By Senator Myers

27-1261A-98

A bill to be entitled

An act relating to the Department of Health; amending s. 499.003, F.S.; providing definitions; amending s. 499.005, F.S.; clarifying prohibited acts; amending s. 499.01, F.S.; conforming listed permits; amending s. 499.012, F.S.; deleting definitions; clarifying wholesale distribution and permitting requirements; authorizing transfers for government purposes in certain situations; authorizing a retail pharmacy to transfer limited quantities of prescription drugs without a wholesaler permit; amending s. 499.0121, F.S.; clarifying existing rulemaking authority for the storage and handling of drugs; providing for notification to the department; amending s. 499.0122, F.S.; providing for an expiration date of a practitioner's order for medical oxygen; deleting a definition; clarifying provisions related to the sale of veterinary drugs to the public; amending s. 499.013, F.S.; providing an exemption from permitting requirements; amending s. 499.014, F.S.; revising statutory references; amending s. 499.015, F.S.; revising statutory references; amending s. 499.024, F.S.; providing drug product classification; revising statutory references; amending s. 499.028, F.S.; authorizing government officers and employees to possess complimentary prescription drugs when acting within the scope

of employment; amending s. 499.03, F.S.; revising statutory references; prohibiting possession of certain drugs unless they are lawfully dispensed pursuant to a valid prescription; amending s. 499.041, F.S.; deleting a fee; providing that fees are nonrefundable; amending s. 499.051, F.S.; authorizing agents of the Department of Health to inspect and investigate at any time, if necessary, to protect the public health; deleting a requirement that the Department of Business and Professional Regulation inspect retail pharmacy wholesalers; amending s. 499.066, F.S.; authorizing immediate effectiveness of cease and desist order with provision for motion to abate or modify the order; amending s. 499.069, F.S.; correcting cross-references to the prohibited acts for criminal punishment; creating s. 499.072, F.S.; creating the Drug Regulation Advisory Group; providing membership; providing per diem and travel expenses; providing purpose and duties; authorizing the department to publish compliance policy guidelines setting forth the group's recommendations; amending s. 499.62, F.S.; providing an intracompany exception to permitting ether; 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) "Authorized distributor of record" means a distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products.

(3)~~(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.

(4)~~(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.

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

(6)~~(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.

(7) "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.

(8)~~(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.

(9)~~(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.

(10)~~(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.

(11)~~(9)~~ "Department" means the Department of Health ~~and Rehabilitative Services~~.

(12)~~(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.

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

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

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

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

(17)~~(15)~~ "Immediate container" does not include package liners.

(18)~~(16)~~ "Investigational drug" means any drug recommended by the Florida Drug Technical Review Panel for a specific use under a protocol approved by the department and intended solely for investigational use in the state by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs.

(19)~~(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.

(20)~~(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.

(21)~~(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(7), s. 499.007(12), or s. 499.0122(1)(b) or (c).

(22)~~(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.

(23)~~(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.

(24)~~(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.

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

(26)~~(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.

(27)~~(25)~~ "Prepackaged drug product" means a drug that originally was in finished packaged form sealed by a manufacturer and hat 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.

(28)~~(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.

(29)~~(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.

(30) "Retail pharmacy" means a community pharmacy permitted under chapter 465 which purchases prescription drugs only at fair market prices and not for its own use and provides prescription services to the public. A retail pharmacy may not also be a health care entity.

(31)~~(28)~~ "Technical panel" means the Florida Drug Technical Review Panel.

(32)~~(29)~~"Veterinary legend drug" or "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."

(33) "Wholesale distribution" means the distribution of a prescription drug to a person other than a consumer or patient.

(34) "Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs in or into this state, including manufacturers; repackers; own-label distributors; jobbers; private-label distributors; brokers;

warehouses, including manufacturers' and distributors' warehouses, drug chain warehouses, and wholesale drug warehouses; independent wholesale drug traders; exporters; retail pharmacies; and the agents thereof that conduct wholesale distributions.

Section 2. Section 499.005, Florida Statutes, is amended to read:

499.005 Prohibited acts.--It is unlawful 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:

(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 ~~the law of the state in which the person resides~~ to distribute legend drugs.

(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 ~~resides~~ to purchase or possess legend drugs.

(16) The purchase or receipt of a compressed medical gas from a person that is not authorized under this chapter ~~the law of the state in which the person resides~~ 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 chapter 499 ~~a drug, device, or cosmetic~~.

(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 ~~as~~ required by ss. 499.001-499.081 for that activity.

(23) 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.

Section 3. Subsection (1) of 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 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 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. Restricted prescription drug distributor ~~Retail pharmacy drug wholesaler~~;
10. Veterinary legend drug retail establishment;
11. Medical oxygen retail establishment; or
12. Complimentary drug distributor.

Section 4. Section 499.012, Florida Statutes, is amended to read:

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

(1) As used in this section and for the purposes of s. 499.005(21), the term wholesale distribution does not include:

(a) The following activities provided the activity is conducted under the provisions of s. 499.014~~"Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include~~:

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

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

3. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control. ~~For purposes of this 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.~~

(b) The following activities when performed under rules adopted by the department:

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

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

a. The entity obtains written authorization for the sale, purchase, trade, or other transfer of a prescription drug under this paragraph from the Secretary of the Department of Health. This written authorization must be based on a favorable recommendation by the Drug Regulation Advisory Group that has reviewed the entity's submission to the department of a detailed plan and justification for the sale, purchase, trade, or other transfer of a prescription drug under this paragraph and must enhance the public's health by improving needed access, quality, or safety because current patient drug delivery systems are inadequate;

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

c. In the case of a subcontractor, the entity must be a part of and execute the subcontract;

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

e. The contract provider and subcontractor shall maintain and produce immediately for inspection all records of movement or transfer of all the prescription drugs belonging to the entity including, but not limited to, the records of receipt and disposition of prescription drugs. Each contractor

and subcontractor dispensing or administering these drugs shall maintain and produce records documenting the dispensing or administration. Records required to be maintained include a perpetual inventory itemizing drugs received and drugs dispensed by prescription number or administered by patient identifier, which shall be submitted to the entity monthly;

f. The contract provider or subcontractor shall either administer or dispense the prescription drugs only to the eligible patients of the entity or shall return the prescription drug for or to the entity. The contract provider or subcontractor shall require proof from each person seeking to fill a prescription or obtain treatment that the person is an eligible patient of the entity and shall at a minimum maintain a copy of this proof as part of the records of the contractor or subcontractor required by sub-subparagraph 2.d.; and

g. In addition to the department's inspection authority provided in s. 499.051, the establishment of the contract provider and subcontractor and all records pertaining to prescription drugs subject to this subparagraph are subject to inspection by the entity.

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

4.~~6.~~ The transfer ~~purchase or acquisition~~ of a prescription drug acquired by a medical director on behalf of a licensed ~~an~~ emergency medical services provider to that ~~medical director for use by~~ emergency medical services

provider and its transport vehicles for use pursuant to the provider's license under ~~providers acting within the scope of their professional practice pursuant to~~ chapter 401.

5.~~7.~~ The dispensing of a prescription drug pursuant to a prescription under chapter 465.~~;~~

6.~~8.~~ The distribution of prescription drug samples by manufacturers' representatives or distributors' representatives conducted under s. 499.028.~~; or~~

7.~~9.~~ The sale, purchase, or trade of blood and blood components intended for transfusion. As used in this section, 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.

~~(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 that applies to the department after January 1, 1993, must submit a bond of $200, payable to the Florida Drug, Device, and Cosmetic Trust Fund. 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.

(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.

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) 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 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 <u>first</u> 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) A retail pharmacy may distribute approved drugs as in s. 499.023, up to 5 percent of its retail pharmacy purchases of prescription drugs prescribed to other licensed pharmacies in this state or to health care practitioners licensed and located in this state and authorized by law to dispense or prescribe prescription drugs without obtaining a permit under this section. If wholesale distribution activity exceeds the 5-percent threshold or the intended distribution is to a person not authorized under this paragraph, a prescription drug wholesaler's permit must be obtained as provided by law. All records of prescription drug distributions under this section must be maintained separate and distinct from dispensing or other records and must comply with the recordkeeping requirements of s. 499.0121 and the rules adopted thereunder.

(d)~~(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.

Section 5. Subsections (6) and (7) of section 499.0121, Florida Statutes, are amended to read:

499.0121 Storage and handling of prescription drugs.--The department shall adopt such rules relating to wholesale drug distribution as are 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.

(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. Records that document the distribution of prescription drugs must be prepared at the time of the distribution.

(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.

(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.

(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 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. <u>A copy of the written statement must be maintained by each recipient.</u>

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

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.

~~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.~~

(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 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. This procedure must include notification to the department within 3 business days after any occurrence that may have exposed prescription drugs to damage or adulteration. Such notification may be verbal but must be followed by written notification within 15 days after the occurrence.

(d) A procedure to ensure that any outdated prescription drugs are segregated from other drugs and either returned to the manufacturer 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.

(e) A procedure to notify the department within 3 business days after the discovery of any loss or theft of prescription drugs valued at $50,000 or more.

Section 6. 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 to dispense 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. An order for medical oxygen is not valid for more than 1 year.

(b) "Prescription medical oxygen" means oxygen USP that is a compressed medical gas and which 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.

~~(c) "Veterinary legend 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 use by or on the order of a licensed veterinarian."~~

(c)~~(d)~~ "Veterinary legend drug retail establishment" means a person permitted to sell veterinary legend drugs to the public or to veterinarians, but does not include a pharmacy licensed under chapter 465.

1. A veterinary legend drug retail establishment must sell a veterinary legend drug ~~The sale to the public must be~~ based on a valid written order from a veterinarian licensed in this state who has a valid client-veterinarian-patient relationship with the purchaser's animal.

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

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

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

5. A veterinary legend drug retail establishment must sell veterinary drugs in original, sealed manufacturer's containers with all labeling intact and legible.

(2)(a) A person that engages in the retail sale of medical oxygen or veterinary legend drugs in this state must first have a retail establishment permit issued by the department.

(b) The department shall adopt rules relating to information required from each retail establishment pursuant to s. 499.01(2).

(c) A retail establishment must comply with all of the wholesale distribution requirements of s. 499.0121 except those set forth in s. 499.0121(6)(d).

(d) Legend drugs sold by a retail establishment pursuant to a practitioner's order may not be returned into the retail establishment's inventory.

Section 7. Section 499.013, Florida Statutes, is amended to read:

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

(1) As used in this section, the term "manufacture" has the meaning assigned to it under s. 499.003. A pharmacy is exempt from 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 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.

1. A person that operates an establishment permitted as a prescription drug manufacturer may engage in wholesale distribution of prescription drugs manufactured at that establishment and must comply with all the provisions of ss. 499.001-499.081 and the rules adopted under those sections that apply to a wholesale distributor.

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

(b) A person authorized to distribute prescription drugs under this chapter is exempt from obtaining a permit under this section if the person performs the limited manufacturing operation of attaching a manufacturer's package insert to an individual unit for further distribution of prescription drugs packaged by the manufacturer in multi-unit packages under the following conditions:

1. The person does not open the immediate container sealed by the manufacturer;

2. The manufacturer has not stated the package cannot be broken;

3. The prescription drug is not available from the manufacturer in an individual unit;

4. The individual unit is fully labeled for further distribution;

5. The person has complied with all appropriate federal registration requirements and state and federal current good manufacturing practices including, but not limited to, fully labeling all individual units of a multi-unit package concurrent with penetrating the secondary container;

6. The individual unit is distributed only to a health care practitioner or EMS service provider for the purpose of administration and not for dispensing or further wholesale distribution; and

7. Notification is provided to the department in writing that the person intends to engage in this activity.

(c)~~(b)~~ An over-the-counter drug manufacturer's permit is required for any person that engages in the manufacture 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.

(d)~~(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.

(e)~~(d)~~ A device manufacturer's permit is required for any person that engages in the manufacture or assembly of medical devices for human use in this state.

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

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

(f)~~(e)~~ A cosmetic manufacturer's permit is required for any person that manufactures cosmetics in this state.

1. 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.

2. The department may adopt such rules as are necessary for the protection of the public health, safety, and welfare regarding good manufacturing practices that cosmetic manufacturers must follow to ensure the safety of the products.

Section 8. Subsection (1) of section 499.014, Florida Statutes, is amended to read:

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

(1) A restricted prescription drug distributor permit is required for any person that engages in the distribution of a legend drug, which distribution ~~is made in accordance with and~~ is not considered "wholesale distribution" under paragraph (1)(a)~~subparagraph (1)(a)1., subparagraph (1)(a)2., or subparagraph (1)(a)3.~~of s. 499.012.

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

499.015 Registration of drugs, devices, and cosmetics; issuance of certificates of free sale.--

(1) Except for those persons exempted from the definition in s. 499.003(23)~~s. 499.003(21)~~, any person who manufactures, packages, repackages, labels, or relabels a drug, device, or cosmetic in this state must register such drug, device, or cosmetic biennially with the department; pay a fee in accordance with the fee schedule provided by s. 499.041; and comply with this section. The registrant must list each separate and distinct drug, device, or cosmetic at the time of registration.

(3) Except for those persons exempted from the definition in s. 499.033(23)~~s. 499.003(21)~~, a person may not sell any product that he or she has failed to register in conformity with this section. Such failure to register subjects such drug, device, or cosmetic product to seizure and condemnation as provided in ss. 499.062-499.064, and subjects such person to the penalties and remedies provided in ss. 499.001-499.081.

Section 10. Section 499.024, Florida Statutes, is amended to read:

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

(1) The Florida Drug Technical Review Panel may review and make recommendations on products.

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

~~(3) If a product is distributed without required labeling, it is misbranded while held for sale.~~

(3)~~(4)~~ Any product that falls under the drug definition, s. 499.003(13)~~s. 499.003(11)~~, may be classified under the authority of this section. This section does not subject portable emergency oxygen inhalators to classification; however, this section does not exempt any person from ss. 499.01 and 499.015.

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

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

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

Section 11. Paragraph (d) is added to subsection (15) of section 499.028, Florida Statutes, to read:

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

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

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

Section 12. Section 499.03, Florida Statutes, is amended to read:

499.03 Possession of new drugs or legend drugs without prescriptions unlawful; exemptions and exceptions.--

(1) A person may not possess, or possess with intent to sell, dispense, or deliver, any habit-forming, toxic, harmful, or new drug subject to ss. 499.003(24) and 499.023 ~~s. 499.003(22)~~, or legend drug as defined in s. 499.003, unless the possession of the drug has been lawfully dispensed pursuant to ~~obtained by~~ a valid prescription of a practitioner licensed by law to prescribe the drug. However, this section does not apply to the delivery of such drugs to persons included in any of the classes named in this subsection, or to the agents or employees of such persons, for use in the usual course of their businesses or practices or in the performance

of their official duties, as the case may be; nor does this section apply to the possession of such drugs by those persons or their agents or employees for such use:

(a) A licensed pharmacist or any person under the licensed pharmacist's supervision while acting within the scope of the licensed pharmacist's practice and a pharmacy's permit;

(b) A licensed practitioner authorized by law to prescribe legend drugs or any person under the licensed practitioner's supervision while acting within the scope of the licensed practitioner's practice;

(c) A qualified person who uses legend drugs for lawful research, teaching, or testing, and not for resale;

(d) A licensed hospital or other institution that procures such drugs for lawful administration or dispensing by practitioners;

(e) An officer or employee of a federal, state, or local government; or

(f) A person that holds a valid permit issued by the department pursuant to ss. 499.001-499.081 which authorizes that person to possess prescription drugs.

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

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

dispense, or deliver is a third degree felony, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

Section 13. Subsection (2) of section 499.041, Florida Statutes, is amended and a new subsection (12) is added to that section to read:

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

(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 $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 $200 or more than $300 annually.~~;~~

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

(12) The fees provided in this section are not refundable.

Section 14. Section 499.051, Florida Statutes, is amended to read:

499.051 Inspections and investigations.--

(1) The agents of the Department of Health and Rehabilitative Services and of the Department of Law Enforcement, after they present proper identification, may inspect, monitor, and investigate any establishment permitted

pursuant to ss. 499.001-499.081 during business hours for the purpose of enforcing ss. 499.001-499.081, chapters 465~~, 501,~~ and 893, and the rules of the department that protect the public health, safety, and welfare.

(2) In addition to the authority set forth in subsection (1), the department and any duly designated officer or employee of the department may enter and inspect any other establishment for the purpose of determining compliance with 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 and Rehabilitative Services.~~

(3) Agents of the Department of Health, upon presentation of proper identification, may inspect, monitor, and investigate, consistent with the purposes of this chapter, any establishment at any time under exigent circumstances if necessary to protect the public health and safety.

(4)~~(3)~~ Any application for a permit or product registration or for renewal of such permit or registration made pursuant to ss. 499.001-499.081 and rules adopted under those sections constitutes permission for any entry or inspection of the premises in order to verify compliance with those sections and rules; to discover, investigate, and

determine the existence of compliance; or to elicit, receive, respond to, and resolve complaints and violations.

(5)~~(4)~~ The authority to inspect under this section includes the authority to secure:

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

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

(6)~~(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 15. Subsection (1) of section 499.066, Florida Statutes, is amended to read:

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

(1) 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. Such cease and desist order takes effect immediately upon issuance and remains in effect until the department takes final agency action. A cease and desist order is reviewable at the request of the person to whom it is directed as follows:

(a) If formal proceedings have been requested and the matter has been referred to the Division of Administrative Hearings, a motion to abate or modify the cease and desist order may be filed with the division. Any interlocutory order of the presiding administrative law judge is binding on the parties until final agency action is taken by the department.

(b) If informal proceedings have been requested, the department may consider and determine a request from the affected person to abate or modify the cease and desist order.

(c) If a person is aggrieved by a cease and desist order after seeking to have the order abated or modified under paragraph (a) or paragraph (b), the person may seek interlocutory judicial review by the appropriate district court of appeal under the applicable rules of appellate procedure.

Section 16. Subsection (1) of 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 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), subsection (10), subsection (14), subsection (15), ~~subsection (16),~~ or subsection (17) of s. 499.005 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.

Section 17. Section 499.072, Florida Statutes, is created to read:

499.072 Drug Regulation Advisory Group; Exemptions.--

(1) There is created an independent advisory group, designated as the Drug Regulation Advisory Group. The group consists of 11 members appointed by the Secretary of the Department of Health as follows:

(a) One member representing the prescription drug wholesale industry in this state.

(b) One member representing pharmaceutical manufacturers, who may represent pharmaceutical manufacturers nationwide.

(c) One member who is a practicing pharmacist.

(d) One member representing the Agency for Health Care Administration.

(e) One member who is a currently licensed medical doctor in this state.

(f) One consumer representative.

(g) One member representing the cosmetic industry.

(h) One member representing the compressed medical gas industry.

(i) One member representing the medical device manufacturing industry.

(j) The Executive Director of the Board of Pharmacy who is an ex officio member.

(k) One member representing the department who will chair group meetings.

(2) Members serve a term of 4 years, with the exception of the Executive Director of the Board of Pharmacy and the department representative who may serve indefinitely. Members of the group may be reappointed. A vacancy in membership occurring before the expiration of a term must be filled by a member appointed by the Secretary of the Department of Health for a full term.

(3) The group will meet upon request of the department, but no more than 4 times a year. Members of the group serve without compensation, but may be reimbursed for per diem and travel expenses as provided in s. 112.061.

(4) The purpose and duties of this group include:

(a) Making recommendations to the Secretary regarding authorizations for the sale, purchase, trade or other transfer of a prescription drug under s. 499.012(1)(b)2.

(b) Making recommendations to the department regarding enforcement priorities under chapter 499.

(c) Briefing the department on industry trends that affect chapter 499.

(d) Providing information and guidance on issues submitted by the department to the group.

(e) Facilitating the dissemination of relevant information of current issues affecting the public health within the scope and responsibility of chapter 499.

(5) The department may publish Compliance Policy Guidelines that set forth enforcement priorities or other recommendations of the Drug Regulation Advisory Group when it is in the best interest of the public health.

Section 18. Subsection (2) of section 499.62, Florida Statutes, is amended to read:

499.62 License or permit required of manufacturer, distributor, dealer, or purchaser of ether.--

(2) Any person who manufactures, distributes, or deals in ether in this state must possess a current valid license issued by the department, except that:

(a) A manufacturer, distributor, or dealer who also purchases ether in this state shall not be required to obtain an additional permit as a purchaser of ether.

(b) A permit is not required for an establishment located outside of this state which is only engaged in an intracompany sale or transfer of ether from the out-of-state establishment to a permitted person in this state if both locations are under common control. The recordkeeping requirements of s. 499.66 must be followed for this transaction.

Section 19. This act shall take effect July 1, 1998.

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SENATE SUMMARY

Amends various sections of ch. 499, F.S., relating to the Department of Health's regulation, inspection, and permitting of persons dealing in prescription drugs, cosmetics, and household products. Salient provisions include clarifying prohibited acts; clarifying wholesale distribution and permitting requirements; authorizing transfers for government purposes under certain conditions; authorizing a retail pharmacy to transfer limited quantities of prescription drugs without a wholesaler permit; clarifying existing rulemaking authority for the storage and handling of drugs; providing an expiration date of a practitioner's order for medical oxygen; clarifying provisions relating to the sale of veterinary drugs to the public; the authorization of government officers and employees to possess complimentary prescription drugs when acting within the scope of employment; making fees for drug, device, and cosmetic applications and permits nonrefundable; authorization of department agents to inspect and investigate during nonbusiness hours, if necessary, to protect the public health; authorizing cease and desist orders to take effect immediately with provision for the person affected to move to abate or modify the order; creation of the Drug Regulation Advisory Group to make recommendations to the Secretary of the Department of Health regarding authorizations for the sale, purchase, trade, or transfer of prescription drugs and enforcement priorities; and the deletion of a requirement that the Department of Business and Professional Regulation inspect retail pharmacy wholesalers. (See bill for details.)