By Senator Peaden

2-1382-03 See HB 1481

A bill to be entitled

An act relating to pharmaceutical wholesalers; amending s. 499.003, F.S.; defining the term "affiliated party"; amending s. 499.005, F.S.; prohibiting acts relating to previously dispensed drugs; amending s. 499.01, F.S.; revising permit requirements; amending s. 499.012, F.S.; providing definitions; providing additional permit requirements for prescription drug wholesalers, out-of-state prescription drug wholesalers, and retail pharmacy drug wholesalers; providing for renewal on an annual basis; requiring designation of a natural person as a wholesaler's representative; amending s. 499.0121, F.S.; providing for wholesale distributor due diligence; requiring reporting with respect to previous sales of prescription drugs, including high-risk prescription drugs; requiring wholesale distributors to submit annually a list of the wholesalers from whom they purchase drugs; prohibiting a wholesale drug distributor from paying for any drug with currency; creating s. 499.0125, F.S.; creating the Drug Wholesaler Advisory Council; providing for the council's organization, powers, and duties; amending ss. 499.015, 499.024, and 499.03, F.S.; conforming cross-references; amending s. 499.041, F.S.; increasing permit fees for prescription drug wholesalers, out-of-state prescription drug wholesalers, and retail pharmacy drug

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

wholesalers; amending s. 499.05, F.S.; conforming a cross-reference; amending s. 499.051, F.S.; expanding authority of the Department of Health and the Department of Law Enforcement to inspect financial records and investigate complaints and violations; creating s. 499.0671, F.S.; providing enforcement provisions, including cease and desist orders and removal of affiliated parties; amending s. 499.069, F.S.; providing penalties; providing an effective date.

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

Section 1. Subsections (2) through (28) of section 499.003, Florida Statutes, are renumbered as subsections (3) through (29), respectively, and a new subsection (2) is added to that section, to read:

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

(2) "Affiliated party" means any person who directs or participates in the conduct of the affairs of a permittee or applicant pursuant to s. 499.012 and who is:

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

(b) A person who has filed or is required to file a personal information statement pursuant to s. 499.012(4) or is required to be identified in an application for a permit or to renew a permit pursuant to s. 499.012(3); or

(c) A stockholder who participates in the conduct of the affairs of the permittee or applicant.

Section 2. Subsections (26) and (27) are added to section 499.005, Florida Statutes, to read:

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

(26) Removing the label of a pharmacy licensed pursuant to chapter 465 from a dispensed prescription drug with the intent to further distribute the prescription drug.

(27) Knowing distribution of a prescription drug that was previously dispensed by a pharmacy licensed pursuant to chapter 465, unless such distribution was authorized in chapter 465 or the rules adopted thereunder.

Section 3. Section 499.01, Florida Statutes, is amended to read:

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

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

(a) Prescription drug manufacturer;

(b) Over-the-counter drug manufacturer;

(c) Compressed medical gas manufacturer;

(d) Device manufacturer;

(e) Cosmetic manufacturer;

(f) Prescription drug wholesaler;

(g) Compressed medical gas wholesaler;

(h) Out-of-state prescription drug wholesaler;

(i) Retail pharmacy drug wholesaler;

(j) Veterinary legend drug retail establishment;

(k) Medical oxygen retail establishment;

(l) Complimentary drug distributor; or

(m) Restricted prescription drug distributor.

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

(2)(a) A permit issued pursuant to ss. 499.001-499.081 may be issued only to 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 establishment that operates as a:~~

~~1. Prescription drug manufacturer;~~

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

~~3. Compressed medical gas manufacturer;~~

~~4. Device manufacturer;~~

~~5. Cosmetic manufacturer;~~

~~6. Prescription drug wholesaler;~~

~~7. Compressed medical gas wholesaler;~~

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

~~9. Retail pharmacy drug wholesaler;~~

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

~~11. Medical oxygen retail establishment;~~

~~12. Complimentary drug distributor; or~~

~~13. Restricted prescription drug distributor.~~

(d)~~(e)~~ A permit for a prescription drug manufacturer, prescription drug wholesaler, or retail pharmacy drug wholesaler may not be issued to the address of a health care entity.

(3)~~(f)~~ Notwithstanding subsection(7)~~(4)~~, a permitted person in good standing may change the type of permit issued to that person by completing a new application for the requested permit, paying the amount of the difference in the permit fees if the fee for the new permit is more than the fee for the original permit, and meeting the applicable permitting conditions for the new permit type. The new permit expires on the expiration date of the original permit being changed, provided, however, that a new permit for a prescription drug wholesaler, an out-of-state prescription drug wholesaler, or a retail pharmacy drug wholesaler shall expire on the expiration date of the original permit or 1 year after the date of issuance of the new permit, whichever is earlier. A refund may not be issued if the ~~biennial~~ fee for the new permit is less than the fee that was paid for the original permit ~~for which a fee was paid~~.

(4)~~(2)~~ A written application for a permit shall be filed with the department on forms furnished by the department.The department shall establish, by rule, the form and content of the application to obtain or renew a permit. The applicant must submit to the department with the

application a statement that swears or affirms that the information contained in the application is true and correct.

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

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

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

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

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

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

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

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

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

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

e. Any other relevant information that the department requires.

(b) Upon approval of the application by the department and payment of the required fee, the department shall issue a permit to the applicant, if the applicant meets the

requirements of ss. 499.001-499.081 and rules adopted under those sections.

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

(d) The department shall consider, at a minimum, the following factors in reviewing the qualifications of persons to be permitted under ss. 499.001-499.081:

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

2. The applicant's having been disciplined by a regulatory agency in any state for any offense that would constitute a violation of ss. 499.001-499.081.

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

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

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

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

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

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

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

(6)~~(3)~~ Except for permits for prescription drug wholesalers, out-of-state prescription drug wholesalers, and retail pharmacy drug wholesalers:

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

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

(c)~~(b)~~ A permit, unless sooner suspended or revoked, automatically expires 2 years after the last day of the anniversary month in which the permit was originally issued. 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 by the expiration date of the permit, the 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.

(d)~~(c)~~ Failure to renew a 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 requires a new permit application and

payment of an application fee, initial permit fee, and applicable penalties.

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

(a) A person permitted under ss. 499.001-499.081 must notify the department before making a change of address. The department shall set a change of location fee not to exceed $100.

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

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

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

(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.

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

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

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

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

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

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

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

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

a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended and revised, to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

c. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control. For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise.

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

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

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

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

(IV) A contract provider or subcontractor must maintain separate and apart from other prescription drug

inventory any prescription drugs of the agency or entity in its possession.

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

(VI) The contract provider or subcontractor may administer or dispense the prescription drugs only to the eligible patients of the agency or entity or must return the prescription drugs for or to the agency or entity. The contract provider or subcontractor must require proof from each person seeking to fill a prescription or obtain treatment that the person is an eligible patient of the agency or entity and must, at a minimum, maintain a copy of this proof as part of the records of the contractor or subcontractor required under sub-sub-subparagraph (V).

(VII) In addition to the departmental inspection authority set forth in s. 499.051, the establishment of the contract provider and subcontractor and all records pertaining to prescription drugs subject to this sub-subparagraph shall be subject to inspection by the agency or entity. All records relating to prescription drugs of a manufacturer under this sub-subparagraph shall be subject to audit by the manufacturer

of those drugs, without identifying individual patient information.

2. Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with rules established by the department:

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

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

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

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

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

f. The transfer of a prescription drug by a person authorized to purchase or receive prescription drugs to a person licensed or permitted to handle reverse distributions

or destruction under the laws of the jurisdiction in which the person handling the reverse distribution or destruction receives the drug.

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.

(d) "Primary wholesaler" means any wholesale distributor that purchased 90 percent or more of its

prescription drugs directly from a manufacturer, in the immediately preceding 12 calendar months.

(e) "Directly from a manufacturer" means:

1. Purchases made by the wholesale distributor directly from the manufacturer of prescription drugs.

2. Transfers from a member of an affiliated group, as defined in s. 1504 of the Internal Revenue Code, of which the wholesale distributor is a member, if:

a. The affiliated group purchases 90 percent or more of all of its prescription drugs from a manufacturer.

b. The wholesale distributor discloses to the department the names of all members of the affiliated group of which the wholesale distributor is a member and the affiliated group agrees in writing to provide records on such transfers not later than 48 hours after the department requests access to such records, regardless of the location where the records are stored.

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

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

(a) A prescription drug wholesaler's permit. A prescription drug wholesaler is a wholesale distributor that may engage in the wholesale distribution of prescription drugs. A prescription drug wholesaler that applies to the department after July 1, 2003 ~~January 1, 1993~~, must submit a bond or letter of credit of$100,000~~$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. If a permittee ~~that~~ fails to notify the department

before changing the address of the business, fails to notify the department before closing the business, fails to pay any administrative fine levied by the department within 30 days after any such fine becomes final,or fails to notify the department before a change of ownership, the department shall collect the applicable administrative fines from the bond's surety ~~forfeits its bond~~. The department may adopt rules for issuing a prescription drug wholesaler-broker permit to a person who engages in the wholesale distribution of prescription drugs and does not take physical possession of any prescription drugs.

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

(c) An out-of-state prescription drug wholesaler's permit. An out-of-state prescription drug wholesaler is a wholesale distributor located outside this state which engages in the wholesale distribution of prescription drugs into this state and which must be permitted by the department and comply with all the provisions required of a wholesale distributor

under ss. 499.001-499.081. An out-of-state prescription drug wholesaler that applies to the department after July 1, 2003, must submit a bond or letter of credit of $100,000, payable to the Florida Drug, Device, and Cosmetic Trust Fund. This bond shall be refunded to the permittee when the permit is returned to the department and the permittee ceases to function as a business. If a permittee fails to notify the department before changing the address of the business, fails to notify the department before closing the business, fails to pay any administrative fine levied by the department within 30 days after any such fine becomes final, or fails to notify the department before a change of ownership, the department shall collect the applicable administrative fines from the bond's surety.

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(7)~~(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 drug wholesaler's permit. A retail pharmacy drug 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 drug wholesaler's permit pursuant to ss. 499.001-499.081 and the rules adopted under those sections.

2. The wholesale distribution activity does not exceed 30 percent of the total annual purchases of prescription drugs. If the wholesale distribution activity exceeds the 30-percent maximum, the pharmacy must obtain a prescription drug wholesaler's permit.

3. The transfer of prescription drugs that appear in any schedule contained in chapter 893 is subject to chapter 893 and the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

4. The transfer is between a retail pharmacy and another retail pharmacy, or a Modified Class II institutional pharmacy, or a health care practitioner licensed in this state and authorized by law to dispense or prescribe prescription drugs.

5. All records of sales of prescription drugs subject to this section must be maintained separate and distinct from

other records and comply with the recordkeeping requirements of ss. 499.001-499.081.

(3) An application for a permit or to renew a permit for a prescription drug wholesaler, an out-of-state prescription drug wholesaler, or a retail pharmacy drug wholesaler submitted to the department on or after July 1, 2003, must include:

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

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

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

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

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

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

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

3. If a corporation:

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

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

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

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

(f)1. For an application for a new permit, the estimated annual dollar volume of prescription drug sales of the applicant and the estimated percentage of applicant's total company sales that are prescription drugs.

2. For an application to renew a permit, the total dollar volume of prescription drug sales in the previous year, the total dollar volume of prescription drug sales made in the previous 6 months, the percentage of total company sales that were prescription drugs, the total dollar volume of purchases of prescription drugs, and the total volume of prescription drug purchases made directly from the manufacturers of prescription drugs. However, if the prescription drug wholesaler, out-of-state prescription drug wholesaler, or retail pharmacy drug wholesaler made no sales of prescription drugs in the previous 6 months, the permit may not be renewed.

(g) The tax year of the applicant.

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

(i) A list of all licenses and permits issued to the applicant by any other state which authorize the applicant to purchase or possess prescription drugs, except when the applicant is applying for a retail pharmacy drug wholesaler permit.

(j) The name of the manager of the establishment that is applying for the permit or to renew the permit and the next four highest ranking employees responsible for prescription drug wholesale operations, together with the personal

information statement and fingerprints required pursuant to subsection (4) for each of such persons.

(k) The name of the applicant's initial wholesaler's representative as required by subsection (6), together with the personal information statement and fingerprints required pursuant to subsection (4) for that person.

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

1. A personal background information statement containing the background information and fingerprints required pursuant to subsection (4) for each person named in applicant's response to paragraphs (a)-(i) and for each affiliated party of the applicant.

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

3. The name and address of all financial institutions in which the applicant has an account which is used to pay for the operation of the establishment or to pay for drugs purchased for the establishment, together with the names of all persons that are authorized signatories on such accounts.

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

5. If any of the funds identified in subparagraph 3. were borrowed, copies of all promissory notes or loans used to obtain such funds.

(m) Any other relevant information that the department requires.

(4)(a) Each person required by subsection (3) to provide a personal information statement and fingerprints shall provide the following information to the department on forms prescribed by the department:

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

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

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

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

5. Whether the person was, at any time during such 7-year period, convicted of or pleaded nolo contendere to any criminal offense other than a traffic violation, regardless of whether adjudication of guilt was withheld, and a description of the circumstances involved with the criminal offense. A criminal offense committed in another state which would have been a felony in this state must be reported.

6. Whether the person has been, during such 7-year period, the subject of any proceeding for the revocation of any license and, if so, the nature of the proceeding and the disposition of the proceeding.

7. Whether, during the 7-year period, the person has been the subject of any proceeding under the federal

Bankruptcy Act or whether, during the 7-year period, any corporation, partnership, firm, trust, or association in which the person was a director, officer, trustee, partner, or other official has been subject to any such proceeding, either during the time in which the person was a director, officer, trustee, partner, or other official or within 12 months thereafter.

8. Whether, during the 7-year period, the person has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs, together with details as to any such event.

9. A description of any involvement by the person with any business, including any investments (other than the ownership of stock in a publicly traded company or mutual fund), during the 7-year period, that manufactured, administered, prescribed, distributed, or stored pharmaceutical products.

10. The names of, dates of attendance at, and degrees awarded by all postsecondary education institutions attended by the person.

11. A description of all lawsuits in which the person was a party during the 7-year period.

12. A description of any criminal offense of which the person was found guilty, regardless of whether adjudication of guilt was withheld, or to which the person pleaded guilty or nolo contendere. A criminal offense committed in another jurisdiction which would have been a felony in this state must be reported. If the person indicates that a criminal conviction is under appeal and submits a copy of the notice of

appeal of that criminal offense, the applicant must, within 15 days after the disposition of the appeal, submit to the department a copy of the final written order of disposition.

13. A photograph of the person taken in the previous 30 days.

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

15. The names, addresses, occupations, and date and place of birth for the members of the person's immediate family and a description of any criminal offense, other than a traffic infraction, which any of such persons was convicted during the 7-year period, regardless of whether adjudication of guilt was withheld, or to which the person pleaded guilty or nolo contendere. A criminal offense committed in another jurisdiction which would have been a felony in this state must be reported. For the purposes of this subsection, the "members of the person's immediate family" includes the person's spouse, children, parents, siblings, the spouses of the person's children, and the spouses of the person's siblings.

16. Any other relevant information that the department requires.

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

(c) The department shall submit the fingerprints provided by a person for initial licensure to the Department of Law Enforcement for a statewide criminal history check, and the Department of Law Enforcement shall forward the

fingerprints to the Federal Bureau of Investigation for a national criminal history check of the person. The department shall submit the fingerprints provided by a person as a part of a renewal application to the Department of Law Enforcement for a statewide criminal background history check, and the Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for a national criminal background history check, for the initial renewal of a permit after July 1, 2003. For any subsequent renewal of a permit, the department shall submit the required information for a statewide criminal history check of the person. Any person who, as a part of an initial permit application or initial permit renewal after July 1, 2003, submits to the department a set of fingerprints required for the criminal history check required in this subsection shall not be required to provide a subsequent set of fingerprints for a criminal history check to the department, if the person has undergone a criminal history check as a condition of the issuance of an initial permit or the initial renewal of a permit after July 1, 2003.

(5)(a) The department shall consider, at a minimum, the following factors in reviewing the qualifications of persons to be permitted pursuant to this section:

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 past experience in distributing drugs.

3. The applicant's compliance with permitting requirements under any previously granted permits.

4. The applicant's 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.

5. The applicant or any affiliated party of 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.

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

(b) The department shall not approve a permit or renew a permit for a prescription drug wholesaler, an out-of-state prescription drug wholesaler, or a retail pharmacy drug wholesaler, if the department finds:

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

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

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

4. It has good reason to believe the applicant is affiliated directly or indirectly, through ownership, control, or other business relations, with any person or persons whose

business operations are or have been marked to the detriment of the public health or by bad faith;

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

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

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

(c) The department shall not approve or renew any permit for any prescription drug wholesaler, out-of-state prescription drug wholesaler, or retail pharmacy drug wholesaler if any affiliated party who exercises or has the ability to exercise effective control of the applicant, or who influences or has the ability to influence the transaction of the business of the applicant, does not possess the financial standing and business experience for the successful operation of the applicant.

(d) The department shall suspend or revoke the permit and shall deny the renewal of the permit of any prescription drug wholesaler, out-of-state prescription drug wholesaler, or retail pharmacy drug wholesaler if any affiliated party who exercises or has the ability to exercise effective control of the applicant, or who influences or has the ability to

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

(e) The department shall suspend or revoke the permit and shall deny the renewal of the permit of any prescription drug wholesaler, out-of-state prescription drug wholesaler, or retail pharmacy drug wholesaler in this state if any affiliated party who exercises or has the ability to exercise effective control of the permittee or applicant, or who influences or has the ability to influence the transaction of the business of the permittee or applicant, the department has good reason to believe is now or was in the past affiliated directly or indirectly, through ownership interest of 5 percent or more control, with any business, corporation, or other entity that has been found guilty of or has pleaded guilty or nolo contendere to any felony or crime punishable by imprisonment for 1 year or more under the laws of the United States, any state, or any other country, regardless of whether adjudication of guilt was withheld.

(f) Upon approval of the application by the department and payment of the required fee, the department shall issue or renew a prescription drug wholesaler, out-of-state prescription drug wholesaler, or retail pharmacy drug wholesaler permit to the applicant, if the applicant meets the requirements of ss. 499.001-499.081 and rules adopted under those sections.

(6) For permits for prescription drug wholesalers, out-of-state prescription drug wholesalers, and retail pharmacy drug wholesalers:

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

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

(c) A permit, unless sooner suspended or revoked, automatically expires 1 year after the last day of the anniversary month in which the permit was originally issued. Such permit 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 by the expiration date of the permit, the 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.

(d) Failure to renew a permit in accordance with this section precludes any future renewal of that permit. If a permit issued pursuant to this section has expired and cannot

be renewed, before an establishment may continue to engage in activities that require a permit under ss. 499.001-499.081, the establishment must submit an application for a new permit, pay the applicable application fee, initial permit fee, and all applicable penalties.

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

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

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

2. The pharmacy maintains its permit under chapter 465;

3. The consignor wholesaler, which has no legal authority to dispense prescription drugs, complies with all wholesale distribution requirements of s. 499.0121 with respect to the consigned drugs and maintains records documenting the transfer of title or other completion of the wholesale distribution of the consigned prescription drugs;

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

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

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

(b) A wholesale distributor's permit is not required for the one-time transfer of title of a pharmacy's lawfully acquired prescription drug inventory by a pharmacy with a valid permit issued under chapter 465 to a consignor prescription drug wholesaler, permitted under this chapter, in accordance with a written consignment agreement between the pharmacy and that wholesaler if: the permitted pharmacy and the permitted prescription drug wholesaler comply with all of the provisions of paragraph (a) and the prescription drugs continue to be within the permitted pharmacy's inventory for dispensing in accordance with the limitations of the pharmacy permit under chapter 465. A consignor drug wholesaler may not use the pharmacy as a wholesale distributor through which it distributes the legend drugs to other pharmacies. Nothing in this section is intended to prevent a wholesale drug distributor from obtaining this inventory in the event of nonpayment by the pharmacy.

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

(8)~~(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.

(9)(a) Each establishment that is issued a prescription drug wholesaler's permit, an out-of-state prescription drug permit, or a retail pharmacy drug wholesaler's permit must designate in writing to the department at least one natural person to serve as the wholesaler's representative.

(b) Each such natural person must meet the following qualifications:

1. Is at least 18 years of age.

2. Has at least 2 years' experience working full-time in a pharmacy or with a wholesale distributor that holds a prescription drug wholesaler permit or that holds an out-of-state wholesaler permit.

3. Has received a passing score of at least 75 percent on an examination given by the department regarding federal laws governing distribution of prescription drugs and ss. 499.001-499.081 and the rules adopted by the department governing the wholesale distribution of prescription drugs. Such requirement shall be effective 1 year after the results of the initial examination are mailed to the persons that took the examination. The department shall offer such examinations at least four times each calendar year. A pharmacist licensed under chapter 465 shall be exempt from the requirements of this subparagraph.

4. Has provided the department with a personal information statement and fingerprints pursuant to subsection (4).

(c) The wholesaler's representative:

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

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

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

4. May serve as a wholesaler's representative for only one wholesale distributor at one time.

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

(e) A wholesale distributor may not operate under a prescription drug permit or an out-of-state prescription drug permit for more than 10 business days after the wholesale representative leaves the employ of the wholesale distributor, unless the wholesale distributor employs another wholesaler's representative.

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

Section 5. Section 499.0121, Florida Statutes, is amended to read:

499.0121 Storage and handling of prescription drugs; wholesale distributor due diligence;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, for the due diligence that wholesale distributors must perform on their suppliers, and for the establishment and maintenance of prescription drug distribution records.

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

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

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

(c) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

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

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

(2) SECURITY.--

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

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

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

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

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

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

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

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

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

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

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

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

(4) EXAMINATION OF MATERIALS.--

(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.

(5) DUE DILIGENCE.--

(a) Prior to purchasing any prescription drugs from another wholesale drug distributor, a wholesale drug distributor must:

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

2. Determine that the selling wholesale drug distributor has insurance coverage of not less than the greater of 1 percent of the amount of total dollar volume of the prescription drug sales reported to the department

pursuant to paragraph (7)(f) or $500,000, provided such coverage does not have to exceed $2 million.

3. Obtain information about the selling wholesale drug distributor, including the length of time the selling wholesale drug distributor has been licensed in Florida, a copy of the selling wholesale drug distributor's licenses or permits, and appropriate background information concerning the selling wholesale drug distributor.

4. Verify that the selling wholesale drug distributor's Florida permit is valid.

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

a. Purchasing any drug from the wholesale drug distributor, and at least once each subsequent year; or

b. Purchasing any drug from the wholesale drug distributor, and each subsequent year obtaining a complete copy of the most recent annual inspection report for the establishment that was prepared by the department or the regulatory authority responsible for wholesale drug distributors in the state in which the establishment is located and that indicates that no regulatory violations were found at the establishment.

(b) The department shall publish on the department's website:

1. A list of the prescription drug wholesalers, out-of-state prescription drug wholesalers, and retail pharmacy drug wholesalers against whom the department has initiated enforcement action pursuant to ss. 499.001 499.081 and their permit numbers.

2. A list of all prescription drug wholesalers, out-of-state prescription drug wholesalers, and retail pharmacy drug wholesalers to which the department has issued a permit together with the date on which each permit will expire.

3. A list of all prescription drug wholesaler, out-of-state prescription drug wholesaler, and retail pharmacy drug wholesaler permits that became inactive, were suspended, were revoked or were not renewed in the previous year.

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

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

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

(b) Any prescription drugs of which the immediate or sealed outer containers or sealed secondary containers have been opened or used must be identified as such and must be quarantined and physically separated from other prescription

drugs until they are either destroyed or returned to the supplier.

(c) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug must be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor must consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the conditions of the drug and its container, carton, or labeling, as a result of storage or shipping.

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

(7)~~(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.

(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 <u>for the drug manufacturer's products</u> ~~of such drug~~, must provide to each wholesale distributor of such drug, before the sale is made to such wholesale distributor, a written statement <u>under oath</u> identifying each previous sale of the drug <u>back to the last authorized distributor of record, the lot number of the drug,</u>

and the sales invoice number of the invoice evidencing the sale of the drug. The written statement ~~identifying all sales of such drug~~ must accompany the drug ~~for each subsequent wholesale distribution of the drug~~ to the next ~~a~~ wholesale distributor. The department shall adopt rules relating to the requirements of this written statement.

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

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

(e)1. Notwithstanding paragraph (d), each person who is engaged in the wholesale distribution of a high-risk prescription drug must provide to each wholesale distributor of such high-risk prescription drug, before any sale of such high-risk prescription drug is made to such wholesale distributor, a written statement under oath identifying each previous sale of the high-risk prescription drug back to the manufacturer of the high-risk prescription drug, the lot number of the high-risk prescription drug, and the sales invoice number of the invoice evidencing each previous sale of the high-risk prescription drug. The written statement identifying all sales of such high-risk prescription drug must accompany the high-risk prescription drug for each subsequent wholesale distribution of the high-risk prescription drug to a wholesale distributor. The department shall adopt rules relating to the requirements of this written statement.

2. For the purposes of this paragraph, a "high-risk prescription drug" is a specific drug on the list of drugs adopted by the department by rule each of which is a specific drug seized by the department on at least five separate occasions because such drug was adulterated, counterfeited, or diverted from legal prescription drug distribution channels and the department has begun an administrative action to revoke the permits of two or more wholesale distributors that engaged in the illegal distribution of that specific drug.

(f) Each wholesale distributor, except for a manufacturer, shall annually provide the department with a written list of all prescription drug wholesalers and out-of-state prescription drug wholesalers from whom the wholesale distributor purchases drugs. A wholesale distributor, except a manufacturer, shall notify the department not later than 10 days after any change to said list.

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, without regard to whether the wholesale distributor acquired the products directly from the manufacturer. An ongoing relationship is deemed to exist when a wholesale distributor is listed on the manufacturer's current list of authorized distributors or when a wholesale distributor has made at least three purchases of a manufacturer's products directly from that manufacturer within a 6-month period from the date for which the authorized distributor-of-record relationship is claimed.

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

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

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

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

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

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

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

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

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

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

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

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

(c) A wholesale drug distributor shall not pay for any drug with currency, as defined in s. 560.103(6).

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

Section 6. Paragraphs (b) and (c) of subsection (2) of section 499.0122, Florida Statutes, are amended to read:

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

(2)

(b) The department shall adopt rules relating to information required from each retail establishment pursuant to s. 499.01(4) and (5)~~(2)~~, including requirements for prescriptions or orders.

(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(7)~~(6)~~(d) and (e).

Section 7. Section 499.0125, Florida Statutes, is created to read:

499.0125 Drug Wholesaler Advisory Council.--

(1) There is created the Drug Wholesaler Advisory Council in the department. The council shall meet at least three times each year. Staff for the council shall be provided by the department. The council shall consist of nine members who shall serve without compensation.

(2) The secretary of the department shall appoint three members, one of whom must be a pharmacist licensed pursuant to chapter 465 who is employed in a retail pharmacy drug wholesaler licensed pursuant to this chapter, one of whom

must be a person employed by a prescription drug wholesaler licensed pursuant to this chapter, and one of whom must be the department employee responsible for supervising the administration of ss. 499.001-499.081. The Speaker of the House of Representatives shall appoint three members, one of whom must be a person knowledgeable about the pharmaceutical distribution industry who is employed by a primary wholesaler, as defined in s. 499.012(1)(d), that is licensed pursuant to this chapter, one of whom must be an employee of a retail pharmacy chain located in Florida, and one of whom must be a member of the Florida House of Representatives. The President of the Senate shall appoint three members, one of whom must be a person knowledgeable about the pharmaceutical distribution industry who is employed by a secondary wholesaler, as defined in s. 499.012(1)(f), that is licensed pursuant to this chapter, one of whom must be an employee of a retail grocery chain that operates a retail pharmacy in Florida, and one of whom must be a member of the Senate. The members of the council shall elect a chair and a vice chair who will serve a term of 1 year each.

(3) The council shall review ss. 499.001-499.081 and the rules adopted to implement ss. 499.001-499.081 annually, provide input to the department regarding all proposed rules to implement ss. 499.001-499.081, make recommendations to the department to improve the protection of prescription drugs and the public health, improve the technology and means used in the wholesale distribution of drugs, make recommendations to improve coordination with other states' regulatory agencies and the Federal Government concerning wholesale distribution of drugs, and make recommendations to minimize the impact of

regulation of the wholesale distribution industry while ensuring protection of the public health.

Section 8. Paragraph (a) of subsection (1) and subsection (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)(a) Except for those persons exempted from the definition in s. 499.003(22)~~(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. 499.003(22)~~(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 9. Subsection (3) of 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.

(3) Any product that falls under the drug definition, s. 499.003(13)~~(12)~~, 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.

Section 10. Subsection (1) of 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 s. 499.003(23)~~(22)~~, or legend drug as defined in s. 499.003(20)~~(19)~~, unless the possession of the drug has been obtained by a valid prescription of a practitioner licensed by law to prescribe the drug. However, this section does not apply to the delivery of such drugs to persons included in any of the classes named in this subsection, or to the agents or employees of such persons, for use in the usual course of their businesses or practices or in the performance of their official duties, as the case may be; nor does this section apply to the possession of such drugs by those persons or their agents or employees for such use:

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

(b) A licensed practitioner authorized by law to prescribe 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.

Section 11. Subsection (2) and subsection (4) of section 499.041, Florida Statutes, are amended to read:

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

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

(a) The fee for a prescription drug wholesaler's permit may not be less than $300 or more than$800~~$400~~ annually;

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

(c) The fee for an out-of-state prescription drug wholesaler's permit may not be less than$300~~$200~~ or more than$600~~$300~~ annually;

(d) The fee for a retail pharmacy drug wholesaler's permit may not be less than $35 or more than$100~~$50~~ annually.

(4) The department shall assess an applicant that is required to have a restricted prescription drug distributor's

permit an annual fee of not less than $200 or more than $600 ~~$300~~.

Section 12. Paragraph (g) of subsection (1) of section 499.05, Florida Statutes, is amended to read:

499.05 Rules.--

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

(g) Inspections and investigations conducted under s. 499.051, and the identification of information claimed to be a trade secret and exempt from the public records law as provided in s. 499.051(6)~~(5)~~.

Section 13. Section 499.051, Florida Statutes, is amended to read:

499.051 Inspections and investigations.--

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

(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.

(4) Any application for a permit made pursuant to s. 499.012 and rules adopted under those sections constitutes permission for agents of the Department of Health and the Department of Law Enforcement, after they present proper identification, to inspect and copy any financial document or record related to the distribution of a drug as is necessary to verify compliance with ss. 499.001-499.081 and the rules adopted by the department to implement those sections, 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(7) ~~(6)~~(d) or (e), and the pedigree papers required in that subsection shall not be deemed a trade secret.

Section 14. Section 499.0671, Florida Statutes, is created to read:

499.0671 Enforcement; cease and desist orders; removal of certain persons.--

(1) DEFINITION.--For the purposes of this section, the term "permittee" means any person holding a permit issued pursuant to s. 499.021.

(2) ENFORCEMENT GENERALLY.--The department may institute such suits or other legal proceedings as may be required to enforce any provision of ss. 499.001-499.081. If it appears that any person has violated any provision of ss. 499.001-499.081 for which criminal prosecution is provided,

the department shall provide the appropriate state attorney or other prosecuting agency having jurisdiction with respect to such prosecution with the relevant information in its possession.

(3) CEASE AND DESIST ORDERS.--

(a) The department may issue and serve a complaint stating charges upon any permittee or upon any affiliated party, whenever the department has reasonable cause to believe that the person or individual named therein is engaging in or has engaged in conduct that is:

1. An act that demonstrates a lack of fitness or trustworthiness to engage in the business authorized under the permit issued pursuant to ss. 499.001-499.081, is hazardous to the public health, or constitutes business operations that are a detriment to the public health, stockholders, investors, creditors, or the public;

2. A violation of any provision of ss. 499.001-499.081;

3. A violation of any rule of the department;

4. A violation of any order of the department; or

5. A breach of any written agreement with the department.

(b) The complaint shall contain a statement of facts and notice of opportunity for a hearing pursuant to ss. 120.569 and 120.57.

(c) If no hearing is requested within the time allowed by ss. 120.569 and 120.57, or if a hearing is held and the department finds that any of the charges are proven, the department may enter an order directing the permittee or the affiliated party named in the complaint to cease and desist from engaging in the conduct complained of and take corrective

action to remedy the effects of past improper conduct and ensure future compliance.

(d) If the permittee or affiliated party named in the order fails to respond to the complaint within the time allotted by ss. 120.569 and 120.57, the failure constitutes a default and justifies the entry of a cease and desist order.

(e) A contested or default cease and desist order is effective when reduced to writing and served upon the permittee or affiliated party named therein. An uncontested cease and desist order is effective as agreed.

(f) Whenever the department finds that conduct described in paragraph (a) is likely to cause an immediate threat to the public health, it may issue an emergency cease and desist order requiring the licensee or any affiliated party to immediately cease and desist from engaging in the conduct complained of and to take corrective and remedial action. The emergency order is effective immediately upon service of a copy of the order upon the permittee or affiliated party named therein and remains effective for 90 days. If the department begins nonemergency cease and desist proceedings under this subsection, the emergency order remains effective until the conclusion of the proceedings under ss. 120.569 and 120.57.

(4) REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.--

(a) The department may issue and serve a complaint stating charges upon any affiliated party and upon the licensee involved, whenever the department has reason to believe that an affiliated party is engaging in or has engaged in conduct that constitutes:

1. An act that demonstrates a lack of fitness or trustworthiness to engage in the business authorized under the

permit issued pursuant to ss. 499.001-499.081, is hazardous to the public health, or constitutes business operations that are a detriment to the public health, stockholders, investors, creditors, or the public;

2. A willful violation of ss. 499.001-499.081; however, if the violation constitutes a misdemeanor, no complaint shall be served as provided in this section until the affiliated party is notified in writing of the matter of the violation and has been afforded a reasonable period of time, as set forth in the notice, to correct the violation and has failed to do so;

3. A violation of any other law involving fraud or moral turpitude that constitutes a felony;

4. A willful violation of any rule of the department;

5. A willful violation of any order of the department;

6. A material misrepresentation of fact, made knowingly and willfully or made with reckless disregard for the truth of the matter; or

7. An act of commission or omission or a practice which is a breach of trust or a breach of fiduciary duty.

(b) The complaint shall contain a statement of facts and notice of opportunity for a hearing pursuant to ss. 120.569 and 120.57.

(c) If no hearing is requested within the time allotted by ss. 120.569 and 120.57, or if a hearing is held and the department finds that any of the charges in the complaint are proven true and that:

1. The permittee has suffered or will likely suffer loss or other damage;

2. The interests of the permittees' stockholders or creditors, or the public are, or could be, seriously

prejudiced by reason of the violation or act or breach of fiduciary duty;

3. The affiliated party has received financial gain by reason of the violation, act, or breach of fiduciary duty; or

4. The violation, act, or breach of fiduciary duty is one involving personal dishonesty on the part of the affiliated party or the conduct jeopardizes or could reasonably be anticipated to jeopardize the public health or financial soundness of the permittee,

the department may enter an order removing the affiliated party or restricting or prohibiting participation by the person in the affairs of that particular permittee or of any other permittee.

(d) If the affiliated party fails to respond to the complaint within the time allotted by ss. 120.569 and 120.57, the failure constitutes a default and justifies the entry of an order of removal, suspension, or restriction.

(e) A contested or default order of removal, restriction, or prohibition is effective when reduced to writing and served on the licensee and the affiliated party. An uncontested order of removal, restriction, or prohibition is effective as agreed.

(f)1. The chief executive officer, designated representative, or the person holding the equivalent office, of a permittee shall promptly notify the department if she or he has actual knowledge that any affiliated party is charged with a felony in a state or federal court.

2. Whenever any affiliated party is charged with a felony in a state or federal court or with the equivalent of a felony in the courts of any foreign country with which the

United States maintains diplomatic relations, and the charge alleges violation of any law involving prescription drugs, pharmaceuticals, fraud, theft, or moral turpitude, the department may enter an emergency order suspending the affiliated party or restricting or prohibiting participation by the affiliated party in the affairs of the particular permittee or of any other permittee upon service of the order upon the permittee and the affiliated party charged. The order shall contain notice of opportunity for a hearing pursuant to ss. 120.569 and 120.57, where the affiliated party may request a postsuspension hearing to show that continued service to or participation in the affairs of the licensee does not pose a threat to the public health or the interests of the permittee and does not threaten to impair public confidence in the permittee. In accordance with applicable departmental rules, the department shall notify the affiliated party whether the order suspending or prohibiting the person from participation in the affairs of a permittee will be rescinded or otherwise modified. The emergency order remains in effect, unless otherwise modified by the department, until the criminal charge is disposed of. The acquittal of the person charged, or the final, unappealed dismissal of all charges against the person, dissolves the emergency order, but does not prohibit the department from instituting proceedings under paragraph (a). If the person charged is convicted or pleads guilty or nolo contendere, whether or not an adjudication of guilt is entered by the court, the emergency order shall become final.

(g) Any affiliated party removed from office pursuant to this section is not eligible for reemployment by the permittee or reelection or appointment to the position, to any other official position in any licensee in this state

except upon the written consent of the department. Any affiliated party who is removed, restricted, or prohibited from participation in the affairs of a permittee pursuant to this section may petition the department for modification or termination of the removal, restriction, or prohibition.

(h) Resignation or termination of an affiliated party does not affect the department's jurisdiction to proceed under this subsection.

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 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 (9), subsection (10), subsection (14), subsection (15), ~~or~~ subsection (17), subsection (18), subsection (19), subsection (20), subsection (21), subsection (22), subsection (26), or subsection (27) of s. 499.005 is guilty of a felony of the second ~~third~~ degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in ss. 499.001-499.081.

(2) A person is not subject to the penalties of subsection (1) for having violated any of the provisions of s. 499.005 if he or she establishes a guaranty or undertaking, which guaranty or undertaking is signed by and contains the

name and address of the person residing in the state, or the manufacturer, from whom he or she received the article in good faith, to the effect that such article is not adulterated or misbranded within the meaning of ss. 499.001-499.081, citing such sections.

(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. This act shall take effect July 1, 2003.