By Senator Peaden

2-1448-03

A bill to be entitled

An act relating to the Florida Drug and Cosmetic Act; amending s. 499.003, F.S.; providing definitions; amending s. 499.005, F.S.; prohibiting the removal of a dispensing label from a legend drug; prohibiting the distribution of a previously dispensed legend drug without authorization; prohibiting certain transactions for cash; amending s. 499.006, F.S.; providing that a legend drug is adulterated if certain documentation cannot be verified; amending s. 499.007, F.S.; revising certain labeling requirements; amending s. 499.01, F.S.; providing permit requirements for prescription drug repackagers, nonresident prescription drug manufacturers, and freight forwarders; authorizing the Department of Health to issue certain permits to an applicant at the same address as a licensed nuclear pharmacy and a community pharmacy; revising requirements for permit applications and renewals; requiring annual renewal of certain permits; amending s. 499.012, F.S.; authorizing a hospital or other health care entity to transfer a prescription drug to a licensed repackager under certain circumstances; providing certain restrictions on the sale of drug acquisitions to unaffiliated wholesalers; increasing the amount of the bond that must be obtained by prescription drug wholesalers; authorizing the Department of Health to adopt

rules by which it may assess an applicant's experience and financial viability; requiring that applicants undergo criminal history record checks; providing requirements for out-of-state prescription drug wholesalers; requiring a performance bond and a criminal history record check; providing licensing and permitting requirements for nonresident prescription drug manufacturers; providing requirements for a freight forwarder's permit; amending s. 499.0121, F.S.; providing additional recordkeeping requirements; requiring certain written statements; providing requirements for shipping and transporting a prescription drug in wholesale distribution; amending s. 499.0122, F.S.; providing permit requirement for an establishment that refills medical oxygen for an individual patient; creating s. 499.0123, F.S.; requiring a prescription drug wholesaler to designate a representative; requiring such representative to be certified by the department; providing requirements for certification; requiring a criminal history record check amending s. 499.013, F.S.; providing permit requirements for a prescription drug repackager; amending s. 499.041, F.S.; revising the schedule of fees for an application or permit; providing fees for nonresident prescription drug manufacturers and out-of-state prescription drug wholesalers; amending s. 499.051, F.S.; requiring the

department to maintain the confidentiality of certain financial documents; authorizing such documents to be used for regulatory or enforcement proceedings; amending s. 499.066, F.S.; providing for the jurisdiction of the department to impose penalties and take enforcement actions; amending s. 499.067, F.S.; providing for the denial, suspension, or revocation of a certification; specifying additional grounds for such denial, suspension, or revocation; specifying circumstances under which the department is not required to publish notice of intended agency action; amending s. 499.069, F.S.; providing enhanced penalties for certain violations; requiring the department to establish a Drug Wholesale Advisory Board; providing for membership; providing duties; providing for board members to be reimbursed for per diem and travel expenses; providing for severability; providing an effective date.

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

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

499.003 Definitions of terms used in 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 group" has the same meaning as in s. 1504 of the Internal Revenue Code.

(3) "Affiliated person" means any person who directly or indirectly manages, controls, or oversees the operation of a corporation or other business entity that is a permittee or applicant, regardless of whether such person is a partner, shareholder, owner, officer, director, agent, independent contractor, or employee of the entity.

(4) "Applicant" means a person applying for a permit or certification under ss. 499.001-499.081 in the form of a sole proprietorship, corporation, partnership, or other business entity, and any owner, officer, director, agent, managing employee, general manager, or affiliated person, or any partner or shareholder having an ownership interest equal to 5 percent or more in the corporation, partnership, or other business entity.

(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 classified as a prescription drug or medical device, whether it is alone or in combination with other gases.

(10)~~(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.

(11)~~(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.

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

(13)~~(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.

(14)~~(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.

(15)~~(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.

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

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

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

(19)~~(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.

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

(21)~~(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.

(22)~~(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.

(23)~~(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).

(24)~~(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.

(25)~~(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.

(26)~~(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.

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

(28)~~(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.

(29)~~(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.

(30)~~(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.

(31)~~(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.

(32)~~(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 2. Section 499.005, Florida Statutes, is amended to read:

499.005 Prohibited acts.--It is unlawful for any 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) 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 <u>to that purchaser or recipient</u>.

(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 <u>from the person selling or transferring the legend drug</u>.

(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 legend drug with the intent to further distribute the legend drug.

(27) The knowing distribution of a previously dispensed legend drug unless authorized under chapter 465 and rules adopted under chapter 465.

(28) The failure to obtain or pass on a statement as required under s. 499.0121(6)(d).

(29) The purchase or sale of legend drugs in a wholesale transaction for cash; except through the use of a funds transfer as defined in chapter 670 which is documented and may be verified through a financial institution.

Section 3. 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 and verifiable documentation does not support that it has been purchased, held, sold, or distributed at all times by a person authorized under federal or state law to do so.

Section 4. 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 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.

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

Section 5. Section 499.01, Florida Statutes, is 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 fictitious person registered with the Division of Corporations. Each person affiliated with the applicant for a permit or the permittee must be ~~an individual who is at least 18 years of age or to 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 person and establishment that intends to operate and prior to operating ~~operates~~ as a:

1. Prescription drug manufacturer;

2. Prescription drug repackager;

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

4.~~3.~~ Compressed medical gas manufacturer;

5.~~4.~~ Device manufacturer;

6.~~5.~~ Cosmetic manufacturer;

7.~~6.~~ Prescription drug wholesaler;

8.~~7.~~ Compressed medical gas wholesaler;

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

10. Nonresident prescription drug manufacturer;

11.~~9.~~ Retail pharmacy drug wholesaler;

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

13.~~11.~~ Medical oxygen retail establishment;

14.~~12.~~ Complimentary drug distributor; ~~or~~

15.~~13.~~ Restricted prescription drug distributor; or~~.~~

16. Freight fowarder.

(e) The department may not issue 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 follows. 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.

(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. A refund may not be issued if the biennial fee for the new permit is less than the original permit for which a fee was paid.

(2) 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.

(a) 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 and manager;

f. If a parent corporation or other entity owns the applicant, the names of all officers and directors of this entity; and

g.~~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.~~

(b)~~(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.~~

(3) The department shall adopt rules for the annual renewal of permits established under s. 499.012, except for the compressed medical gases wholesaler permit, and for the biennial renewal of the compressed medical gases permit and other permits established under ss. 499.001-499.081.

~~(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.~~

(a)~~(b)~~ A permit, unless sooner suspended or revoked, automatically expires 1 year after the last day of the anniversary month in which a wholesaler permit was originally issued or, in the case of other permits,2 years after the last day of the anniversary month in which the permit was originally issued. A permit issued under ss. 499.001-499.081 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 90 days prior to ~~by~~ the expiration date of the permit, the applicant must submit ~~permit may be reinstated~~

~~only upon payment of~~ a delinquent fee of $100, plus the required renewal fee~~, within 60 days after the expiration date~~.

(b)~~(c)~~ A wholesaler that does not have an active permit must cease operating as a wholesaler until a valid and active permit is issued to the person at that establishment. Failure to renew a permit, other than a wholesaler permit in accordance with this section precludes any future renewal of that permit. Continuing to engage in activities that require a permit under ss. 499.001-499.081 after the expiration date of the permit requires a new permit application and payment of an application fee, initial permit fee, and applicable penalties.

(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.

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

Section 6. Subsections (1) and (2) of section 499.012, Florida Statutes, are amended to read:

499.012 Wholesale distribution; definitions; permits; 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 under common control, if ownership of the prescription drug 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; 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 may not wholesale more than 10 percent of its annual prescription drug acquisitions in dollars, net of returns, to other prescription drug wholesalers located in or outside this state which are not

members of the same affiliated group.A prescription drug wholesaler that submits an initial application or renewal application ~~applies~~ to the department after October 1, 2003 ~~January 1, 1993~~, must submit a performance bond or evidence of a performance bond of$100,000 for each application~~$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, as well as and any fees or costs incurred by the department, regarding that permit as authorized under state law.This bond will be refunded to the permittee when the permit is returned to the department and the permittee ceases to engage in prescription drug wholesaling activities unless the ~~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 pursuant to s. 499.01(4)(d), ~~or~~ fails to notify the department before a change of ownership or controlling interest, or fails to provide records related to the wholesale distribution of prescription drugs required by s. 499.0121(6)~~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. The department may also adopt rules for requiring additional information from initial applicants and renewal applicants, and minimum standards to assess their ownership, experience, and financial viability for distributing prescription drugs. These rules must include, but need not be limited to:

1. Identifying information of an applicant and his or her spouse, children over 18 years of age, siblings, parents, siblings-in-law, and parents-in-law; and the business background concerning prescription drugs for each of these persons;

2. Designation of a representative who has demonstrated, through testing and certification standards established by rule, a minimum proficiency in the laws and rules related to the wholesale distribution of prescription drugs as set forth in s. 499.0123;

3. Information and supporting documentation regarding the financing of the physical establishment, equipment, and prescription drug inventory;

4. Information regarding the dollar volume of prescription drug wholesaling activities of the applicant and those activities as a percentage of total operations for the applicant's establishment;

5. Information regarding the dollar volume of purchases of prescription drugs directly from manufacturers; and

6. Names and addresses of all members comprising the affiliated group, if applicable.

An applicant must submit a complete set of fingerprints to the department for the purpose of conducting a criminal history record check of the applicant, but in the case of a corporation, fingerprint cards must be submitted for the five highest corporate officers and any person who participates in administering or operating the prescription drug activities of the applicant's establishment. The department shall submit the fingerprints to the Department of Law Enforcement for a state

criminal background investigation and for forwarding to the Federal Bureau of Investigation for a national criminal history record check. The cost of the state and national criminal record check shall be borne by the applicant in addition to the permit application fee. The department shall adopt rules regarding the frequency of the submission of fingerprints and associated fees, which may not exceed the actual cost of processing by the Department of Law Enforcement and Federal Bureau of Investigation.

(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, except those set forth in s. 499.0123. An out-of-state prescription drug wholesaler may not

wholesale more than 10 percent of its annual prescription drug acquisitions in dollars, net of returns, to prescription drug wholesalers located in or outside this state which are not members of the same affiliated group. An out-of-state prescription drug wholesaler that submits an initial application or renewal application to the department after October 1, 2003, must submit a performance bond or evidence of a performance bond of $100,000 for each application, 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, as well as any fees or costs incurred by the department, regarding that permit as authorized under state law. This bond shall be refunded to the permittee when the permit is returned to the department and the permittee ceases to engage in prescription drug wholesaling activities, unless the permittee fails to notify the department before closing the business pursuant to s. 499.01(4)(d), fails to notify the department before a change of ownership or controlling interest, or fails to provide records related to the wholesale distribution of prescription drugs required by s. 499.0121(6). The department may also adopt rules for requiring additional information from initial applicants and renewal applicants to assess their ownership, experience, and financial viability for distributing prescription drugs as set forth in paragraph (a).

1. An applicant must submit a complete set of fingerprints to the department for the purpose of conducting a criminal history record check of the applicant, but in the case of a corporation, fingerprint cards must be submitted for the five highest corporate officers and any person who participates in administering or operating the prescription

drug activities of the applicant's establishment. The department shall submit the fingerprints to the Department of Law Enforcement for a state criminal background investigation and for forwarding to the Federal Bureau of Investigation for a national criminal history record check. The cost of the state and national criminal record check shall be borne by the applicant in addition to the permit application fee. The department shall adopt rules regarding the frequency of the submission of fingerprints and associated fees, which may not exceed the actual cost of processing by the Department of Law Enforcement and Federal Bureau of Investigation.

2.~~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 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) Nonresident prescription drug manufacturer. A nonresident prescription drug manufacturer is a manufacturer of prescription drugs or the distribution point for a manufacturer of prescription drugs located outside this state, an entity to whom an approved new drug application has been issued by the Federal Drug Administration, or a contracted manufacturer of the approved new drug application holder located out of the United States which engages in the wholesale distribution of the prescription drugs it manufactures or is responsible for manufacturing 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, except s. 499.0121(6)(d). A person who also distributes prescription drugs that it did not manufacture must also obtain an out-of-state prescription drug wholesaler permit pursuant to paragraph (b) to engage in the wholesale distribution of the prescription drugs manufactured by another person and must comply with the requirements of an out-of-state prescription drug wholesaler.

1. The nonresident manufacturer 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.

2. If a nonresident manufacturer intends to import 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 Federal Drug Administration for such importation.

(e)~~(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.

(f) A freight forwarder's permit. A freight forwarder's permit is required for any person that engages in the distribution of a legend drug as a freight forwarder or transporter unless the transporter is a common carrier.

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

2. A person who applies for a permit as a freight forwarder, or for the renewal of such a permit, must provide to the department the information required under s. 499.01.

Section 7. Subsections (4) and (6) 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.

(e) If a wholesaler documents that it has performed the required examination for a particular purchase and the results of the review did not disclose a reasonable suspicion of adulterated or misbranded prescription drugs, but an adulterated or misbranded prescription drug was acquired and subsequently distributed, these facts shall be considered by the department in mitigation of any administrative penalties; however, the prescription drug may be subject to recall or seizure or both. Repeat occurrences of adulterated or misbranded drugs are grounds for the department to impose penalties authorized under this chapter.

(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.

5. Financial documentation supporting the transaction, if applicable.

(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 date the drugs were created, 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. Any person who distributes a prescription drug that he or she did not manufacture must provide at the time of

the distribution to each purchaser or recipient that is a wholesale distributor a written statement:

a. On the invoice or transfer document which states:

(I) If the establishment is not a member of an affiliated group, "This establishment purchased the specific unit(s) of the prescription drug(s) represented on this document directly from the manufacturer."

(II) If the establishment is a member of an affiliated group, "This establishment or a member of our affiliated group that is licensed or permitted as a drug wholesaler purchased the specific unit(s) of the prescription drug(s) represented on this document directly from the manufacturer."

b. That identifies each previous wholesale distributor of that unit of the drug, beginning with the manufacturer of the drug.

2. For purposes of subsection (3), a repackager that purchased a specific unit of prescription drug that it repackages directly from the manufacturer must comply with paragraph (3)(a). For purposes of subsection (3), a repackager that does not obtain a specific unit of a prescription drug that it repackages directly from the manufacturer must comply with paragraph (3)(b).

3.~~(d)1. Each person who is engaged in the wholesale distribution of a prescription drug, and who is not an authorized distributor of record of such drug, must provide to each wholesale distributor of such drug, before the sale is made to such wholesale distributor, a written statement identifying each previous 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 a wholesale distributor.~~The department shall adopt rules relating to the requirements of this written statement.

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

5.~~3.~~ In order to verify compliance with subparagraph 1., 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 distribution documentation concerning its sales of prescription drugs, regardless of whether the prescription drug was sold directly by the manufacturer to a person in this state.

~~For the purposes of this subsection, the term "authorized distributors of record" means those distributors with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products.~~

(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 shall 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 8. Paragraph (a) of subsection (1) of section 499.0122, Florida Statutes, is amended to read:

499.0122 Medical oxygen and veterinary legend drug retail establishments; definitions, permits, general requirements.--

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

(a) "Medical oxygen retail establishment" means a person licensed to sell medical oxygen to patients only. The sale must be based on an order from a practitioner authorized by law to prescribe. The term does not include a pharmacy licensed under chapter 465.

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

2. A medical oxygen retail establishment may refill medical oxygen for an individual patient based on an order from a practitioner authorized by law to prescribe if the establishment is also permitted as a compressed medical gases manufacturer. ~~A medical oxygen retail establishment that refills medical oxygen must comply with all appropriate state and federal good manufacturing practices.~~

Section 9. Section 499.0123, Florida Statutes, is created to read:

499.0123 Designated representative; certification and general requirements.--

(1) An applicant for a prescription drug wholesaler permit shall designate at least one natural person to serve as the representative of the wholesaler. The designated representative must have an active certification from the department as a designated representative under this section.

(2) Upon receipt of an application on a form furnished by the department and submission of the appropriate fees, the department may certify a person as a designated representative for the purposes of this chapter under the following conditions:

(a) The person must provide verifiable evidence of at least 1 year's experience in the management of a licensed prescription drug wholesaler or licensed pharmacy where the responsibilities included, but were not limited to, recordkeeping for prescription drugs;

(b) The person must have received a score of at least 75 percent on an examination given by the department or its agent regarding federal and state drug laws and wholesaler practices;

(c) The person is at least 21 years of age; and

(d) The person is of good moral character such that his or her presence in a wholesale establishment does not jeopardize the public health and the person does not have any deficiencies under s. 499.067(1)(b)1.-11.

(3) The designated representative must submit a complete set of fingerprints to the department for the purpose of conducting a criminal history record check for certification and recertification. The department shall submit the fingerprints to the Department of Law Enforcement for a

state criminal background investigation and for forwarding to the Federal Bureau of Investigation for a national criminal history record check. The cost of the state and national criminal record check shall be borne by the applicant in addition to the certification application fee. The department shall develop rules regarding the frequency of the submission of fingerprints and associated fees which may not exceed the actual cost of processing by the Department of Law Enforcement and Federal Bureau of Investigation.

(4) The department may deny an application for certification, or suspend or revoke a certification, under this section based on the provisions in s. 499.067(1)(b)1.-11.

(5) The natural person's certification is valid for 2 years unless the certification is suspended or revoked.

(6) A representative of a wholesaler designated pursuant to this section:

(a) Must be actively involved in and aware of the actual daily operation of the wholesaler;

(b) Must be employed full time in a managerial position with the wholesaler;

(c) Must be physically present at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leave, vacation leave, and other authorized absences; and

(d) May serve in this representative capacity for only one applicant and permitted establishment at a time.

(7) A wholesaler that is required to designate a representative pursuant to this section may not open or operate a facility unless that representative is actually employed full time in the operation of the wholesaler and is physically present at the permitted establishment of the

wholesaler during regular working hours, not including sick leave, vacation leave and other authorized absences from work. If the natural person designated as the representative of a wholesaler leaves the employ of the wholesaler, thus leaving the wholesaler without a representative in violation of this section, the wholesaler shall:

(a) Immediately cease conducting business in prescription drugs until another certified representative is employed and the wholesaler notifies the department in writing of the identity of the new representative; and

(b) Not later than 48 hours after that person leaves its employ, notify the department that the person designated as the representative of the wholesaler has left the employ of the wholesaler.

(8) Among other penalties authorized by law, a wholesaler that operates without a representative in violation of this section is subject to the immediate suspension of its license until it employs a person certified under this section to be its representative.

(9) The department shall adopt rules for the application content and process and for the testing required under this section.

Section 10. Paragraph (a) of subsection (2) of section 499.013, Florida Statutes, is amended to read:

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

(2) Any person that engages in the manufacture 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; however, a person performing the manufacturing operations of repackaging prescription drugs must obtain a prescription drug repackager permit.

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 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.

Section 11. 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 $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 $600 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$750~~$300~~ or more than $950~~$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$400~~$200~~ or more than$600~~$300~~ annually;

(d) The fee for a nonresident prescription drug manufacturer's permit may not be less than $300 or more than $500 annually; however, a nonresident prescription drug manufacturer that distributes its prescription drugs from multiple distribution establishments throughout the country may obtain additional permits for each establishment

distributing the manufacturer's prescription drugs into this state under the manufacturer's name at a cost of $50 per additional establishment.

(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. However, a medical oxygen retail establishment permit shall be issued to a compressed medical gases manufacturer or to a compressed medical gases wholesaler at an annual cost of $25.

(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 a person applying for certification as a wholesaler 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 12. Subsection (2) of section 499.051, Florida Statutes, is amended, and subsection (6) is 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.~~

(6) The authority to inspect under this section includes the authority to access, review, and copy financial documents related to activity regulated under this chapter. The department shall maintain the confidentiality of financial documents, other than invoices, accessed or copied and in the possession of 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 as provided in this subsection.

Section 13. Subsection (7) is added to section 499.066, Florida Statutes, to read:

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

(7) Resignation or termination of an affiliated party does not affect the department's jurisdiction to proceed with action to suspend or revoke a permit, impose other penalties, or take other enforcement actions authorized by law.

Section 14. Section 499.067, Florida Statutes, is amended to read:

499.067 Denial, suspension, or revocation of permit, certification, or registration.--

(1)(a) The department may deny, suspend, or revoke a permit if it finds that there has been a substantial failure

to comply with 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 if 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;.

2. The applicant has not met the requirements for the permit or certification;

3. The applicant has 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;

4. The applicant has been disciplined by a regulatory agency in any state for any offense that would constitute a violation of ss. 499.001-499.081;

5. The applicant has a felony conviction under a federal, state, or local law;

6. The applicant's past experience in manufacturing or distributing drugs, devices, or cosmetics poses a public health risk;

7. The applicant furnished false or fraudulent material in any application made in connection with manufacturing or distributing drugs, devices, or cosmetics;

8. Any permit currently or previously held by the applicant for the manufacture or distribution of any drugs,

devices, or cosmetics was suspended or revoked by a federal, state, or local government;

9. The applicant failed to comply with permitting requirements under any previously granted permits;

10. The applicant failed to comply 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 chapter;

11. The applicant or any affiliated person of the applicant has been arrested for a crime that is a felony and the disposition of the charge is pending during the application review period;

12. The applicant is lacking in prescription drug wholesaling experience;

13. The applicant does not possess the financial or physical resources to operate in compliance with this chapter and the rules adopted under this chapter;

14. The applicant receives directly or indirectly financial support and assistance from a person who was an affiliated person of a permit that authorized the wholesale distribution of prescription drugs which was suspended or revoked, other than through the ownership of stock in a publicly traded company or a mutual fund;

15. The applicant 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;

16. The applicant for renewal of a permit under s. 499.012(2)(a) or (c) has not actively engaged in the wholesale distribution of prescription drug as demonstrated by the regular and systematic distribution of prescription drugs throughout the year as evidenced by at least 12 transactions annually; or

17. Information obtained in response to s. 499.012(2)(a) or (c), demonstrates it would not be in the best interest of the public health, safety, and welfare to issue the applicant a permit.

(2) The department may deny, suspend, or revoke any registration required by the provisions of ss. 499.001-499.081 for the violation of any provision of ss. 499.001-499.081 or of any rules adopted under those sections.

(3) The department may revoke or suspend a permit:

(a) If the permit was obtained by misrepresentation or fraud or through a mistake of the department;

(b) If the permit was procured, or attempted to be procured, for any other person by making or causing to be made any false representation; ~~or~~

(c) If the permittee has violated any provision of ss. 499.001-499.081 or rules adopted under those sections; or~~.~~

(d) If a prescription drug wholesaler or out-of-state prescription drug wholesaler permittee wholesales more than 10 percent of annual prescription drug purchases, net of returns, to other wholesalers that are not members of the same affiliated group.

(4) If any permit issued under ss. 499.001-499.081 is revoked or suspended, the owner, manager, operator, or

proprietor of the establishment shall cease to operate as the permit authorized, from the effective date of the suspension or revocation until the person is again registered with the department and possesses the required permit. If a permit is revoked or suspended, the owner, manager, or proprietor shall remove all signs and symbols that identify the operation as premises permitted as a drug wholesaling establishment; drug, device, or cosmetic manufacturing establishment; or retail establishment. The department shall determine the length of time for which the permit is to be suspended. If a permit is revoked, the person that owns or operates the establishment may not apply for any permit under ss. 499.001-499.081 for a period of 1 year after the date of the revocation. A revocation of a permit may be permanent if the department considers that to be in the best interest of the public health.

(5) The department may deny, suspend, or revoke a permit issued under ss. 499.001-499.081 which authorizes the permittee to purchase prescription drugs, if any owner, officer, employee, or other person who participates in administering or operating the establishment has been found guilty of any violation of ss. 499.001-499.081 or chapter 465, chapter 501, or chapter 893, any rules adopted under any of those sections or chapters, or any federal or state drug law, regardless of whether the person has been pardoned, had her or his civil rights restored, or had adjudication withheld.

(6) The department shall deny, suspend, or revoke the permit of any person or establishment if the assignment, sale, transfer, or lease of an establishment permitted under ss. 499.001-499.081 will avoid an administrative penalty, civil action, or criminal prosecution.

(7) Section 120.60(5) to the contrary notwithstanding and pursuant to s. 499.01(4), the department is not required to publish notice of the intended agency action to revoke a permit and of the opportunity for hearing in a newspaper if the person moved or ceased operations but did not notify the department and the department mailed a certified letter to the most recent mailing address on record with the department and to the registered agent listed by the Division of Corporations for the permittee, but service was not accomplished.

Section 15. Section 499.069, Florida Statutes, is amended to read:

499.069 Punishment for violations of s. 499.005; 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 commits ~~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) Any person who violates any of the provisions of s. 499.005 with respect to a drug 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 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.~~

(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 16. The Department of Health shall form a Drug Wholesaler Advisory Board to meet at least annually, for the purpose of reviewing and providing input into the drug wholesaler licensing requirements and process, and to advise the department on issues affecting the wholesale distribution of drugs within or into this state.

(1) The Secretary of Health shall appoint members to the board as follows:

(a) Two persons representing prescription drug wholesalers;

(b) One person representing prescription drug manufacturers;

(c) One person representing pharmacies in this state;

(d) One person from the Agency for Health Care Administration; and

(e) Two persons from the Department of Health.

(2) Members shall be appointed to 4-year terms and may be reappointed.

(3) The members shall elect a chair among the members of the board who shall serve for 1 year or until a successor is elected.

(4) The members of the advisory committee shall serve without compensation, but are entitled to reimbursement for travel and per diem expenses as provided in section 112.061, Florida Statutes, while in the performance of their official duties.

Section 17. 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 18. This act shall take effect July 1, 2003.

****

SENATE SUMMARY

Revises various provisions of the Florida Drug and Cosmetic Act. Provides for the regulation of prescription drug repackagers, nonresident prescription drug manufacturers, and freight forwarders. Revises permit requirements for prescription drug wholesalers. Increases permit and certification fees. Provides enhanced penalties for certain violations. Establishes the Drug Wholesale Advisory Board. (See bill for details.)