A bill to be entitled

An act relating to the Florida Drug and Cosmetic Act; reordering and amending s. 499.003, F.S.; revising definitions; amending s. 499.01, F.S.; deleting permit requirements for medical oxygen retail establishments, compressed medical gas wholesale distributors, and compressed medical gas manufacturers; conforming cross-references; amending s. 499.0121, F.S.; deleting reference to establishments that handle medical oxygen; amending s. 499.01211, F.S.; revising membership of the Drug Wholesale Distributor Advisory Council; conforming cross-references; amending s. 499.041, F.S.; deleting certain permitting fees for compressed medical gas manufacturers, medical gas wholesale distributors, or medical oxygen retail establishments; amending ss. 499.051, 499.066, 499.0661, and 499.067, F.S.; conforming provisions to changes made by the act; creating part III of chapter 499, F.S., relating to medical gases; providing for applicability and preemption; authorizing the department to administer and enforce the part; requiring a state, county, or municipal attorney to institute appropriate proceedings for a violation; providing notice requirements for the department; providing definitions; requiring a permit for distribution of medical gas as a wholesale

distributor, manufacturer, or medical oxygen retail establishment; authorizing the department to adopt rules; providing permitting standards; providing requirements to obtain a permit; providing for permit renewal; providing guidelines to change certain information; authorizing the department to revoke permits for failure to comply; requiring certain distributors of medical gases to obtain a permit and maintain permit renewal; requiring an applicant to provide a sworn statement disclosing certain information; providing minimum qualifications for licensure; requiring an applicant or permittee to designate and maintain a registered agent for service of process; providing minimum requirements for the storage and handling of gases and patient information; requiring a facility of wholesale distribution of medical gases to secure the facility from unauthorized entry; providing recommended security measures; requiring medical gases to be stored and packaged in accordance with certain regulations or standards; requiring a visual examination of a medical gas container upon receipt; requiring that a damaged or unfit medical gas be quarantined; requiring inspection of outgoing shipments; requiring a wholesale distributor of medical gases to review the records that accompany a medical gas received by the

distributor; requiring returned medical gases to be reprocessed for resale; requiring certain medical gases to be quarantined; requiring an acquiring distributor or manufacturer to provide notice of adulteration, misbranding, or suspected adulteration or misbranding; requiring certain medical gases to be retained; requiring a wholesale distributor of medical gases to comply with certain due diligence requirements; requiring that certain information must be provided by the supplying distributor to the acquiring distributor; providing an exception; requiring a wholesale distribution of medical gases to establish and maintain certain records; requiring the records to be made available for a certain amount of time; providing requirements related to trade secret information; requiring a wholesale distributor to establish, maintain, and adhere to written policies and procedures; providing certain mandatory policies; prohibiting certain acts; providing that certain acts are felonies of the third degree; providing additional penalties of forfeiture; providing requirements related to salvaging and reprocessing; authorizing the department to recognize a third party inspection of wholesale distributors of medical gases or recognize other states inspections; providing for a right of review; providing notice requirements; providing for

the deposit of fees in a trust fund and authorizing the department to use such funds; amending ss. 409.9201, 460.403, 465.0265, 499.01212, 499.015, 499.024, and 499.05, F.S.; conforming cross-references; providing an effective date.

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

Section 1. Subsections (12) through (32) and subsections (47) through (55) of section 499.003, Florida Statutes are renumbered as sections (11) through (31) and subsections (46) through (54), respectively, present subsection (11) is reordered and amended, and present subsections (43) and (46) of that section are amended, to read:

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

(32) ~~(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, and as defined in the federal act.

(43) "Prescription drug" means a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active pharmaceutical ingredients subject to, defined by, or described by s. 503(b) of the federal ~~Food, Drug, and Cosmetic~~ act or s. 465.003(8), s. 499.007(13), or subsection (32) ~~(11), subsection (46),~~ or subsection (52) ~~(53)~~, except that

an active pharmaceutical ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in this state are also prescription drugs.

~~(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.~~

Section 2. Paragraphs (m), (n), and (o) of 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) Prior to operating, a permit is required for each person and establishment that intends to operate as:

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

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

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

(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) ~~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) ~~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) ~~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) ~~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 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. ~~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 3. 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 4. Subsection (2) of section 499.01211, Florida Statutes, is amended, and paragraph (h) is added to that subsection, to read:

499.01211 Drug Wholesale Distributor Advisory Council.—

(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 10 ~~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 permitted ~~licensed~~ under this part which operates nationally and is a primary wholesale distributor, as defined in s. 499.003(46) ~~499.003(47)~~.

(b) One person employed by a prescription drug wholesale distributor permitted ~~licensed~~ under this part which is a secondary wholesale distributor, as defined in s. 499.003(51) ~~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.

(h) One person who is an employee of a medical gas manufacturer or medical gas wholesale distributor and who has been recommended by the Compressed Gas Association.

Section 5. 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.

~~(e) 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 6. 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 chapter ~~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. 499.831 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 7. Subsections (1) through (4) of section 499.066, Florida Statutes, are 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~~.

Section 8. 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 a ~~any~~ permittee or upon an ~~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 a ~~any~~ provision of this chapter ~~part~~;

3. A violation of a ~~any~~ rule of the department;

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

5. A breach of a ~~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 an ~~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 a ~~any other~~ law involving fraud or moral turpitude which constitutes a felony;

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

5. A willful violation of an ~~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 9. Subsections (1) and (2), paragraph (c) of subsection (3), and subsections (4) through (9) of section 499.067, Florida Statutes, are 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 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 or this chapter.

(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:

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

(4) If a ~~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 a ~~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 part which authorizes the permittee to purchase prescription drugs if an ~~any~~ owner, officer, employee, or other person who participates in administering or operating the establishment has been found guilty of a ~~any~~ violation of this chapter ~~part~~ or chapter 465, chapter 501, or chapter 893, any rules adopted under ~~this 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 a ~~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. 499.831, 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 10. Part III of chapter 499, Florida Statutes, consisting of sections 499.81 through 499.99, is created to read:

PART III

MEDICAL GASES

499.81 Administration and enforcement.—

(1) The provisions of this part are cumulative and shall be construed and applied as being in addition to, and not in

substitution for or limitation of, any powers, duties, or authority of the department under any other law of this state; except that, with respect to the regulation of medical gas, the provisions of this part shall control over any conflicting provisions.

(2) The department shall administer and enforce this part to prevent fraud, adulteration, misbranding, or false advertising in the manufacture or distribution of medical gas.

(3) For the purpose of an investigation or proceeding conducted by the department under this part, the department may administer oaths, take depositions, subpoena witnesses, and compel the production of books, papers, documents, or other records. Challenges to, and enforcement of, subpoenas and orders shall be handled as provided in s. 120.569.

(4) Each state attorney, county attorney, or municipal attorney to whom the department or its designated agent reports a violation of this part shall cause appropriate proceedings to be instituted in the proper courts without delay and prosecuted in the manner required by law.

(5) This part does not require the department to report, for the institution of proceedings under this part, minor violations of this part when the department believes that the public interest will be adequately served by a written notice or warning.

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

(1) "Adulterated" means:

(a) Consisting in whole or in part of impurities or deleterious substances exceeding normal specifications;

(b) Produced, prepared, packed, or held under conditions whereby the medical gas may have been contaminated causing it to be rendered injurious to health; or if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practices to ensure that the medical gas meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it is represented to possess;

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

(d) Represented as a medical gas, with strength differing from, or quality or purity falling below, the standard set forth in the USP-NF. Such determination shall be made in accordance with the tests or methods of assay in the USP-NF, or validated equivalent, or in the absence of or inadequacy of these tests or methods of assay, tests or methods of assay prescribed under the federal act. No medical gas defined in USP-NF shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity set forth in the USP-NF, if its difference in strength, quality, or purity from that standard is plainly stated on its label.

(2) "Distribution" means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a medical gas, whether by passage of title, physical movement, or both. The term does not include:

(a) The dispensation or administration of medical gas;

(b) The delivery of, or an offer to deliver, a medical gas by a common carrier in the usual course of business as a common carrier; or

(c) Sales activities taking place in a location owned or controlled by, or staffed by persons employed by, a person or entity permitted in this state to distribute medical gas, where the locations where such sales activities are taking place do not physically store or move medical gas.

(3) "Emergency" means any act or circumstance during a state of emergency declared pursuant to s. 252.36, including, but not limited to:

(a) Transfer of a medical gas between wholesale distributors of medical gases or between a wholesale distributor of medical gases and a retail pharmacy or health care entity to alleviate a temporary shortage of a medical gas arising from a delay in or interruption of regular distribution schedules.

(b) Sales to licensed emergency medical services, including ambulance companies and firefighting organizations in this state, or licensed practitioners allowed to dispense medical gases in the treatment of acutely ill or injured persons.

(c) Provision of emergency supplies of medical gases to nursing homes during hours of the day when necessary medical gases cannot be obtained.

(d) Transfer of medical gases between retail pharmacies to alleviate a temporary shortage.

(4) "Emergency use oxygen" means oxygen USP administered in emergency situations without a prescription for oxygen deficiency and resuscitation. The container must be labeled in accordance with requirements of the United States Food and Drug Administration.

(5) "Federal act" means the Federal Food, Drug, and Cosmetic Act.

(6) "Intracompany transaction" means a transaction between a division, subsidiary, parent, or affiliated or related company under the common ownership and control of a corporate entity.

(7) "Medical gas" means a liquefied or vaporized gas that is a prescription drug, whether alone or in combination with other gases, and as defined in the federal act.

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

(9) "Misbranded " means having a label that is false or misleading; a label without the name and address of the manufacturer, packer, or distributor and without an accurate

statement of the quantities of active ingredients; or a label without an accurate monograph for the medical gas, except in the case of mixtures of designated medical gases where the label identifies the component percentages of each designated medical gas used to make the mixture.

(10) "Prescription medical oxygen" means oxygen USP which can only be sold on the order or prescription of a practitioner authorized to prescribe. The label of prescription medical oxygen must comply with labeling requirements for oxygen under the federal act.

(11) "Product labeling" means the labels and other written, printed, or graphic matter upon an article, or the containers or wrappers that accompany an article, except for letters, numbers, and symbols stamped into the container as required by the federal Department of Transportation.

(12) "USP" means United States Pharmacopeia.

(13) "USP-NF" means United States Pharmacopeia-National Formulary.

(14) "Wholesale distribution" means the distribution of medical gas by a wholesale distributor of medical gases to a person other than a consumer or patient. Wholesale distribution of medical gases 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 a medical gas pursuant to a prescription;

(b) The sale, purchase, or trade of a medical gas or an

offer to sell, purchase, or trade a medical gas for emergency medical reasons;

(c) Intracompany transactions;

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

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

(f) The purchase or other acquisition by a hospital or other similar health care entity that is a member of a group purchasing organization of a medical gas for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of such organizations;

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

(h) Activities exempt from wholesale distribution as defined in s. 499.003(53); or

(i) Other transactions excluded from the definition of wholesale distribution under the federal act or regulations implemented under the federal act related to medical gas.

(15) "Wholesale distributor" means any person engaged in wholesale distribution of medical gas within or into this state, including, but not limited to, manufacturers, own-label distributors, private-label distributors, warehouses, including manufacturers' and distributors' warehouses, and wholesale medical gas warehouses.

499.831 Permits.—

(1) Before operating, unless exempted under this part, a permit is required for each person and establishment, whether inside or outside of this state, that intends to distribute medical gas within or into this state and operate as:

(a) A medical gas wholesale distributor;

(b) A medical gas manufacturer; or

(c) A medical oxygen retail establishment.

(2) The following permits are established:

(a) Medical gas wholesale distributor permit.—A medical gas wholesale distributor permit is required for the wholesale distribution of medical gases, whether within or into this state, to a person other than the consumer or patient. The medical gas must be in the original container obtained by the wholesale distributor without further manufacturing operations. A medical gas wholesale distributor may not possess or engage in the wholesale distribution of a prescription drug that is not a

medical gas. The department shall adopt rules to govern the wholesale distribution of prescription medical oxygen for emergency use. Rules regarding the emergency use of prescription medical oxygen may not be inconsistent with rules and regulations of federal agencies unless the Legislature specifically directs otherwise.

(b) Medical gas manufacturer permit.—A medical gas manufacturer permit is required for a person that engages in the manufacture of medical gases by physical air separation, chemical action, purification, or filling containers by a liquid to liquid, liquid to gas, or gas to gas process and that distributes those medical gases within or into this state.

1. A medical gas manufacturer may not manufacture or possess a prescription drug that is not a medical gas.

2. A medical gas manufacturer may engage in wholesale distribution of medical gases manufactured without a medical gas wholesale distributor permit, but must comply with the provisions of this part and the rules adopted under this part that apply to a wholesale distributor.

3. A medical gas manufacturer 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 that sells medical oxygen directly to patients. The sale must be based on an order from a practitioner authorized by law to prescribe. The medical oxygen retail establishment permit

excludes a pharmacy licensed under chapter 465.

1. A medical oxygen retail establishment may not possess, purchase, sell, or trade a prescription drug that is not 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.

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

4. A medical oxygen retail establishment that refills medical oxygen shall comply with all appropriate state and federal good manufacturing practices.

5. A medical oxygen retail establishment shall comply with the requirements of s. 499.87.

(3) The department shall adopt rules establishing the form and content of the application to obtain or renew a permit. The applicant must submit to the department with the application a statement that swears or affirms that the information is true and correct. An application for a permit must include:

(a) All trade or business terms used by the permittee, including "doing business as (d/b/a)" and "formerly known as," which cannot be identical to the name used by an unrelated wholesale distributor permitted to purchase medical gas in the state;

(b) The name of the owner and operator of the permittee

including:

1. The name, business address, and date of birth, if the permittee is an individual.

2. The name, business address, date of birth of each partner, the name of the partnership, and federal employer identification number, if the permittee is a partnership.

3. The name, business address, and title of each corporate officer and director, the corporate names, the state of incorporation, the federal employer identification number, and the name and business address of the parent company, if one exists, if the permittee is a corporation.

4. The full name and business address of the sole proprietor and the name and federal employer identification number of the business entity, if the permittee is a sole proprietorship.

5. The name, business address, and title of each company officer, the name of the limited liability company and federal employer identification number, and the name of the state in which the limited liability company was organized, if the permittee is a limited liability company.

(c) A list of all disciplinary actions pertinent to wholesale distributors of prescription drugs or controlled substances by any state and federal agencies against the wholesale distributor distributing medical gas into the state and any disciplinary actions against principals, owners, directors, or officers; and

(d) An address and description of each facility and warehouse, including all locations used for medical gas storage or wholesale distribution including a description of the security system.

(4) A permit issued pursuant to this part may be issued to a natural person who is at least 18 years of age or to an applicant who is not a natural person if the person who, directly or indirectly, manages, controls, or oversees the operation of that applicant is at least 18 years of age.

(5) An applicant for a permit shall submit the appropriate fee for the permit for which he or she is applying. The fee shall be determined by the department.

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

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

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

(6) Upon approval of the application by the department and payment of the required fee, the department shall issue a permit to the applicant pursuant to the rules adopted under this part.

(7)(a) 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.

(b) If a renewal application and fee are submitted and postmarked after expiration of the permit, a late renewal

delinquent fee of $100, plus the required renewal fee must be paid within 60 days after expiration of the permit.

(c) Upon approval of the renewal application by the department and payment of the required renewal fee, the department shall issue a permit to the applicant pursuant to the rules adopted under this part.

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

(8)(a) A permit, unless suspended or revoked, automatically expires 2 years after the last day of the month in which the permit was issued.

(b) Failure to renew a permit in accordance with this section precludes any future renewal of that permit. If a permit issued pursuant to this part has expired and cannot be renewed, the establishment must submit an application for a new permit, pay the application fee, the initial permit fee, and all applicable penalties, and be issued a new permit by the department before the establishment may engage in activities that require a permit under this part.

(9) A permitted person in good standing may change permit type to a different permit under s. 499.831 by completing a new application for the requested permit, paying the additional amount due for the permit fee if the fee for the new permit is more than the fee for the original permit, and meeting the applicable permitting conditions for the new permit type. The new permit shall expire on the expiration date of the original

permit. 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.

(10)(a) A permit issued by the department is valid only for the person or governmental unit to which it is issued and is not subject to sale, assignment, or other transfer, voluntarily or involuntarily, and is not valid for any establishment other than the establishment for which it was originally issued except as provided in this part. The department is authorized to approve a change of the permit holder.

(b) Changes by authorized persons are permitted as follows:

1. A person permitted under this part must notify the department 30 days before making a change of location. The department shall set a change of location fee not to exceed $100.

2. When a majority of the ownership or controlling interest of a permitted establishment is transferred or assigned, or when a lessee agrees to undertake or provide services to the extent that legal liability for operation of the establishment will rest with the lessee, an application for a new permit shall be required. The application for the new permit must be made 30 days before the change of ownership. If the application for the new permit is not made 30 days before the change of ownership, and if the new owner acquires a permitted wholesale distributor or manufacturer, and the new owner has held another permit under this chapter for at least 18 months

and has not been found to have violated the provisions of this chapter in the preceding 18 months, the new owner can operate under the permit of the acquired entity if the application for a new permit is submitted by the first business day after ownership is transferred or assigned. The new owner is responsible for compliance with all laws and regulations governing medical gas. If the application is denied, the new owner shall immediately cease operation at the establishment until a permit is issued to the new owner.

3. A permit holder may make a change of business name without submitting a new permit application and must notify the department 30 days before making the name change. The permit holder may continue to operate the establishment under the old name until the department approves of the name change and issues a permit under the new name.

4. 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:

a. Return the permit to the department.

b. 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 contact with access to records that are required to be maintained under this part. Transfer of ownership of medical gas may be made only to persons authorized to possess medical gas under this part.

(11) Any change in information required under this section shall be submitted to the department 30 days before such change. The department may revoke the permit of any person that fails to comply with this part.

499.841 Additional requirements for licensure of a wholesale distributor of medical gases.—

(1) A wholesale distributor of medical gases that resides in the state or provides services within or into this state must obtain a permit from the department and must renew the permit with the department biennially on an application provided by the department. In order to distribute medical gases into this state pursuant to this subsection, out-of-state medical gas wholesale distributors must maintain a valid license or permit in the state in which they reside, if required, and proof of registration set forth in s. 499.98(4)(a), if required.

(2) Wholesale distributors may not operate from or receive a permit for a residence, except that a place of residence may be used for on call delivery of homecare oxygen by a home respiratory care technician. If wholesale distribution operations are conducted at more than one location within the state or distributed from more than one location into the state, each location must be permitted by the department.

499.85 Minimum qualifications.—

(1) The department shall consider the following factors in determining the eligibility for, and renewal of, a permit of persons who engage in the wholesale distribution of medical gas:

(a) A finding by the department that the applicant has violated or been disciplined by a regulatory agency in any state for violating a federal, state, or local law relating to the wholesale distribution of medical gases.

(b) A criminal conviction of the applicant under a federal, state, or local law.

(c) The applicant's past experience in the manufacture or wholesale distribution of medical gases.

(d) False or fraudulent material provided by the applicant in an application made in connection with the manufacturing or wholesale distribution of medical gases.

(e) A suspension, sanction, or revocation by a federal, state, or local government against a license or permit currently or previously held by the applicant or its owners for violations of a federal, state, or local law regarding medical gas.

(f) Compliance with previously granted licenses or permits.

(g) Compliance with the requirements of wholesale distributors to medical gases to maintain records or make records available to the department licensing authority or federal, state, or local law enforcement officials.

(h) Other factors or qualifications the department considers relevant to and consistent with the public health and safety.

(2) The applicant shall provide a sworn statement providing complete disclosure of any past criminal convictions

and violations of federal, state, or local laws regarding medical gases or a sworn statement that the applicant has not been convicted of or disciplined for any criminal or prohibited acts.

499.86 Registered agent.—Each applicant or permittee under this part shall designate and maintain a registered agent in this state for service of process. If an applicant or permittee does not designate a registered agent, or if, after reasonable diligence, service of process cannot be completed, service of process may be effected by service upon the Secretary of State as agent of the applicant or permittee. A copy of the service of process shall be mailed to the applicant or permittee by the department by certified mail, return receipt requested, or postage prepaid, at the address such applicant or permittee has designated on the applicant's or permittee's application for licensure in this state.

499.87 Minimum requirements for the storage and handling of medical gases; establishment and maintenance of medical gas records.—

(1) Minimum requirements shall be established for the storage, handling, transport, and shipment of medical gases and for the maintenance of wholesale distribution records by wholesale distributors of medical gases and their officers, agents, representatives, and employees.

(2) A facility at which a medical gas is received, stored, warehoused, handled, held, offered, marketed, displayed, or

transported from, as necessary to avoid a negative effect on the identity, strength, quality, or purity of the medical gas, shall:

(a) Be of suitable construction to ensure that medical gases are maintained in accordance with the product labeling of the medical gas or in compliance with the USP-NF.

(b) Be of suitable size and construction to facilitate cleaning, maintenance, and proper wholesale distribution operations.

(c) Have adequate storage areas with appropriate lighting, ventilation, space, equipment, and security conditions.

(d) Have a quarantined area for storage of medical gases that are suspected of being misbranded, adulterated, or otherwise unfit for distribution.

(e) Be maintained in an orderly condition.

(f) Be a commercial location and not a personal dwelling or residence location, except for a personal dwelling location used for on-call delivery of oxygen USP for homecare use where the person providing on-call delivery is employed by or acting under a written contract with a permittee.

(g) Provide for the secure and confidential storage of patient information, if applicable, with restricted access and policies and procedures to protect the integrity and confidentiality of the patient information.

(h) Provide and maintain appropriate inventory controls to detect and document any theft of nitrous oxide.

499.88 Security.—

(1) A facility used for wholesale distribution of medical gases shall protect such gases within the facility from unauthorized entry by using the following security measures:

(a) Keep access from outside the premises well-controlled and to a minimum.

(b) Ensure the outside perimeter of the premises is well-lit.

(c) Limit entry into areas where medical gas is held to authorized personnel.

(d) Equip all facilities with a fence or other system to detect or deter entry after hours.

(2) A facility used for wholesale distribution of medical gases shall be equipped with a system that will provide suitable protection against theft, including when appropriate, protection against theft of computers or electronic records and that will protect the integrity and confidentiality of data and documents.

(3) A facility used for wholesale distribution of medical gases shall be equipped with inventory management and control systems that protect against, detect, and document any instances of theft of nitrous oxide.

(4) Where a wholesale distributor of medical gases uses electronic distribution records, the wholesale distributor shall employ, train, and document the training of personnel in the proper use of such technology and equipment.

(5) Vehicles used for on-call delivery of oxygen USP and

oxygen related equipment for home care use by home care providers may be parked at a place of residence and must be locked and equipped with an audible alarm when not attended.

499.89 Storage.—

(1) All medical gases shall be stored under appropriate conditions in accordance with regulations created by the department or, in the absence of regulations, in accordance with applicable industry standards and the manufacturers' recommendations on the product labeling.

(2) Packaging of medical gas shall be in accordance with the USP-NF, if applicable.

(3) The record keeping requirements in s. 499.93 shall be followed for the wholesale distribution of all medical gases.

499.90 Examination of materials.—

(1) Upon receipt of a medical gas container, the container shall be visually examined to determine identity and whether the container is damaged or otherwise unfit for wholesale distribution.

(2) A medical gas container that is found to be damaged or unfit under subsection (1) shall be quarantined from the remaining stock until an examination is conducted and a determination is made that the medical gas is not misbranded or adulterated.

(3) Each outgoing shipment shall be carefully inspected for the identity of the medical gas and to ensure that no medical gas shipment has been damaged in storage or held under

improper conditions.

(4) Upon receipt of a medical gas, a wholesale distributor of medical gases must review the accompanying records for accuracy and completeness. A pedigree paper is not required for the wholesale distribution of a medical gas.

(5) The record keeping requirements in s. 499.93 shall be followed for all incoming and outgoing medical gases.

499.91 Returned, damaged, and outdated medical gases.—

(1) Medical gas that has left the control of the wholesale distributor may be returned to the wholesale distributor or manufacturer from which it was acquired but may not be resold as a medical gas unless it is reprocessed by the manufacturer using proper and adequate controls to ensure the identity, strength, quality, and purity of the reprocessed medical gas.

(2) A medical gas, including its container, that is damaged, misbranded, or adulterated shall be quarantined and physically separated from other medical gases until it is destroyed or returned to either the manufacturer or wholesale distributor from which it was acquired. External contamination of medical gas containers or the container's closure system, not impacting the integrity of the medical gas, is not considered damage or adulteration for purposes of this paragraph.

(3) When medical gas is adulterated, misbranded, or suspected of being adulterated or misbranded, notice shall be provided to the manufacturer or wholesale distributer from which they were acquired and the appropriate boards and federal

regulatory bodies.

(4) A medical gas container that has been opened or used, but is not adulterated or misbranded, shall be considered empty, quarantined, and physically separated from nonempty medical gas containers and returned to the manufacturer for destruction or reprocessing.

(5) A medical gas, its container, or its associated documentation or labeling, that is suspected of being involved in a criminal activity shall be retained and not destroyed until its disposition is authorized by the department or applicable law enforcement agency.

(6) The record keeping requirements in s. 499.93 shall be followed for all misbranded or adulterated medical gases.

499.92 Due diligence.—A wholesale distributor of medical gases shall comply with the following due diligence requirements:

(1) Before the initial acquisition of medical gases from a wholesale distributor, including a manufacturer, the supplying wholesale distributor shall provide the following information to the acquiring 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 United States Food and Drug Administration.

(b) If a wholesale distributor is distributing to a wholesale distributor, evidence that the wholesale distributor

supplying the medical gas is licensed or permitted to distribute product into the state.

(c) The name of the responsible facility contact person at the supplying manufacturer or wholesale distributor.

(d) A certification that the manufacturer or wholesale distributor's policies and procedures comply with this part.

(2) A manufacturer or wholesale distributor that distributes or acquires medical gases to or from another wholesale distributor of medical gases shall provide to or obtain from the distributing or acquiring entities, as applicable, the information set forth in s. 499.93(1).

(3) A wholesale distributor of medical gases is exempt from obtaining the information from a manufacturer as required under subsection (1) if the manufacturer is registered with the United States Food and Drug Administration in accordance with s. 510 of the federal act and the manufacturer provides:

(a) Proof of such registration.

(b) Proof of inspection by the United States Food and Drug Administration or other regulatory body within the past 3 years demonstrating substantial compliance with current good manufacturing practices applicable to medical gases.

499.93 Recordkeeping.—

(1) A wholesale distributor of medical gases shall establish and maintain records of all transactions regarding the receipt and wholesale distribution or other disposition of medical gases. These records shall include the following, which

need not appear on the same document:

(a) Dates of receipt and wholesale distribution or other disposition of the medical gas.

(b) The name, address, license or permit number, and license or permit expiration date of the entity purchasing the medical gas.

(c) The name, address, license or permit number, and license or permit expiration date of the entity receiving the medical gas, if different from paragraph (b).

(d) Information sufficient to perform a recall of medical gases received and distributed.

(2) Such records shall be made available for inspection and copying by an authorized official of any federal, state, or local governmental agency for a period of:

(a) Three years following the creation date of high pressure medical gases.

(b) One year following the creation date for cryogenic or refrigerated liquid medical gases.

(3) Records kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be 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 working days of a request by an authorized official of any state or federal governmental agency charged with enforcement of these rules.

(4) A wholesale distributor or manufacturers of medical gases shall maintain an ongoing list of persons from whom they receive or to whom they distribute medical gases.

(5) A wholesale distributor of medical gases shall maintain records sufficient to aid in the mandatory reporting of any theft, suspected theft, or other significant loss of nitrous oxide to the department and other appropriate law enforcement agencies.

499.931 Trade secret information.—The department shall ensure that information required to be provided as part of the application process or information obtained pursuant to an investigation by the department, which is a trade secret, as defined in s. 812.081, and designated as a trade secret by the entity supplying the information to the department, shall be maintained by the department as trade secret information as provided in ss. 499.012(8)(g) and 499.051(7).

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

(1) A process for handling recalls and withdrawals of medical gases. The process shall be adequate to deal with recalls and withdrawals due to:

(a) An action initiated at the request of the United States Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the department; or

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

(2) A procedure to ensure that wholesale distributors of medical gases prepare for, protect against, and handle a crisis that affects the security or operation of any 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 activities involving the inventory of nitrous oxide to the department and applicable law enforcement agencies within 3 business days of becoming aware of the criminal or suspect criminal activity.

499.95 Prohibited acts.—It is unlawful for a person to perform, cause the performance of, or aid and abet the following acts in this state:

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

distribution;

(2) The adulteration or misbranding of a medical gas;

(3) The receipt of a medical gas that is adulterated, misbranded, stolen, 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 a part of the product labeling of a medical gas or the willful commission of an act with respect to a medical gas that results in the medical gas being misbranded;

(5) The purchase or receipt of a medical gas from a person that is not licensed or permitted, or exempt from licensure or permitting, to distribute wholesale medical gas to that purchaser or recipient;

(6) The knowing and willful sale or transfer of a medical gas to a person or other recipient who is not legally authorized to receive a medical gas, except that it is not a violation if a permitted wholesale distributor, at its location, provides oxygen to a medical oxygen retail establishment permit holder that is out of compliance with the notice of location change requirements of s. 499.831(10)(b)1. and if the wholesale distributor with knowledge of the violation notifies the department of the transaction by the next business day;

(7) The failure to maintain or provide records as required by this part and its implementing regulations;

(8) Providing the department or its representatives or any federal, state, or local official with false or fraudulent

records or making false or fraudulent statements regarding a matter within the provisions of this part and its implementing regulations;

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

(a) Purchased by a public or private hospital or other health care entity, except for physical distribution of such medical gas to an authorized recipient at the direction of the 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 license or permit or operating without a valid license or permit when a license or permit is required;

(11) The obtaining of or attempting to obtain a medical gas by fraud, deceit, or misrepresentation in the distribution of a medical gas;

(12) Except for oxygen USP in emergency situations, distribution of a medical gas to a patient without a prescription or prescription order from a practitioner licensed by law to use or prescribe the medical gas;

(13) Distribution of a medical gas that was previously dispensed by a pharmacy or distributed by a practitioner;

(14) Distribution of a medical gas or medical gas related equipment to a patient, unless the patient has been provided

with appropriate information and counseling on use, storage, and disposal;

(15) The failure to report an act prohibited by this part and its implementing regulations; or

(16) The failure to exercise due diligence as provided in s. 499.92.

499.96 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 a medical gas.

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

(c) Engages in the wholesale distribution and knowingly sells, barters, brokers, or transfers medical gases to a person not legally authorized to purchase medical gases under the jurisdiction in which the person receives the medical gas, except that it is not a violation if a permitted wholesale distributor, at its location, provides oxygen to a medical oxygen retail establishment permit holder that is out of compliance with the notice of location change requirements of s. 499.831(10)(b)1. and if the wholesale distributor with knowledge of the violation notifies the department of the transaction by the next business day.

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

(2) A person found guilty of an offense under this section, under the authority of the court convicting and sentencing the person, shall be ordered to forfeit to the state any real or personal property:

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

(b) Constituting, derived from, or traceable to the gross proceeds that the defendant obtained directly or indirectly as a result of the offense. Property or assets subject to forfeiture under this section may be seized pursuant to a warrant obtained in the same manner as a search warrant or as otherwise permitted by law, and held until the case against a defendant is adjudicated. Monies ordered forfeited, or proceeds from the sale of other assets ordered forfeited, shall be equitably divided between the department and other agencies involved in the investigation and prosecution that led to the conviction. Other property ordered 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 that led to the conviction.

499.97 Salvaging and reprocessing.—

(1) Medical gas that has been subjected to improper conditions such as a fire, accident or natural disaster, may not

be salvaged or reprocessed.

(2) Medical gas in a container that has left the control of the wholesale distributor may be returned to the manufacturer and reprocessed if the manufacturer employs proper and adequate controls to ensure the identity, strength, quality, and purity of the reprocessed medical gas.

499.98 Inspections.—

(1) The department is authorized to recognize a third party to inspect wholesale distributors of medical gases in that state or in other states pursuant to a schedule to be determined by the department.

(2) The department is authorized to recognize state inspections of wholesale distributors of medical gases operations in another state, if the state's laws are deemed to be substantially equivalent by the department.

(3) The department's decision to deny issuance of a permit to an applicant is subject to review pursuant to chapter 120.

(4) A manufacturing facility of medical gases is exempt from inspection by the department if:

(a) The manufacturing facility is currently registered with the United States Food and Drug Administration under s. 510 of the federal act and can provide proof of registration, such as a copy of the internet verification page.

(b) The manufacturing facility can provide proof of inspection by the Food and Drug Administration, or if the facility is located in another state, inspection by the Food and

Drug Administration or other governmental entity charged with regulation of good manufacturing practices related to medical gases within the past 3 years.

(5) A wholesale distributor of medical gases must exhibit or have readily available all state licenses or permits and the most recent inspection report administered by the department.

(6) This part does not require the department to report minor violations of this part, including variances in good manufacturing practices, for the institution of proceedings under this part when the department believes that the public interest will be adequately served in the circumstances by written notice.

499.99 Deposit of fees.—All fees collected for licenses and permits required by this part shall be deposited in the Professional Regulation Trust Fund and shall be used by the department in the administration of this part. The Department of Business and Professional Regulation shall maintain a separate account in the Professional Regulation Trust Fund for the Drugs, Devices, and Cosmetics program.

Section 11. 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 by, or described by s. 503(b) of the Federal

Food, Drug, and Cosmetic Act or by s. 465.003(8), s. 499.003(52), ~~499.003(46) or (53)~~ or s. 499.007(13).

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 12. 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. 499.01(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 13. 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 shall not be construed as the filling of a transferred prescription as set forth in s. 465.026 or as a wholesale distribution as set forth in s. 499.003(53) ~~499.003(54)~~.

Section 14. 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 under s. 499.003(30)(e) ~~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 15. Paragraph (a) of subsection (1) and subsection (3) of section 499.015, Florida Statutes, is 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(30) ~~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(30) ~~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 16. 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(18) ~~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 17. 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 part with respect to:

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

Section 18. This act shall take effect October 1, 2014.