By the Committee on Regulated Industries; and Senator Bean

580-02206-14 2014836c1

A bill to be entitled

An act relating to medical gas; creating part III of ch. 499, F.S., entitled "Medical Gas"; creating s. 499.81, F.S.; defining terms; creating s. 499.82, F.S.; requiring a person or establishment located inside or outside the state which intends to distribute medical gas within or into this state to obtain an applicable permit before operating; listing the people or entities that are legally authorized to receive medical gas; establishing categories of permits and setting requirements for each; creating s. 499.821, F.S.; requiring the Department of Business and Professional Regulation to establish the form and content of an application; stating that an applicant who is denied a permit has a right of review pursuant to ch. 120, F.S.; authorizing the department to set fees within certain parameters; creating s. 499.822, F.S.; requiring a permit to expire 2 years after the last day of the month in which the permit was issued; providing requirements for the renewal of a permit; requiring the department to adopt rules for the renewal of permits; creating s. 499.823, F.S.; authorizing the department to consider certain factors in determining the eligibility of an applicant; creating s. 499.824, F.S.; authorizing the department to approve certain permitholder changes; authorizing the department to revoke the permit of a person that fails to comply with this section; creating s. 499.83, F.S.; requiring an applicant for or a holder of a

permit as a wholesale distributor of medical gas or as a medical oxygen retailer to designate a registered agent; creating s. 499.84, F.S.; setting the minimum requirements for the storage and handling of medical gas; creating s. 499.85, F.S.; requiring a wholesale distributor of medical gas to implement measures to secure the location from unauthorized entry; setting facility requirements for security purposes; authorizing a vehicle used for on-call delivery of oxygen USP and oxygen-related equipment to be parked at a place of residence; requiring the department to adopt rules governing the wholesale distribution of prescription medical oxygen; creating s. 499.86, F.S.; requiring a wholesale distributor of medical gases to visually examine an immediate container upon receipt for identity and to determine if the medical gas container has been damaged or is otherwise unfit for distribution; requiring a medical gas container that is damaged or otherwise unfit for distribution to be quarantined; requiring outgoing shipments to be inspected; requiring wholesale distributors to review certain records; creating s. 499.87, F.S.; authorizing the return of medical gas that has left the control of the wholesale distributor; requiring that medical gas that is damaged, misbranded, or adulterated be quarantined from other medical gases until it is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired; creating s. 499.88, F.S.; requiring a wholesale distributor to

obtain certain information before the initial acquisition of the medical gas; providing certain exemptions; creating s. 499.89, F.S.; requiring a wholesale distributor to establish and maintain transactional records; providing a retention period for certain records and requiring that the records be available for inspection during that period; creating s. 499.90, F.S.; requiring a wholesale distributor to establish, maintain, and adhere to certain written policies and procedures; creating s. 499.91, F.S.; prohibiting certain acts; creating s. 499.92, F.S.; establishing criminal penalties; authorizing property or assets subject to forfeiture to be seized pursuant to a warrant; creating s. 499.93, F.S.; authorizing the department to require a facility that engages in wholesale distribution to undergo an inspection; authorizing the department to authorize a third party to inspect wholesale distributors; creating s. 499.931, F.S.; providing that trade secret information required to submitted pursuant to this part must be maintained by the department; creating s. 499.94, F.S.; requiring fees collected pursuant to this part to be deposited into the Professional Regulation Trust Fund; creating s. 499.95, F.S.; authorizing the department for the purpose of initiating an investigation or proceeding under this part to administer oaths, take depositions, issue and serve subpoenas, and compel attendance of witnesses and the production of books, papers, documents or other

evidence; requiring an attorney to whom the department reports a violation of this part to timely institute proceedings in the court of competent jurisdiction; exempting minor violations from reporting requirements at the department's discretion; providing that this part is cumulative and does not repeal or affect the power, duty, or authority of the department; amending ss. 409.9201, 460.403, and 465.0265; conforming provisions to changes made by the act; amending s. 499.001, F.S.; conforming a provision to changes made by the act; amending s. 499.003, F.S.; conforming terminology, deleting a definition, and defining the term "medical gas"; amending ss. 499.01 and 499.0121, F.S.; conforming provisions to changes made by the act; amending s. 499.01211, F.S.; changing the membership of the Drug Wholesale Distributor Advisory Council; requiring the Compressed Gas Association to appoint one person to the council; amending ss. 499.01212, 499.015, 499.024, 499.041, 499.05, 499.051, 499.066, 499.0661, and 499.067, F.S.; conforming provisions to changes made by the act; providing an effective date.

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

Section 1. Part III of chapter 499, Florida Statutes, consisting of ss. 499.81-499.95, Florida Statutes, is created and is entitled "Medical Gas."

Section 2. Section 499.81, Florida Statutes, is created to

read:

499.81 Definitions.—As used in this part, the term:

(1) "Adulterated" with respect to medical gas means medical gas that:

(a) Consists, in whole or in part, of impurities or deleterious substances that exceed normal specifications;

(b) Has been produced, prepared, packed, or held under conditions whereby the gas may have been contaminated, causing it to be rendered injurious to health; or was manufactured, processed, packed, or held using methods, facilities, or controls that do not conform to or are not operated or administered in conformity with current good manufacturing practices;

(c) Has a container interior that is composed, in whole or in part, of a poisonous or deleterious substance that may render the container contents injurious to health; or

(d) Has a strength that differs from, or that is of a quality or purity that fails to meet, the standards established in the USP-NF, if the gas is purported to be, or is represented as, medical gas as recognized in the USP-NF. Such a determination as to strength, quality, or purity must be made in accordance with the tests or methods of assay set forth in the USP-NF or a validated equivalent, or, in the absence or inadequacy of these tests or methods of assay, those prescribed under the authority of the federal act shall be used. However, a gas that is purported to be, or is represented as, medical gas as recognized in the USP-NF but that differs in strength, quality, or purity from the standards established in the USP-NF may not be deemed adulterated for purposes of this paragraph if

the difference is plainly stated on its label.

(2) "Department" means the Department of Business and Professional Regulation.

(3) "Distribute" or "distribution" means to sell or offer to sell, deliver or offer to deliver, broker, give away, or transfer medical gas, by passage of title or by physical movement. The term does not include:

(a) Dispensing or administering medical gas;

(b) Delivering or offering to deliver medical gas by a common carrier in its usual course of business; or

(c) A sales activity that takes place in an establishment that is owned or controlled by a person or business entity authorized to distribute medical gas within or into this state or staffed by persons employed by such person, if the location where the sales activity takes place does not physically store or transport medical gas.

(4) "Emergency use oxygen" means oxygen USP that is administered without a prescription for an emergency situation concerning oxygen deficiency or resuscitation and that is in a container labeled in accordance with FDA standards.

(5) "FDA" means the federal Food and Drug Administration.

(6) "Federal act" means the federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.

(7) "Health care entity" means a person, including an organization business entity, which provides diagnostic, medical, surgical, or dental treatment or rehabilitative care. The term includes a home respiratory care provider or a person or entity authorized to administer emergency use oxygen, but does not include a retail pharmacy or wholesale distributor.

(8) "Immediate container" means a compressed gas cylinder or liquid container that contains medical gas. The term does not include a large-bulk liquid or high pressure container, such as a storage tank, vehicle-mounted vessel, trailer, or railcar.

(9) "Intracompany transaction" means a transaction between divisions, subsidiaries, parents, or affiliated or related companies under the common ownership and control of a single corporate entity.

(10) "Label" means a display of a written, printed, or graphic matter upon an immediate container. The term does not include the letters, numbers, or symbols stamped onto a container as required by the United States Department of Transportation.

(11) "Manufacturer" means a person or entity that manufactures medical gas in bulk or that transfers the gas or liquefied gas product from one container to another.

(12) "Medical gas" is defined in accordance with the federal act and means a liquefied or vaporized gas that is a prescription drug, regardless of whether it is alone or combined with other gases.

(13) "Medical gas-related equipment" means a device used as an accessory or component part to contain or control flow, delivery, or pressure during the administration of medical gas, such as liquid-oxygen base and portable units, pressure regulators, flow meters, and oxygen concentrators.

(14) "Misbranded" means medical gas that has a label that is false or misleading or a label that does not:

(a) Display the name and address of the manufacturer, packer, or distributor;

(b) Provide an accurate statement of the quantity of active ingredients or show an accurate monograph for the medical gas; or

(c) In the case of mixtures of designated medical gases, identify the component percentages of each designated medical gas used to make the mixture.

(15) "Prescription medical oxygen" means oxygen USP, a drug that may be sold only by the order or prescription of a licensed practitioner authorized by law to prescribe.

(16) "USP-NF" or "USP" means the standards published in the official book, "The United States Pharmacopeia and the National Formulary."

(17) "Wholesale distribution" means the distribution of medical gas by a wholesale distributor of medical gas to a person other than a consumer or patient. The term does not include:

(a) The sale, purchase, or trade of a medical gas, an offer to sell, purchase, or trade a prescription drug or device, or the dispensing of medical gas pursuant to a prescription;

(b) The sale, purchase, or trade of a medical gas or an offer to sell, purchase, or trade medical gas for an emergency medical reason that includes, but is not limited to:

1. A transfer of a medical gas between wholesale distributors or between a wholesale distributor and a retail pharmacy or health care entity to alleviate a temporary shortage of medical gas resulting from a delay in or an interruption of a regular distribution schedule;

2. Sales to a licensed emergency medical service provider, such as an ambulance company, a firefighting organization, or a

licensed practitioner authorized to prescribe medical gases;

3. Provision of minimal emergency supplies of medical gas to a nursing home for use in an emergency or during the hours of the day when necessary medical gas cannot be obtained; or

4. Transfers of medical gases to alleviate a temporary shortage between retail pharmacies;

(c) An intracompany transaction;

(d) The sale, purchase, or trade of medical gas or an offer to sell, purchase, or trade medical gas among hospitals, pharmacies, or other health care entities that are under common control;

(e) The sale, purchase, or trade of medical gas, or the offer to sell, purchase, or trade medical gas by a charitable organization that has been granted an exemption under s. 501(c)(3) of the Internal Revenue Code to a nonprofit affiliate of the organization, to the extent otherwise permitted by law;

(f) The purchase or other acquisition of medical gas by a hospital or other similar health care entity that is a member of a group purchasing organization, for the hospital's or the health care entity's own use, from the group purchasing organization or from another hospital or similar health care entity that is a member of such organization;

(g) The return of residual medical gas that may be reprocessed in accordance with the manufacturer's procedures or the return of recalled, expired, damaged, or otherwise nonsalable medical gas, when returned by a hospital, health care entity, pharmacy, or charitable institution to a wholesale distributor;

(h) An activity that is exempt from the definition of the

term "wholesale distribution" as provided in s. 499.003; or

(i) A transaction that is excluded from the definition of the term "wholesale distribution" under the federal act or regulations implemented under the federal act related to medical gas.

(18) "Wholesale distributor" means a person or entity engaged in the wholesale distribution of medical gas within or into this state, including, but not limited to, a manufacturer, an own-label distributor, a private-label distributor, a warehouse, including a manufacturers' and distributors' warehouse, and a wholesale medical gas warehouse.

Section 3. Section 499.82, Florida Statutes, is created to read:

499.82 Permits.—

(1) A person or establishment, located inside or outside the state, which intends to distribute medical gas within or into this state must obtain the applicable permit before operating.

(2) All of the following are legally authorized to receive medical gas: permitted medical gas manufacturers or permitted wholesale distributors, licensed pharmacies or health care entities, people authorized to receive emergency use oxygen without a prescription, locations with automated external defibrillation machines where emergency use oxygen is intended to be used with such machines, or companies that need medical gas in the installation and refurbishment of piping and equipment used to contain or administer medical gas.

(3) An applicant who is a natural person must be at least 18 years of age or an applicant must be managed, controlled, or

overseen, directly or indirectly, by a natural person who is at least 18 years of age.

(4) An out-of-state wholesale distributor that provides services in this state must be legally authorized as a wholesale distributor in the state in which it resides or is incorporated.

(5) A wholesale distributor may not operate from a place of residence, and a place of residence may not be granted a permit or operate under this part, except for the on-call delivery of home care oxygen by a home respiratory care technician.

(6) If wholesale distribution is conducted at more than one location within this state or more than one location distributing into this state, each location must be permitted by the department.

(7) The following permits are established:

(a) Medical gas wholesale distributor permit.—A medical gas wholesale distributor permit is required for wholesale distribution within or into this state.

1. Such permit does not authorize distribution to a consumer or patient.

2. The medical gas must be in the container that was obtained by that wholesale distributor without further manufacturing operations being performed.

3. A wholesale distributor may not possess or engage in the wholesale distribution of any prescription drug other than medical gas.

(b) Medical gas manufacturer permit.—A medical gas manufacturer permit is required for a person who engages in the manufacture of medical gas by physical air separation, chemical action, purification, or filling containers using a liquid-to-

liquid, liquid-to-gas, or gas-to-gas process and distributes such medical gas within or into this state. A medical gas manufacturer:

1. May not manufacture or possess a prescription drug other than medical gas unless the appropriate permit is obtained.

2. May engage in the wholesale distribution of medical gas that is manufactured at the permitted establishment without obtaining a medical gas wholesale distributor permit, but shall comply with this part and applicable rules.

3. Shall comply with all appropriate state and federal good manufacturing practices.

(c) Medical oxygen retail establishment permit.—A medical oxygen retail establishment permit is required for a person who sells prescription medical oxygen directly to patients. Such sales must be based upon an order or prescription from a licensed practitioner authorized by law to prescribe. A pharmacy licensed under chapter 465 is exempt from this paragraph. A medical oxygen retail establishment:

1. May not possess, purchase, sell, or trade a prescription drug other than medical oxygen unless other appropriate permits are obtained.

2. May refill a prescription medical oxygen container for a patient based on an order or prescription from a licensed practitioner authorized by law to prescribe. A medical oxygen retail establishment that refills prescription medical oxygen shall comply with all appropriate state and federal good manufacturing practices.

3. Shall comply with the storage and handling requirements under s. 499.84.

4. May not receive back into its inventory any prescription medical oxygen that it sold pursuant to a licensed practitioner's order.

Section 4. Section 499.821, Florida Statutes, is created to read:

499.821 Permit application.—

(1) The department shall establish by rule the form and content of an application to obtain a permit listed under s. 499.82.

(a) An application for a permit must be filed with the department and must include the following information:

1. The trade or business names, including fictitious names, currently and formerly used by the applicant, which may not be identical to a name used by an unrelated wholesale distributor authorized in this state to purchase medical gas.

2. The name or names of the owner and operator of the permittee, if not the same person or entity. The application must also include the following if the applicant is:

a. An individual: the applicant's business address and date of birth.

b. A sole proprietorship: the business address of the sole proprietor and the name and federal employer identification number of the business entity.

c. A partnership: the business address and date of birth of each partner and the name and federal employer identification number of the partnership.

d. A limited liability company: the business address and title of each company officer, the name and federal employer identification number of the limited liability company, and the

state of incorporation.

e. A corporation: the business address and title of each corporate officer and director; the name, state of incorporation, and federal employer identification number of the corporation; and the name and business address of any parent company.

3. A list of disciplinary actions pertinent to wholesale distributors of prescription drugs or controlled substances by a state or federal agency against the applicant seeking to distribute into this state and against a principal, owner, director, or officer.

4. An address and description of each facility or warehouse, including a description of the security system for any location used for medical gas storage or wholesale distribution.

(b) The applicant shall attest in writing that the information contained in the application is complete and accurate, that the applicant has not been convicted of or disciplined for a criminal or prohibited act, and that the application contains complete disclosure of any past criminal convictions or violations of state or federal law relating to medical gases.

(2) An applicant that is denied a permit has the right to review of the department's decision pursuant to chapter 120.

(3) An applicant must submit a reasonable fee, to be determined by the department, in order to obtain a permit. The fee for a medical gas wholesale distributor permit may not be less than $200 or more than $300 annually. The fee for a medical gas manufacturer permit may not be less than $400 or more than

$500 annually. The fee for a medical oxygen retail establishment permit may not be less than $200 or more than $300 annually.

Section 5. Section 499.822, Florida Statutes, is created to read:

499.822 Expiration and renewal of a permit.—

(1) A permit issued under this part automatically expires 2 years after the last day of the month in which the permit was originally issued unless the permit is suspended or revoked before the automatic expiration date.

(2) A permit issued under this part may be renewed by submitting an application for renewal on a form furnished by the department and paying the appropriate fee. The application for renewal must contain a statement by the applicant attesting that the information is true and correct. If a renewal application and renewal fee are submitted and postmarked after the expiration date of the permit, the permit may be renewed only upon payment of a late renewal delinquent fee of $100, plus the required renewal fee, within 60 days after the expiration date.

(3) Failure to renew a permit in accordance with this section precludes future renewal. If a permit has expired and cannot be renewed, the person or establishment must submit an application for a new permit, pay the applicable application fee, the initial permit fee, and all applicable penalties, and be issued a new permit by the department before engaging in an activity that requires a permit under this part.

(4) The department shall adopt rules to administer this section, including setting a reasonable fee for a renewal application.

Section 6. Section 499.823, Florida Statutes, is created to

read:

499.823 Minimum qualifications.—The department may deny an application for a permit or refuse to renew a permit based upon:

(1) Whether the applicant has violated, or has been disciplined by a regulatory agency in any state for violating, a federal, state, or local law relating to wholesale distribution;

(2) The applicant's criminal convictions;

(3) The applicant's past experience in manufacturing or distributing medical gas;

(4) Any false or fraudulent material contained in an application;

(5) Suspension, sanction, or revocation of a permit currently or previously held by the applicant for violations of a state or federal law relating to medical gas;

(6) Compliance with previously granted permit requirements;

(7) Compliance with the requirements to maintain or make available to the department or permitting authority or to a federal, state, or local law enforcement official records required to be maintained by a wholesale distributor; and

(8) Any other factors or qualifications that the department considers relevant to and consistent with public health and safety.

Section 7. Section 499.824, Florida Statutes, is created to read:

499.824 Permitholder changes.—

(1) A permit issued by the department is valid only for the person or entity to which it is issued and is not subject to sale, assignment, or other transfer, voluntarily or involuntarily, and is not valid for an establishment other than

the establishment for which it was originally issued, except as provided in this part. The department may approve the following changes, and a person or entity may continue to operate in the following manner:

(a) *Change of location.*—A person or entity permitted under this part must notify the department 30 days before changing location. The department shall set a change-of-location fee not to exceed $100.

(b) *Change in ownership.*—If a majority of the ownership or controlling interest of a permitted establishment is transferred or assigned or if a lessee agrees to undertake or provide services such that legal liability for operation of the establishment will rest with the lessee, an application for a new permit is required. The application for the new permit must be submitted 30 days before the change of ownership. However, if an applicant is a permitholder or is wholly owned by or wholly owns a permitholder under this part, the application for the new permit must be made by the date of the sale, transfer, assignment, or lease. Between the date of the change of ownership and the date of the application approval or denial by the department, an applicant may distribute under the permit number of the previous owner.

(c) *Change of name.*—A permitholder may change its name without submitting a new permit application. However, the permitholder must notify the department 30 days before changing its name. The permitholder may continue to operate the establishment while the notification is being processed.

(d) *Closure.*—If an establishment permitted under this part closes, the owner must notify the department, in writing, before

the effective date of the closure and must:

1. Return the permit to the department; and

2. If the permittee is authorized to distribute medical gas, indicate the disposition of such medical gas, including the name, address, and inventory, and provide the name and address of a person to contact regarding access to the records that are required to be maintained under this part. Transfer of ownership of medical gas may be made only to persons authorized to receive medical gas pursuant to this part.

(e) *Change in information.*—Any change in information required under this part, other than a change of information as set forth in paragraphs (a)-(d), must be submitted to the department within 30 days after such change.

(2) Notwithstanding paragraph (1)(a), a permitholder in good standing may change the type of permit issued by completing a new application for the requested permit, paying the amount of the difference in the permit fees, and meeting the applicable permitting requirements for the new permit type. A refund may not be issued if the fee for the new permit is less than the fee that was paid for the original permit. The new permit expires on the expiration date of the original permit being changed.

(3) The department may revoke a permit for failure to comply with this section.

Section 8. Section 499.83 Florida Statutes, is created to read:

499.83 Registered agent.—An applicant for or a holder of a permit as a medical gas wholesale distributor or as a medical oxygen retail establishment shall designate a registered agent in this state for purposes of service of process. If an

applicant or a permitted wholesale distributor or medical oxygen retailer fails to designate a registered agent, the Secretary of State shall be deemed the true and lawful attorney of the applicant or the permitted wholesale distributor or medical oxygen retailer, and, in such case, the legal processes in any action or proceeding against an applicant or permitted wholesale distributor or medical oxygen retailer which grows out of or arising from wholesale distribution or retail may be served upon the Secretary of State. A copy of the service of process shall be mailed to the applicant or the permitted wholesale distributor or medical oxygen retailer by the department by certified mail, return receipt requested, postage prepaid, at the address of the applicant or the distributor or retailer as designated on the application for a permit in this state.

Section 9. Section 499.84, Florida Statutes, is created to read:

499.84 Minimum requirements for the storage and handling of medical gas.—

(1) A facility that receives, stores, warehouses, handles, holds, offers, markets, displays, or transports medical gas must avoid any negative effect on the identity, strength, quality, or purity of medical gas by:

(a) Being constructed in a way that ensures that medical gas is maintained in accordance with its product labeling recommendations or in compliance with official compendium standards, such as the USP-NF;

(b) Being of a suitable size and construction that facilitates cleaning, maintenance, and proper wholesale distribution;

(c) Having an adequate storage area with appropriate lighting, ventilation, space, equipment, and security conditions;

(d) Having a quarantine area for the storage of medical gas that is suspected of being misbranded, adulterated, or otherwise unfit for distribution;

(e) Being maintained in an orderly condition;

(f) Being in a commercial location, except if a personal dwelling location is used for the on-call delivery of oxygen USP for home care use and the person providing on-call delivery is employed by or acting under a written contract with a permittee;

(g) Providing for the secure storage of patient information, if applicable, by restricting access and implementing policies and procedures that protect the integrity and confidentiality of patient information; and

(h) Providing and maintaining appropriate inventory controls in order to detect and document any theft of nitrous oxide.

(2) Medical gas must be stored under appropriate conditions in accordance with the manufacturers' recommendations on product labeling and department rules or, in the absence of rules, in accordance with applicable industry standards. Medical gas must be packaged in accordance with official compendium standards, such as the USP-NF.

Section 10. Section 499.85, Florida Statutes, is created to read:

499.85 Security.—

(1) A facility that engages in wholesale distribution shall implement measures to secure its facility from unauthorized

entry. Such measures must include the following:

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

(b) The outside perimeter of the premises must be well-lighted.

(c) Areas in which medical gas is held must be restricted by a fence or other system that detects or deters entry after hours and limits access only to authorized personnel.

(2) A facility that engages in wholesale distribution must have:

(a) A security system that provides protection against theft and, if appropriate, theft that is enabled or obscured by tampering with computers or electronic records.

(b) A security system that protects the integrity and confidentiality of data and documents.

(3) If a wholesale distributor uses electronic distribution records, he or she must employ, train, and document the training of personnel for the proper use of the applicable technology and equipment.

(4) A vehicle used for on-call delivery of oxygen USP and oxygen-related equipment for home care use by a home care provider may be parked at a place of residence. Such vehicle while unattended must be locked and equipped with an audible alarm.

(5) The department shall adopt rules that govern the wholesale distribution of prescription medical oxygen for emergency use by persons authorized to receive emergency use oxygen. Unless the laws of this state specifically direct otherwise, such rules must be consistent with federal rules and

regulations, including the labeling requirements of oxygen under the federal act.

Section 11. Section 499.86, Florida Statutes, is created to read:

499.86 Examination of materials.—

(1) A wholesale distributor must visually examine an immediate container upon receipt from the manufacturer in order to identify the medical gas and to determine if the container has been damaged or is otherwise unfit for wholesale distribution. Such examination must occur in a manner that would reveal damage to the container which could suggest possible adulteration or misbranding.

(2) A medical gas container that is damaged or otherwise unfit pursuant to subsection (1) must be quarantined from the rest of the stock of medical gas until it is determined that the medical gas in question was not misbranded or adulterated.

(3) An outgoing shipment must be inspected for identity and to ensure that medical gas containers that have been damaged in storage or held under improper conditions are not delivered.

(4) A wholesale distributor must review records documenting the acquisition of medical gas upon receipt for accuracy and completeness.

Section 12. Section 499.87, Florida Statutes, is created to read:

499.87 Returned, damaged, and outdated medical gas.—

(1) Medical gas that has left the control of a wholesale distributor may be returned to the manufacturer or wholesale distributor from which it was acquired.

(2) Unless medical gas is reprocessed by a manufacturer

employing proper and adequate controls to ensure the identity, strength, quality, and purity of the reprocessed medical gas, the gas may not be resold as a medical gas even if its integrity was maintained.

(3) Medical gas that has been subjected to improper conditions, such as a fire, accident, or natural disaster, may not be salvaged or reprocessed.

(4) Medical gas, including its container, which is damaged, misbranded, or adulterated must be quarantined from other medical gases until it is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired. External contamination to a medical gas container or closure system which does not impact the integrity of the medical gas is not considered damage or adulteration for purposes of this subsection. If medical gas is adulterated or misbranded or suspected of being adulterated or misbranded, notice shall be provided to the manufacturer or wholesale distributor from which the medical gas was acquired and to the appropriate boards and federal regulatory bodies.

(5) A medical gas container that has been opened or used but is not adulterated or misbranded is considered empty and must be quarantined from nonempty medical gas containers and returned to the manufacturer or wholesale distributor from which it was acquired for destruction or reprocessing.

(6) Medical gas, its container, or its associated documentation or labeling that is suspected of being used in criminal activity must be retained until its disposition is authorized by the department or an applicable law enforcement agency.

Section 13. Section 499.88, Florida Statutes, is created to read:

499.88 Due diligence.—

(1) A wholesale distributor shall obtain, before the initial acquisition of medical gas, the following information from the supplying wholesale distributor or manufacturer:

(a) If a manufacturer is distributing to a wholesale distributor, evidence that the manufacturer is registered and the medical gas is listed with the FDA;

(b) If a wholesale distributor is distributing to a wholesale distributor, evidence that the wholesale distributor supplying the medical gas is permitted to distribute medical gas within or into the state;

(c) The name of the contact person for the supplying manufacturer or wholesale distributor; and

(d) Certification that the manufacturer’s or wholesale distributor’s policies and procedures comply with this part.

(2) A wholesale distributor is exempt from obtaining the information from a manufacturer as required under subsection (1) if the manufacturer is registered with the FDA in accordance with s. 510 of the federal act and provides:

(a) Proof of such registration; and

(b) Proof of inspection within the past 3 years by the FDA or other regulatory body or proof of conformance with industry standards or guidelines as identified by the department.

(3) A manufacturer or wholesale distributor that distributes to or acquires medical gas from another wholesale distributor shall provide to or obtain from the distributing or acquiring manufacturer or distributor the information required

by s. 499.89(1), as applicable.

Section 14. Section 499.89, Florida Statutes, is created to read:

499.89 Recordkeeping.—

(1) A wholesale distributor shall establish and maintain a record of transactions regarding the receipt and the distribution, or other disposition, of medical gases. Such records constitute an audit trail and must contain information sufficient to perform a recall of medical gas in compliance with 21 C.F.R. s. 211.196 and 21 C.F.R. s. 820.160(b). Such records must include all the following information, which need not appear in the same document:

(a) The dates of receipt and wholesale distribution, or other disposition, of the medical gas.

(b) The name, address, permit number, and permit expiration date for the entity purchasing the medical gas from the wholesale distributor.

(c) The name, address, permit number, and permit expiration date for the entity receiving the medical gas from the wholesale distributor, if different from the information required under paragraph (b).

(d) Information sufficient to perform a recall of all medical gas received or distributed.

(2) From the time of their creation, such records shall be kept for 3 years for high pressure medical gas and for 1 year for cryogenic or refrigerated liquid medical gas.

(3) During the retention period, such records shall be made available for inspection and photocopying by an authorized official of a state, federal, or local governmental agency. If

such records are kept at the inspection site or could be immediately retrieved by electronic means, they shall be made readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within 2 business days of a request.

(4) A pedigree paper is not required for the wholesale distribution of medical gas.

Section 15. Section 499.90, Florida Statutes, is created to read:

499.90 Policies and procedures.—A wholesale distributor shall establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, transport, shipping, and wholesale distribution of medical gas and shall establish, maintain, and adhere to procedures for maintaining inventories; for identifying, recording, and reporting losses or thefts; and for correcting all errors and inaccuracies in inventories associated with nitrous oxide. A wholesale distributor shall include in its written policies and procedures the following:

(1) A procedure for handling recalls and withdrawals of medical gas. Such procedure must deal with recalls and withdrawals due to:

(a) Action initiated at the request of the FDA or any federal, state, or local law enforcement or other government agency, including the department; or

(b) Voluntary action by the manufacturer of medical gas to remove defective or potentially defective medical gases from the market.

(2) A procedure preparing for, protecting against, and handling a crisis that affects the security or operation of a facility in the event of a strike, fire, flood, or other natural disaster or other situations of local, state, or national emergency.

(3) A procedure for reporting criminal or suspected criminal activity involving the inventory of nitrous oxide to the department and to applicable law enforcement agencies within 3 business days after becoming aware of the criminal or suspected criminal activity.

Section 16. Section 499.91, Florida Statutes, is created to read:

499.91 Prohibited acts.—A person may not perform or cause the performance of, or aid and abet in, any of the following acts in this state:

(1) The manufacture, sale, or delivery, or the holding or offering for sale, of medical gas that is adulterated, misbranded, or has otherwise been rendered unfit for distribution.

(2) The adulteration or misbranding of medical gas.

(3) The receipt of medical gas that is adulterated, misbranded, stolen, or obtained by fraud or deceit or the delivery or proffered delivery of such medical gas for pay or otherwise.

(4) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the product labeling of medical gas or the willful commission of any other act with respect to medical gas that results in it being misbranded.

(5) The purchase or receipt of medical gas from a person

who is not authorized by permit to distribute wholesale medical gas or who is exempted from permitting requirements to distribute wholesale medical gas to such purchaser or recipient.

(6) The knowing and willful sale or transfer of medical gas to a recipient who is not legally authorized to receive medical gas, except that a violation does not exist as to a distributor that provides oxygen to a permitted medical oxygen retail establishment if the distributor is out of compliance with only the change of location notice requirement under s. 499.824.

(7) The failure to maintain or provide records required under this part and its implementing regulations.

(8) Providing the department or any of its representatives or any state or federal official with false or fraudulent records or making false or fraudulent statements regarding this part and its implementing regulations.

(9) The wholesale distribution of medical gas that was:

(a) Purchased by a public or private hospital or other health care entity, except for the physical distribution of such medical gas to an authorized recipient at the direction of a hospital or other health care entity;

(b) Donated or supplied at a reduced price to a charitable organization; or

(c) Stolen or obtained by fraud or deceit.

(10) The failure to obtain a permit or operating without a valid permit when a permit is required.

(11) The obtaining of or attempt to obtain medical gas by fraud, deceit, or misrepresentation or engaging in misrepresentation or fraud in the distribution of medical gas.

(12) Except for oxygen USP in emergency situations, the

distribution of medical gas to a patient without an order or prescription from a licensed practitioner authorized by law to prescribe.

(13) The distribution of medical gas that was previously dispensed by a pharmacy or a licensed practitioner authorized by law to prescribe.

(14) The distribution of medical gas or medical gas-related equipment to a patient, unless the patient has been provided with the appropriate information and counseling on the use, storage, and disposal of medical gas.

(15) The failure to report an act prohibited under this part and its implementing regulations.

(16) The failure to exercise due diligence as provided in s. 499.88.

Section 17. Section 499.92, Florida Statutes, is created to read:

499.92 Criminal acts.—

(1) A person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if he or she:

(a) With intent to defraud or deceive adulterates or misbrands medical gas.

(b) Engages in the wholesale distribution of, and knowingly purchases or receives, medical gas from a person not legally authorized to distribute medical gas.

(c) Engages in the wholesale distribution of, and knowingly sells, barters, brokers, or transfers, medical gas to a person not legally authorized to purchase medical gas in the jurisdiction in which the person receives the medical gas,

except that a violation does not exist as to a distributor that provides oxygen to a permitted medical oxygen retail establishment if the distributor is out of compliance with only the change of location notice requirement under s. 499.824.

(d) Knowingly, falsely creates a label for medical gas or knowingly, falsely represents a factual matter contained in a label for medical gas.

(2) A court that has authority over a person who violates this section and that convicts such person shall order him or her to forfeit to the state real or personal property or assets:

(a) Used or intended to be used to commit, facilitate, or promote the commission of such violation; and

(b) Constituting, derived from, or traceable to the gross proceeds that the defendant obtained as a result of the violation.

(3) Property or assets subject to forfeiture under subsection (2) may be seized pursuant to a warrant obtained in the same manner as a search warrant or as otherwise authorized by law and held until the case against the defendant is adjudicated. Moneys ordered to be forfeited or proceeds from the sale of assets ordered to be forfeited shall be equitably divided between the department and agencies involved in the investigation and prosecution that led to the conviction. Other property ordered to be forfeited after conviction of a defendant may, at the discretion of the investigating agencies, be placed into official use by the department or the agencies involved in the investigation and prosecution.

Section 18. Section 499.93, Florida Statutes, is created to read:

499.93 Inspections.—

(1) The department may require a facility that engages in the manufacture, retail sale, or wholesale distribution of medical gas to undergo an inspection in accordance with a schedule to be determined by the department.

(2) The department may recognize other state inspections of a manufacturer or wholesale distributor in another state if such state's laws are deemed to be substantially equivalent to the laws of this state.

(3) A manufacturing facility is exempt from inspection by the department if the facility:

(a) Is currently registered with the FDA in accordance with s. 510 of the federal act and can provide proof of such registration, such as a copy of the online verification page; and

(b) Can provide proof of inspection within the past 3 years by the FDA or, if the facility is located in another state, by another governmental entity charged with regulation of good manufacturing practices related to medical gas.

(4) A wholesale distributor must exhibit or have readily available its state permits and its most recent inspection report administered by the department. The department may authorize a third party to inspect wholesale distributors who distribute within or into this state.

Section 19. Section 499.931, Florida Statutes, is created to read:

499.931 Trade secret information.—Information required to be submitted under this part which is a trade secret as defined in s. 812.081(1)(c) and designated as a trade secret by an

applicant or permit holder must be maintained as required under s. 499.051.

Section 20. Section 499.94, Florida Statutes, is created to read:

499.94 Fees.—A fee collected for a permit under this part shall be deposited into the Professional Regulation Trust Fund. Moneys collected under this part shall be used for administering this part. The department shall maintain a separate account in the trust fund for the Drugs, Devices, and Cosmetics program.

Section 21. Section 499.95, Florida Statues, is created to read:

499.95 Enforcement and construction of this part.—

(1) For the purpose of initiating an investigation or proceeding under this part, the department may administer oaths, take depositions, issue and serve subpoenas, and compel the attendance of witnesses and the production of books, papers, documents, or other evidence. Challenges to, and enforcement of, a subpoena and an order shall be conducted in accordance with s. 120.569.

(2) A state, county, or municipal attorney to whom the department or its designated agent reports a violation of this part shall timely institute proceedings in the court of competent jurisdiction and shall prosecute in the manner required by law.

(3) The department is not required to report minor violations to a state, county, or municipal attorney if the department determines that the public interest is best served by issuance of a written notice or warning to the violator.

(4) This part is cumulative and does not repeal or affect

the power, duty, or authority of the department. However, relating to the regulation of medical gas, if this part conflicts with other law, this part controls.

Section 22. Section 499.001, Florida Statutes, is amended to read:

499.001 Florida Drug and Cosmetic Act; short title.—Sections 499.001-499.95 ~~499.001-499.081~~ may be cited as the "Florida Drug and Cosmetic Act."

Section 23. Present subsections (11) through (32) and (46) through (55) of section 499.003, Florida Statutes, are amended, and a new subsection (32) is added to that section, to read:

499.003 Definitions of terms used in this part.—As used in this part, the term:

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

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

(12)~~(13)~~ "Cosmetic" means an article, with the exception of soap, that is:

(a) Intended to be rubbed, poured, sprinkled, or sprayed on; introduced into; or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance; or

(b) Intended for use as a component of any such article.

(13)~~(14)~~ "Counterfeit drug," "counterfeit device," or "counterfeit cosmetic" means a drug, device, or cosmetic which, or the container, seal, or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug, device, or cosmetic manufacturer, processor, packer, or distributor other than the person that in fact manufactured, processed, packed, or distributed that drug, device, or cosmetic and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, that other drug, device, or cosmetic manufacturer, processor, packer, or distributor.

(14)~~(15)~~ "Department" means the Department of Business and Professional Regulation.

(15)~~(16)~~ "Device" means any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including its components, parts, or accessories, which is:

(a) Recognized in the current edition of the United States Pharmacopoeia and National Formulary, or any supplement thereof;~~,~~

(b) Intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals;~~,~~ or

(c) Intended to affect the structure or any function of the body of humans or other animals,

and that does not achieve any of its principal intended purposes

through chemical action within or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

(16)~~(17)~~ "Distribute" or "distribution" means to sell; offer to sell; give away; transfer, whether by passage of title, physical movement, or both; deliver; or offer to deliver. The term does not mean to administer or dispense and does not include the billing and invoicing activities that commonly follow a wholesale distribution transaction.

(17)~~(18)~~ "Drop shipment" means the sale of a prescription drug from a manufacturer to a wholesale distributor, where the wholesale distributor takes title to, but not possession of, the prescription drug, and the manufacturer of the prescription drug ships the prescription drug directly to a chain pharmacy warehouse or a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug, as defined in s. 465.003.

(18)~~(19)~~ "Drug" means an article that is:

(a) Recognized in the current edition of the United States Pharmacopoeia and National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of those publications;

(b) Intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals;

(c) Intended to affect the structure or any function of the body of humans or other animals; or

(d) Intended for use as a component of any article specified in paragraph (a), paragraph (b), or paragraph (c), and

includes active pharmaceutical ingredients, but does not include devices or their nondrug components, parts, or accessories. For purposes of this paragraph, an "active pharmaceutical ingredient" includes any substance or mixture of substances intended, represented, or labeled for use in drug manufacturing that furnishes or is intended to furnish, in a finished dosage form, any pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or to affect the structure or any function of the body of humans or other animals.

(19) ~~(20)~~ "Establishment" means a place of business which is at one general physical location and may extend to one or more contiguous suites, units, floors, or buildings operated and controlled exclusively by entities under common operation and control. Where multiple buildings are under common exclusive ownership, operation, and control, an intervening thoroughfare does not affect the contiguous nature of the buildings. For purposes of permitting, each suite, unit, floor, or building must be identified in the most recent permit application.

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

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

(22) ~~(23)~~ "Health care entity" means a closed pharmacy or any person, organization, or business entity that provides diagnostic, medical, surgical, or dental treatment or care, or

chronic or rehabilitative care, but does not include any wholesale distributor or retail pharmacy licensed under state law to deal in prescription drugs. However, a blood establishment is a health care entity that may engage in the wholesale distribution of prescription drugs under s. 499.01(2)(g)1.c.

(23)~~(24)~~ "Health care facility" means a health care facility licensed under chapter 395.

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

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

(26)~~(27)~~ "Immediate container" does not include package liners.

(27)~~(28)~~ "Label" means a display of written, printed, or graphic matter upon the immediate container of any drug, device, or cosmetic. A requirement made by or under authority of this part or rules adopted under this part that any word, statement, or other information appear on the label is not complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such drug, device, or cosmetic or is easily legible through the outside container or wrapper.

(28)~~(29)~~ "Labeling" means all labels and other written, printed, or graphic matters:

(a) Upon a drug, device, or cosmetic, or any of its containers or wrappers; or

(b) Accompanying or related to such drug, device, or cosmetic.

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

(30)~~(31)~~ "Manufacturer" means:

(a) A person who prepares, derives, manufactures, or produces a drug, device, or cosmetic;

(b) The holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), a Biologics License Application (BLA), or a New Animal Drug Application (NADA), provided such application has become effective or is otherwise approved consistent with s. 499.023;

(c) A private label distributor for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged;

(d) A person registered under the federal act as a manufacturer of a prescription drug, who is described in paragraph (a), paragraph (b), or paragraph (c), who has entered into a written agreement with another prescription drug manufacturer that authorizes either manufacturer to distribute the prescription drug identified in the agreement as the manufacturer of that drug consistent with the federal act and its implementing regulations;

(e) A member of an affiliated group that includes, but is not limited to, persons described in paragraph (a), paragraph (b), paragraph (c), or paragraph (d), which member distributes prescription drugs, whether or not obtaining title to the drugs, only for the manufacturer of the drugs who is also a member of the affiliated group. As used in this paragraph, the term "affiliated group" means an affiliated group as defined in s.

1504 of the Internal Revenue Code of 1986, as amended. The manufacturer must disclose the names of all of its affiliated group members to the department; or

(f) A person permitted as a third party logistics provider, only while providing warehousing, distribution, or other logistics services on behalf of a person described in paragraph (a), paragraph (b), paragraph (c), paragraph (d), or paragraph (e).

The term does not include a pharmacy that is operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.

(31) ~~(32)~~ "Medical convenience kit" means packages or units that contain combination products as defined in 21 C.F.R. s. 3.2(e)(2).

(32) "Medical gas" is defined in accordance with the federal act and means a liquefied or vaporized gas that is a prescription drug, regardless of whether it is alone or combined with other gases.

~~(46) "Prescription medical oxygen" means oxygen USP which is a drug that can only be sold on the order or prescription of a practitioner authorized by law to prescribe. The label of prescription medical oxygen must comply with current labeling requirements for oxygen under the Federal Food, Drug, and Cosmetic Act.~~

~~(47)~~ "Primary wholesale distributor" means any wholesale distributor that:

(a) Purchased 90 percent or more of the total dollar volume of its purchases of prescription drugs directly from

manufacturers in the previous year; and

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

2. Has, or the affiliated group, as defined in s. 1504 of the Internal Revenue Code, of which the wholesale distributor is a member has, not fewer than 250 employees.

(c) For purposes of this subsection, "directly from manufacturers" means:

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

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

a. The affiliated group purchases 90 percent or more of the total dollar volume of its purchases of prescription drugs from the manufacturer in the previous year; and

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

(47) ~~(48)~~ "Proprietary drug," or "OTC drug," means a patent or over-the-counter drug in its unbroken, original package, which drug is sold to the public by, or under the authority of, the manufacturer or primary distributor thereof, is not misbranded under the provisions of this part, and can be

purchased without a prescription.

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

(49)~~(50)~~ "Repackager" means a person who repackages. The term excludes pharmacies that are operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.

(50)~~(51)~~ "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.

(51)~~(52)~~ "Secondary wholesale distributor" means a wholesale distributor that is not a primary wholesale distributor.

(52)~~(53)~~ "Veterinary prescription drug" means a prescription drug intended solely for veterinary use. The label of the drug must bear the statement, "Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian."

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

(a) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with s. 499.01(2)(g):

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

group purchasing organization or from other hospitals or health care entities that are members of that organization.

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

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

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

a. The agency or entity must obtain written authorization for the sale, purchase, trade, or other transfer of a prescription drug under this subparagraph from the Secretary of Business and Professional Regulation or his or her designee.

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

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

d. 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.

e. 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-subparagraph d.

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

subparagraph shall be subject to audit by the manufacturer of those drugs, without identifying individual patient information.

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

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

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

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

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

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

6. The transfer of a prescription drug by a person authorized to purchase or receive prescription drugs to a person

licensed or permitted to handle reverse distributions or destruction under the laws of the jurisdiction in which the person handling the reverse distribution or destruction receives the drug.

7. The transfer of a prescription drug by a hospital or other health care entity to a person licensed under this part to repackage prescription drugs for the purpose of repackaging the prescription drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the prescription drugs remains with the hospital or other health care entity at all times. In addition to the recordkeeping requirements of s. 499.0121(6), the hospital or health care entity that transfers prescription drugs pursuant to this subparagraph must reconcile all drugs transferred and returned and resolve any discrepancies in a timely manner.

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

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

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

(f) The sale, purchase, or trade of a prescription drug between pharmacies as a result of a sale, transfer, merger, or

consolidation of all or part of the business of the pharmacies from or with another pharmacy, whether accomplished as a purchase and sale of stock or of business assets.

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

Section 24. Paragraph (a) of subsection (1) of section 409.9201, Florida Statutes, is amended to read:

409.9201 Medicaid fraud.—

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

(a) "Prescription drug" means any drug, including, but not limited to, finished dosage forms or active ingredients that are subject to, defined in ~~by~~, or described in ~~by~~ s. 503(b) of the Federal Food, Drug, and Cosmetic Act or in ~~by~~ s. 465.003(8), s. 499.003(52), ~~s. 499.003(46) or (53) or~~ s. 499.007(13), or s. 499.81(15).

The value of individual items of the legend drugs or goods or services involved in distinct transactions committed during a single scheme or course of conduct, whether involving a single person or several persons, may be aggregated when determining the punishment for the offense.

Section 25. Paragraph (c) of subsection (9) of section

460.403, Florida Statutes, is amended to read:

460.403 Definitions.—As used in this chapter, the term:

(9)

(c)1. Chiropractic physicians may adjust, manipulate, or treat the human body by manual, mechanical, electrical, or natural methods; by the use of physical means or physiotherapy, including light, heat, water, or exercise; by the use of acupuncture; or by the administration of foods, food concentrates, food extracts, and items for which a prescription is not required and may apply first aid and hygiene, but chiropractic physicians are expressly prohibited from prescribing or administering to any person any legend drug except as authorized under subparagraph 2., from performing any surgery except as stated herein, or from practicing obstetrics.

2. Notwithstanding the prohibition against prescribing and administering legend drugs under subparagraph 1. or s. 499.82(7)(c) ~~s. 499.01(2)(m)~~, pursuant to board rule chiropractic physicians may order, store, and administer, for emergency purposes only at the chiropractic physician's office or place of business, prescription medical oxygen and may also order, store, and administer the following topical anesthetics in aerosol form:

a. Any solution consisting of 25 percent ethylchloride and 75 percent dichlorodifluoromethane.

b. Any solution consisting of 15 percent dichlorodifluoromethane and 85 percent trichloromonofluoromethane.

However, this paragraph does not authorize a chiropractic

physician to prescribe medical oxygen as defined in chapter 499.

Section 26. Subsection (3) of section 465.0265, Florida Statutes, is amended to read:

465.0265 Centralized prescription filling.—

(3) The filling, delivery, and return of a prescription by one pharmacy for another pursuant to this section may ~~shall~~ not be construed as the filling of a transferred prescription as described ~~set forth~~ in s. 465.026 or as a wholesale distribution as defined ~~set forth~~ in s. 499.003 ~~s. 499.003(54)~~.

Section 27. Subsection (1), paragraphs (a), (c), (g), (m), (n), and (o) of subsection (2), and subsection (5) of section 499.01, Florida Statutes, are amended to read:

499.01 Permits.—

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

(a) A prescription drug manufacturer;

(b) A prescription drug repackager;

(c) A nonresident prescription drug manufacturer;

(d) A prescription drug wholesale distributor;

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

(f) A retail pharmacy drug wholesale distributor;

(g) A restricted prescription drug distributor;

(h) A complimentary drug distributor;

(i) A freight forwarder;

(j) A veterinary prescription drug retail establishment;

(k) A veterinary prescription drug wholesale distributor;

(l) A limited prescription drug veterinary wholesale distributor;

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

~~(n) A compressed medical gas wholesale distributor;~~

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

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

(n) ~~(q)~~ A device manufacturer;

(o) ~~(r)~~ A cosmetic manufacturer;

(p) ~~(s)~~ A third party logistics provider; or

(q) ~~(t)~~ A health care clinic establishment.

(2) The following permits are established:

(a) *Prescription drug manufacturer permit.*—A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.

1. A person that operates an establishment permitted as a prescription drug manufacturer may engage in wholesale distribution of prescription drugs manufactured at that establishment and must comply with all of the provisions of this part, except s. 499.01212, and the rules adopted under this part, except s. 499.01212, which apply to a wholesale distributor.

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

3. A blood establishment, as defined in s. 381.06014, operating in a manner consistent with the provisions of 21 C.F.R. parts 211 and 600-640, and manufacturing only the prescription drugs described in s. 499.003(53)(d) ~~s. 499.003(54)(d)~~ is not required to be permitted as a prescription drug manufacturer under this paragraph or to register products under s. 499.015.

(c) *Nonresident prescription drug manufacturer permit.*—A nonresident prescription drug manufacturer permit is required for any person that is a manufacturer of prescription drugs, unless permitted as a third party logistics provider, located outside of this state or outside the United States and that engages in the wholesale distribution in this state of such prescription drugs. Each such manufacturer must be permitted by the department and comply with all of the provisions required of a wholesale distributor under this part, except s. 499.01212.

1. A person that distributes prescription drugs for which the person is not the manufacturer must also obtain an out-of-state prescription drug wholesale distributor permit or third party logistics provider permit pursuant to this section to engage in the wholesale distribution of such prescription drugs. This subparagraph does not apply to a manufacturer as defined in s. 499.003(30)(e) ~~s. 499.003(31)(e)~~.

2. Any such person must comply with the licensing or permitting requirements of the jurisdiction in which the establishment is located and the federal act, and any product wholesaled into this state must comply with this part. If a person intends to import prescription drugs from a foreign country into this state, the nonresident prescription drug manufacturer must provide to the department a list identifying each prescription drug it intends to import and document approval by the United States Food and Drug Administration for such importation.

(g) *Restricted prescription drug distributor permit.*—

1. A restricted prescription drug distributor permit is required for:

a. Any person located in this state who engages in the distribution of a prescription drug, which distribution is not considered "wholesale distribution" under s. 499.003(53)(a) ~~s. 499.003(54)(a)~~.

b. Any person located in this state who engages in the receipt or distribution of a prescription drug in this state for the purpose of processing its return or its destruction if such person is not the person initiating the return, the prescription drug wholesale supplier of the person initiating the return, or the manufacturer of the drug.

c. A blood establishment located in this state which collects blood and blood components only from volunteer donors as defined in s. 381.06014 or pursuant to an authorized practitioner's order for medical treatment or therapy and engages in the wholesale distribution of a prescription drug not described in s. 499.003(53)(d) ~~s. 499.003(54)(d)~~ to a health care entity. A mobile blood unit operated by a blood establishment permitted under this sub-subparagraph is not required to be separately permitted. The health care entity receiving a prescription drug distributed under this sub-subparagraph must be licensed as a closed pharmacy or provide health care services at that establishment. The blood establishment must operate in accordance with s. 381.06014 and may distribute only:

(I) Prescription drugs indicated for a bleeding or clotting disorder or anemia;

(II) Blood-collection containers approved under s. 505 of the federal act;

(III) Drugs that are blood derivatives, or a recombinant or

synthetic form of a blood derivative;

(IV) Prescription drugs that are identified in rules adopted by the department and that are essential to services performed or provided by blood establishments and authorized for distribution by blood establishments under federal law; or

(V) To the extent authorized by federal law, drugs necessary to collect blood or blood components from volunteer blood donors; for blood establishment personnel to perform therapeutic procedures under the direction and supervision of a licensed physician; and to diagnose, treat, manage, and prevent any reaction of a volunteer blood donor or a patient undergoing a therapeutic procedure performed under the direction and supervision of a licensed physician,

as long as all of the health care services provided by the blood establishment are related to its activities as a registered blood establishment or the health care services consist of collecting, processing, storing, or administering human hematopoietic stem cells or progenitor cells or performing diagnostic testing of specimens if such specimens are tested together with specimens undergoing routine donor testing. The blood establishment may purchase and possess the drugs described in this sub-subparagraph without a health care clinic establishment permit.

2. Storage, handling, and recordkeeping of these distributions by a person required to be permitted as a restricted prescription drug distributor must be in accordance with the requirements for wholesale distributors under s. 499.0121, but not those described ~~set forth~~ in s. 499.01212 if

the distribution occurs pursuant to sub-subparagraph 1.a. or sub-subparagraph 1.b.

3. A person who applies for a permit as a restricted prescription drug distributor, or for the renewal of such a permit, must provide to the department the information required under s. 499.012.

4. The department may adopt rules regarding the distribution of prescription drugs by hospitals, health care entities, charitable organizations, other persons not involved in wholesale distribution, and blood establishments, which rules are necessary for the protection of the public health, safety, and welfare.

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

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

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

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

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

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

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

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

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

~~wholesale distributor.~~

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

(5) A prescription drug repackager permit issued under this part is not required for a restricted prescription drug distributor permitholder that is a health care entity to repackage prescription drugs in this state for its own use or for distribution to hospitals or other health care entities in the state for their own use, pursuant to s. 499.003(53)(a)3. ~~s. 499.003(54)(a)3.~~, if:

(a) The prescription drug distributor notifies the department, in writing, of its intention to engage in repackaging under this exemption, 30 days before engaging in the repackaging of prescription drugs at the permitted establishment;

(b) The prescription drug distributor is under common control with the hospitals or other health care entities to which the prescription drug distributor is distributing prescription drugs. As used in this paragraph, "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, voting rights, contract, or otherwise;

(c) The prescription drug distributor repackages the prescription drugs in accordance with current state and federal good manufacturing practices; and

(d) The prescription drug distributor labels the prescription drug it repackages in accordance with state and federal laws and rules.

The prescription drug distributor is exempt from the product registration requirements of s. 499.015 with regard to the prescription drugs that it repackages and distributes under this subsection.

Section 28. Paragraph (b) of subsection (2) of section 499.0121, Florida Statutes, is amended to read:

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

(2) SECURITY.—

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

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

Section 29. Section 499.01211, Florida Statutes, is amended to read:

499.01211 Drug Wholesale Distributor Advisory Council.—

(1) There is created the Drug Wholesale Distributor

Advisory Council within the department. The council shall meet at least once each calendar quarter. Staff for the council shall be provided by the department. The council shall consist of 12 ~~11~~ members who shall serve without compensation. The council shall elect a chairperson and a vice chairperson annually.

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

(a) Three different persons each of whom is employed by a different prescription drug wholesale distributor licensed under this part which operates nationally and is a primary wholesale distributor, as defined in s. 499.003 ~~s. 499.003(47)~~.

(b) One person employed by a prescription drug wholesale distributor licensed under this part which is a secondary wholesale distributor, as defined in s. 499.003 ~~s. 499.003(52)~~.

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

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

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

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

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

(3) The Compressed Gas Association shall appoint one person to the council who is an employee of a permitted medical gas wholesale distributor or manufacturer.

(4)~~(3)~~ The council shall review this part and the rules adopted to administer this part annually, provide input to the department regarding all proposed rules to administer this part, make recommendations to the department to improve the protection of the prescription drugs and public health, make recommendations to improve coordination with other states' regulatory agencies and the federal government concerning the wholesale distribution of drugs, and make recommendations to minimize the impact of regulation of the wholesale distribution industry while ensuring protection of the public health.

Section 30. Paragraph (b) of subsection (2) of section 499.01212, Florida Statutes, is amended to read:

499.01212 Pedigree paper.—

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

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

1. The quantity, dosage form, and strength of the prescription drugs.

2. The lot numbers of the prescription drugs.

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

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

5. An invoice number, a shipping document number, or

another number uniquely identifying the transaction.

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

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

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

When an affiliated group member obtains title to a prescription drug before distributing the prescription drug as the manufacturer as defined in s. 499.003(30)(e) ~~under s. 499.003(31)(e)~~, information regarding the distribution between those affiliated group members may be omitted from a pedigree paper required under this paragraph for subsequent distributions of that prescription drug.

Section 31. 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 of manufacturer in s. 499.003 ~~s. 499.003(31)~~, 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 of manufacturer in s. 499.003 ~~s. 499.003(31)~~, 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 s. 499.062, and subjects such person to the penalties and remedies provided in this part.

Section 32. Subsection (3) of section 499.024, Florida Statutes, is amended to read:

499.024 Drug product classification.—The department 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 definition of drug in s. 499.003 ~~s. 499.003(19)~~ 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 33. Paragraph (e) of subsection (1), paragraph (b) of subsection (2), and paragraph (b) of subsection (3) 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.—

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

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

(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.

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

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

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

Section 34. Paragraphs (i) and (m) of subsection (1) of section 499.05, Florida Statutes, are amended to read:

499.05 Rules.—

(1) The department shall adopt rules to implement and enforce this chapter ~~part~~ with respect to:

(i) Additional conditions that qualify as an emergency medical reason under s. 499.003(53)(b)2. ~~s. 499.003(54)(b)2~~.

(m) The recordkeeping, storage, and handling with respect to each of the distributions of prescription drugs specified in s. 499.003(53)(a)-(d) ~~s. 499.003(54)(a)-(d)~~.

Section 35. Subsections (1) through (4) of section 499.051, Florida Statutes, are amended to read:

499.051 Inspections and investigations.—

(1) The agents of the department and of the Department of

Law Enforcement, after they present proper identification, may inspect, monitor, and investigate any establishment permitted pursuant to this chapter ~~part~~ during business hours for the purpose of enforcing this chapter ~~part~~, chapters 465, 501, and 893, and the rules of the department that protect the public health, safety, and welfare.

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

(3) Any application for a permit or product registration or for renewal of such permit or registration made pursuant to this chapter ~~part~~ and rules adopted under this chapter ~~part~~ constitutes permission for any entry or inspection of the premises in order to verify compliance with this chapter ~~part~~ 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 or s. 499.821 and rules adopted under those sections ~~that section~~ constitutes permission for agents of the department and the Department of Law Enforcement, after presenting proper identification, to inspect, review, and copy any financial document or record related to the manufacture, repackaging, or distribution of a drug as is necessary to verify compliance with this chapter ~~part~~ and the rules adopted by the department to administer this chapter ~~part~~, in order to discover, investigate,

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

Section 36. Section 499.066, Florida Statutes, is amended to read:

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

(1) The department may institute such suits or other legal proceedings as are required to enforce any provision of this chapter ~~part~~. If it appears that a person has violated any provision of this chapter ~~part~~ for which criminal prosecution is provided, the department may provide the appropriate state attorney or other prosecuting agency having jurisdiction with respect to such prosecution with the relevant information in the department's possession.

(2) If any person engaged in any activity covered by this chapter ~~part~~ violates any provision of this chapter ~~part~~, any rule adopted under this chapter ~~part~~, or a cease and desist order as provided by this chapter ~~part~~, the department may obtain an injunction in the circuit court of the county in which the violation occurred or in which the person resides or has its principal place of business, and may apply in that court for such temporary and permanent orders as the department considers necessary to restrain the person from engaging in any such activities until the person complies with this chapter ~~part~~, the rules adopted under this chapter ~~part~~, and the orders of the department authorized by this chapter ~~part~~ or to mandate compliance with this chapter ~~part~~, the rules adopted under this chapter ~~part~~, and any order or permit issued by the department under this chapter ~~part~~.

(3) The department may impose an administrative fine, not to exceed $5,000 per violation per day, for the violation of any provision of this chapter ~~part~~ or rules adopted under this chapter ~~part~~. Each day a violation continues constitutes a separate violation, and each separate violation is subject to a separate fine. All amounts collected pursuant to this section shall be deposited into the Professional Regulation Trust Fund and are appropriated for the use of the department in administering this chapter ~~part~~. In determining the amount of the fine to be levied for a violation, the department shall consider:

(a) The severity of the violation;

(b) Any actions taken by the person to correct the violation or to remedy complaints; and

(c) Any previous violations.

(4) The department shall deposit any rewards, fines, or collections that are due the department and which derive from joint enforcement activities with other state and federal agencies which relate to this chapter ~~part~~, chapter 893, or the federal act, into the Professional Regulation Trust Fund. The proceeds of those rewards, fines, and collections are appropriated for the use of the department in administering this chapter ~~part~~.

(5) The department may issue an emergency order immediately suspending or revoking a permit if it determines that any condition in the establishment presents a danger to the public health, safety, and welfare.

(6) The department may issue an emergency order to immediately remove from commerce and public access any drug,

device, or cosmetic, if the department determines that the drug, device, or cosmetic presents a clear and present danger to the public health, safety, and welfare.

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

Section 37. Paragraph (a) of subsection (1) and paragraph (a) of subsection (2) of section 499.0661, Florida Statutes, are amended to read:

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

(1) CEASE AND DESIST ORDERS.—

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

1. An act that demonstrates a lack of fitness or trustworthiness to engage in the business authorized under the permit issued pursuant to this chapter ~~part~~, is hazardous to the public health, or constitutes business operations that are a detriment to the public health;

2. A violation of any provision of this chapter ~~part~~;

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.

(2) REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.—

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

1. An act that demonstrates a lack of fitness or trustworthiness to engage in the business authorized under the permit issued pursuant to this chapter ~~part~~, is hazardous to the public health, or constitutes business operations that are a detriment to the public health;

2. A willful violation of this chapter ~~part~~; however, if the violation constitutes a misdemeanor, a complaint may not be served as provided in this section until the affiliated party is notified in writing of the matter of the violation and has been afforded a reasonable period of time, as set forth in the notice, to correct the violation and has failed to do so;

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

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

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

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

Section 38. Section 499.067, Florida Statutes, is amended to read:

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

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

with this chapter ~~part~~ or chapter 465, chapter 501, or chapter 893, the rules adopted under this chapter ~~part~~ or those chapters, any final order of the department, or applicable federal laws or regulations or other state laws or rules governing drugs, devices, or cosmetics.

(b) The department may deny an application for a permit or certification, or suspend or revoke a permit or certification, if the department finds that:

1. The applicant is not of good moral character or that it would be a danger or not in the best interest of the public health, safety, and welfare if the applicant were issued a permit or certification.

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

3. The applicant is not eligible for a permit or certification for any of the reasons enumerated in s. 499.012.

4. The applicant, permittee, or person certified under s. 499.012(16) demonstrates any of the conditions enumerated in s. 499.012.

5. The applicant, permittee, or person certified under s. 499.012(16) has committed any violation of ss. 499.005-499.0054.

(2) The department may deny, suspend, or revoke any registration required by the provisions of this chapter ~~part~~ for the violation of any provision of this chapter ~~part~~ or of any rules adopted under this chapter ~~part~~.

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

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

(b) If the permit was procured, or attempted to be

procured, for any other person by making or causing to be made any false representation; or

(c) If the permittee has violated any provision of this chapter ~~part~~ or rules adopted under this chapter ~~part~~.

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

(5) The department may deny, suspend, or revoke a permit issued under this chapter ~~part~~ which authorizes the permittee to purchase prescription drugs if any owner, officer, employee, or other person who participates in administering or operating the establishment has been found guilty of any violation of this chapter ~~part~~ or chapter 465, chapter 501, or chapter 893, any rules adopted under this chapter ~~part~~ or those chapters, or any federal or state drug law, regardless of whether the person has

been pardoned, had her or his civil rights restored, or had adjudication withheld.

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

(7) Notwithstanding s. 120.60(5), if a permittee fails to comply with s. 499.012(6) or s. 499.83, as applicable, the department may revoke the permit of the permittee and shall provide notice of the intended agency action by posting a notice at the department's headquarters and by mailing a copy of the notice of intended agency action by certified mail to the most recent mailing address on record with the department and, if the permittee is not a natural person, to the permittee's registered agent on file with the Department of State.

(8) The department may deny, suspend, or revoke a permit under this part if it finds the permittee has not complied with the credentialing requirements of s. 499.0121(15).

(9) The department may deny, suspend, or revoke a permit under this part if it finds the permittee has not complied with the reporting requirements of, or knowingly made a false statement in a report required by, s. 499.0121(14).

Section 39. This act shall take effect October 1, 2014.