, relating to the manufacture, distribution, and use of explosives.

12.~~11.~~ Chapter 560, relating to money transmitters, if the violation is punishable as a felony.

13.~~12.~~ Chapter 562, relating to beverage law enforcement.

14.~~13.~~ Section 624.401, relating to transacting insurance without a certificate of authority, s. 624.437(4)(c)1., relating to operating an unauthorized multiple-employer welfare arrangement, or s. 626.902(1)(b), relating to representing or aiding an unauthorized insurer.

15.~~14.~~ Section 655.50, relating to reports of currency transactions, when such violation is punishable as a felony.

16.~~15.~~ Chapter 687, relating to interest and usurious practices.

17.~~16.~~ Section 721.08, s. 721.09, or s. 721.13, relating to real estate timeshare plans.

18.~~17.~~ Chapter 782, relating to homicide.

19.~~18.~~ Chapter 784, relating to assault and battery.

20.~~19.~~ Chapter 787, relating to kidnapping.

21.~~20.~~ Chapter 790, relating to weapons and firearms.

22.~~21.~~ Section 796.03, s. 796.04, s. 796.05, or s. 796.07, relating to prostitution.

23.~~22.~~ Chapter 806, relating to arson.

24.~~23.~~ Section 810.02(2)(c), relating to specified burglary of a dwelling or structure.

25.~~24.~~ Chapter 812, relating to theft, robbery, and related crimes.

26.~~25.~~ Chapter 815, relating to computer-related crimes.

27.~~26.~~ Chapter 817, relating to fraudulent practices, false pretenses, fraud generally, and credit card crimes.

28.~~27.~~ Chapter 825, relating to abuse, neglect, or exploitation of an elderly person or disabled adult.

29.~~28.~~ Section 827.071, relating to commercial sexual exploitation of children.

30.~~29.~~ Chapter 831, relating to forgery and counterfeiting.

31.~~30.~~ Chapter 832, relating to issuance of worthless checks and drafts.

32.~~31.~~ Section 836.05, relating to extortion.

33.~~32.~~ Chapter 837, relating to perjury.

34.~~33.~~ Chapter 838, relating to bribery and misuse of public office.

35.~~34.~~ Chapter 843, relating to obstruction of justice.

36.~~35.~~ Section 847.011, s. 847.012, s. 847.013, s. 847.06, or s. 847.07, relating to obscene literature and profanity.

37.~~36.~~ Section 849.09, s. 849.14, s. 849.15, s. 849.23, or s. 849.25, relating to gambling.

38.~~37.~~ Chapter 874, relating to criminal street gangs.

39.~~38.~~ Chapter 893, relating to drug abuse prevention and control.

40.~~39.~~ Chapter 896, relating to offenses related to financial transactions.

41.~~40.~~ Sections 914.22 and 914.23, relating to tampering with a witness, victim, or informant, and retaliation against a witness, victim, or informant.

42.~~41.~~ Sections 918.12 and 918.13, relating to tampering with jurors and evidence.

Section 32. Section 905.34, Florida Statutes, is amended to read:

905.34 Powers and duties; law applicable.--The jurisdiction of a statewide grand jury impaneled under this chapter shall extend throughout the state. The subject matter jurisdiction of the statewide grand jury shall be limited to the offenses of:

(1) Bribery, burglary, carjacking, home-invasion robbery, criminal usury, extortion, gambling, kidnapping, larceny, murder, prostitution, perjury, and robbery;

(2) Crimes involving narcotic or other dangerous drugs;

(3) Any violation of the provisions of the Florida RICO (Racketeer Influenced and Corrupt Organization) Act, including any offense listed in the definition of racketeering activity in s. 895.02(1)(a), providing such listed offense is investigated in connection with a violation of s. 895.03 and is charged in a separate count of an information or indictment containing a count charging a violation of s. 895.03, the prosecution of which listed offense may continue independently if the prosecution of the violation of s. 895.03 is terminated for any reason;

(4) Any violation of the provisions of the Florida Anti-Fencing Act;

(5) Any violation of the provisions of the Florida Antitrust Act of 1980, as amended;

(6) Any violation of the provisions of chapter 815;

(7) Any crime involving, or resulting in, fraud or deceit upon any person;

(8) Any violation of s. 847.0135, s. 847.0137, or s. 847.0138 relating to computer pornography and child exploitation prevention, or any offense related to a violation of s. 847.0135, s. 847.0137, or s. 847.0138; or

(9) Any criminal violation of part I of chapter 499.

or any attempt, solicitation, or conspiracy to commit any violation of the crimes specifically enumerated above, when any such offense is occurring, or has occurred, in two or more judicial circuits as part of a related transaction or when any such offense is connected with an organized criminal conspiracy affecting two or more judicial circuits. The statewide grand jury may return indictments and presentments irrespective of the county or judicial circuit where the offense is committed or triable. If an indictment is returned, it shall be certified and transferred for trial to the county where the offense was committed. The powers and duties of, and law applicable to, county grand juries shall apply to a statewide grand jury except when such powers, duties, and law are inconsistent with the provisions of ss. 905.31-905.40.

Section 33. If any provision of this act or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.

Section 34. The sum of $451,672 is appropriated from the Florida Drugs, Devices, and Cosmetic Trust Fund and three additional full-time-equivalent positions are authorized to implement this act.

Section 35. Except as otherwise expressly provided in this act, this act shall take effect July 1, 2003.

STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN
COMMITTEE SUBSTITUTE FOR
Senate Bill 2312

The Prescription Drug Protection Act is created to revise the permitting requirements for the wholesale distribution of prescription drugs from and into Florida. Criteria for pedigree papers are provided to further document the movement of prescription drugs. The Department of Health is authorized to inspect and copy financial documents or records related to the distribution of a drug in order to determine compliance with the Florida Drug and Cosmetic Act. A new cease and desist enforcement remedy is established, and the bill authorizes procedures for the department to issue an order to remove key personnel of a prescription drug wholesaler if she or he is engaged in specified prohibited acts.

Stiffer criminal penalties for unlawful activities related to prescription drugs are created. The authority of the Statewide Grand Jury is enhanced to investigate violations of the Florida Drug and Cosmetic Act and the jurisdiction of the Office of the Statewide Prosecution is expanded to include such violations.