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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/01/2014	.	
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The Committee on Health Policy (Bean) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

Section 1. Section 499.001, Florida Statutes, is amended to read:

499.001 Florida Drug and Cosmetic Act; short title.—Sections 499.001-499.94 ~~499.001-499.081~~ may be cited as the "Florida Drug and Cosmetic Act."

Section 2. Subsections (12) through (32) and subsections (47) through (55) of section 499.003, Florida Statutes, are


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renumbered as subsections (11) through (31) and subsections (46) through (54), respectively, and present subsections (11), (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 3. 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.—


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(1) 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


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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 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~~


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~~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.~~

~~(c) *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 4. 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 5. Subsections (1) and (2) of section 499.01211, Florida Statutes, are 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 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


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~~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 permitted ~~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.

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

Section 6. 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


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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 7. Section 499.05, Florida Statutes, is amended to read:

499.05 Rules.—

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

(a) The definition of terms used in this chapter ~~part~~, and used in the rules adopted under this chapter ~~part~~, when the use of the term is not its usual and ordinary meaning.

(b) Labeling requirements for drugs, devices, and cosmetics.

(c) The establishment of fees authorized in this chapter ~~part~~.

(d) The identification of permits that require an initial


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application and onsite inspection or other prerequisites for permitting which demonstrate that the establishment and person are in compliance with the requirements of this chapter ~~part~~.

(e) The application processes and forms for product registration.

(f) Procedures for requesting and issuing certificates of free sale.

(g) Inspections and investigations conducted under s. 499.051 or s. 499.93 ~~s. 499.051~~, and the identification of information claimed to be a trade secret and exempt from the public records law as provided in s. 499.051(7).

(h) The establishment of a range of penalties, as provided in s. 499.066; requirements for notifying persons of the potential impact of a violation of this chapter ~~part~~; and a process for the uncontested settlement of alleged violations.

(i) Additional conditions that qualify as an emergency medical reason under s. 499.003(53)(b)2. or s. 499.82 ~~s. 499.003(54)(b)2~~.

(j) Procedures and forms relating to the pedigree paper requirement of s. 499.01212.

(k) The protection of the public health, safety, and welfare regarding good manufacturing practices that manufacturers and repackagers must follow to ensure the safety of the products.

(l) Information required from each retail establishment pursuant to s.499.012(3) or s 499.83(2)(c) ~~s. 499.012(3)~~, including requirements for prescriptions or orders.

(m) The recordkeeping, storage, and handling with respect to each of the distributions of prescription drugs specified in


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s. 499.003(53)(a)-(d) or s. 499.82(14) ~~s. 499.003(54)(a)-(d)~~.

(n) Alternatives to compliance with s. 499.01212 for a prescription drug in the inventory of a permitted prescription drug wholesale distributor as of June 30, 2006, and the return of a prescription drug purchased prior to July 1, 2006. The department may specify time limits for such alternatives.

(o) Wholesale distributor reporting requirements of s. 499.0121(14).

(p) Wholesale distributor credentialing and distribution requirements of s. 499.0121(15).

(2) With respect to products in interstate commerce, those rules must not be inconsistent with rules and regulations of federal agencies unless specifically otherwise directed by the Legislature.

(3) The department shall adopt rules regulating recordkeeping for and the storage, handling, and distribution of medical devices and over-the-counter drugs to protect the public from adulterated products.

Section 8. 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


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(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 9. 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


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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


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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 10. 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


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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 11. 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 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.


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5. The applicant, permittee, or person certified under s. 499.012(16) has committed any violation of this chapter ~~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 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


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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. 499.833, 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

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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 12. Part III of chapter 499, Florida Statutes, consisting of ss. 499.81-499.94, Florida Statutes, is created and entitled "Medical Gas."

Section 13. Section 499.81, Florida Statutes, is created to read:

499.81 Administration and enforcement.—

(1) This part is cumulative and shall be construed and applied as being in addition to, and not in substitution for or limiting 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, this part controls over any conflicting provisions.

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

(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

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a violation of this part shall cause appropriate proceedings to be instituted in the proper courts without delay and prosecuted as required by law.

(5) This part does not require the department to report, for the purpose of instituting 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.

Section 14. Section 499.82, Florida Statutes, is created to read:

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

(1) "Adulterated," means a medical gas that:

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

(b) Is 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 the medical gas is represented to possess;

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

(d) Is represented as having a strength differing from, or quality or purity falling below, the standard set forth in the

USP-NF. A medical gas defined in USP-NF may not be deemed to be adulterated under this paragraph merely 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. The determination as to strength, quality, or purity shall be made:

1. In accordance with the tests or methods of assay in the USP-NF or its validated equivalent; or

2. In the absence or inadequacy of such tests or methods of assay, in accordance with the tests or methods of assay prescribed under the federal act.

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

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

(a) The dispensing or administration of a medical gas;

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

(c) Sales activities taking place in a location owned, controlled, or staffed by persons employed by a person or entity permitted in this state to distribute a medical gas, if that location is not used to physically store or move a medical gas.

(4) "Emergency medical reasons" include:

(a) Transfers between wholesale distributors or between a wholesale distributor and a retail pharmacy or health care entity to alleviate a temporary shortage of a medical gas arising from a long-term delay or interruption of regular


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distribution schedules.

(b) Sales or transfers to licensed emergency medical services in this state, including ambulance companies and firefighting organizations.

(c) The provision of emergency supplies of medical gases to nursing homes during the hours of the day when necessary medical gases cannot normally be obtained from the nursing home's regular distributors.

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

(5) "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.

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

(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, repackager, or distributor and without an accurate statement of the quantities of active ingredients; or a label


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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) "Medical oxygen" means oxygen USP which must be labeled in compliance 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 Pharmacopeial Convention.

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

(14) "Wholesale distribution" means the distribution of medical gas 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 medical gas; or the dispensing of a medical gas pursuant to a prescription;

(b) Activities exempt from the definition of wholesale distribution in s. 499.003; or

(c) 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 or entity engaged in wholesale distribution of medical gas within or into this state, including, but not limited to, manufacturers; own-

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label distributors; private-label distributors; warehouses, including manufacturers' and distributors' warehouses; and wholesale medical gas warehouses.

Section 15. Section 499.83, Florida Statutes, is created to read:

499.83 Permits.—

(1) A person or entity that intends to distribute medical gas within or into this state, unless exempted under this part, must obtain the applicable permit before operating 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 wholesale distribution, whether within or into this state. A medical gas must remain in the original container obtained by the wholesale distributor and the wholesale distributor may not engage in further manufacturing operations unless it possesses a medical gas manufacturer permit. A medical gas wholesale distributor may not possess or engage in the wholesale distribution of a prescription drug that is not a medical gas or distribute a medical gas other than by wholesale distribution unless otherwise authorized.

(b) *Medical gas manufacturer permit.*—A medical gas manufacturer permit is required for a person or entity located in this state which 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-


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to-gas process and distributes those medical gases within this state.

1. A permitted medical gas manufacturer may not manufacture or possess a prescription drug other than a medical gas, unless otherwise authorized.

2. A permitted medical gas manufacturer may not distribute a medical gas without obtaining the applicable permit, except that it may engage in wholesale distribution of medical gases that it manufactured without obtaining a medical gas wholesale distributor permit if it complies with this part and the rules adopted under this part that apply to a wholesale distributor.

3. A permitted medical gas manufacturer shall comply with all of the requirements applicable to a wholesale distributor under this part and all appropriate state and federal good manufacturing practices.

(c) *Medical oxygen retail establishment permit.*—A medical oxygen retail establishment permit is required for an entity that is located in the state and that dispenses medical oxygen directly to patients in this state. The sale and delivery must be based on an order from a practitioner authorized by law to prescribe. A pharmacy licensed under chapter 465 does not require a permit as a medical oxygen retail establishment.

1. A medical oxygen retail establishment may not possess, purchase, sell, or trade a medical gas other than medical oxygen, unless otherwise authorized.

2. A medical oxygen retail establishment may fill and deliver medical oxygen to an individual patient based on an order from a practitioner authorized by law to prescribe. The medical oxygen retail establishment must comply with all


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appropriate state and federal good manufacturing practices. Medical oxygen sold or delivered by a medical oxygen retail establishment pursuant to an order from a practitioner may not be returned into the retail establishment's inventory.

3. A medical oxygen retail establishment shall comply with all of the requirements applicable to a wholesale distributor under this part, except for those requirements that pertain solely to nitrous oxide.

(3) An out-of-state wholesale distributor that engages in wholesale distribution into this state must be legally authorized to engage in the wholesale distribution of medical gases as a wholesale distributor in the state in which it resides or is incorporated and provide proof of registration as set forth in s. 499.93(3), if required.

(4) 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 for wholesale distributors that also maintain a medical oxygen retail establishment permit.

(5) 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.

Section 16. Section 499.831, Florida Statutes, is created to read:

499.831 Permit application.—

(1) The department shall adopt rules to establish the form and content of the application to obtain a permit and to renew a permit listed under this part.

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(2) An applicant must be at least 18 years of age or be managed, controlled, or overseen, directly or indirectly, by a natural person who is at least 18 years of age.

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

(a) The trade or business name of the applicant, including a fictitious name, which may not be identical to a name used by an unrelated entity permitted in this state to dispense or distribute medical gas.

(b) The name or names of the owner and operator of the applicant, if not the same person or entity. The application must also include:

1. If the applicant is an individual, the applicant's name, business address, and date of birth.

2. If the applicant is a sole proprietorship, the business address of the sole proprietor and the name and federal employer identification number of the business entity.

3. If the applicant is a partnership, the name, business address, date of birth of each partner, the name of the partnership, and the partnership's federal employer identification number.

4. If the applicant is a limited liability company, 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.

5. If the applicant is a corporation, 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, if applicable, the name and business address of the parent company.

(c) A list of disciplinary actions pertinent to wholesale distributors, manufacturers, and retailers of prescription drugs or controlled substances by a state or federal agency against the applicant seeking to distribute into this state and any such disciplinary actions against such applicant's principals, owners, directors, or officers.

(d) A complete disclosure of all of the applicant's past felony convictions.

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

(4) An applicant shall attest in writing that the information contained in its application is complete and accurate.

(5) An applicant must submit a reasonable fee, to be determined by the department, in order to obtain a permit.

(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.

Section 17. Section 499.832, Florida Statutes, is created


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to read:

499.832 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.

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

(3) A renewal application may be accepted up to 60 days after the expiration date of the permit if, along with the permit renewal fee, the applicant submits an additional renewal delinquent fee of $100. A permit that expired more than 60 days before a renewal application was submitted or postmarked may not be renewed.

(4) Failure to renew a permit in accordance with this section precludes future renewal. If a permit has expired and cannot be renewed, the person, entity, or establishment holding the permit must cease all permit related activities. In order to engage in activities that require a permit the person, entity, 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.


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

Section 18. Section 499.833, Florida Statutes, is created to read:

499.833 Permitholder changes.—

(1) A permit issued under this part 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.

(2) A permit issued under this part is not valid for an establishment other than the establishment for which it was originally issued.

(3) The department may approve the following permit changes:

(a) *Change of location.*—A person or entity permitted under this part must notify and receive approval from the department 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. Such application must be submitted and approved by the department before the change of ownership takes place. However, if a permitted wholesale distributor or manufacturer is changing ownership and the new owner has held another permit that allows the wholesale distribution of medical


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gas under this chapter for the preceding 18 months without having been found in violation of the provisions of this chapter relating to medical gases, then the new owner may operate under the permit of the acquired entity if the new owner submits the application for a new permit by the first business day after ownership is transferred or assigned. A new owner operating under the original permit 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.

(c) *Change of name.*—A permitholder may make a change of business name without submitting a new permit application. However, the permitholder must notify the department before making the name change.

(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. Indicate the disposition of any medical gas authorized to be distributed or dispensed under the permit, 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 the information required under this part, other than the changes in paragraphs (a)-(d), shall be submitted to the department within 30 days after such change occurs.


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(4) A permitholder in good standing may change the type of permit issued by completing a new application for the requested permit, meeting the applicable permitting requirements for the new permit type, and paying any difference between the permit fees. 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 retains the expiration date of the original permit.

Section 19. Section 499.834, Florida Statutes, is created to read:

499.834 Minimum qualifications.—The department shall consider all of the following factors in determining eligibility for, and renewal of, a permit for a person or entity under this part:

(1) 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 prescription drugs.

(2) Felony convictions of the applicant under a federal, state, or local law.

(3) The applicant’s past experience in the manufacture, retail, or distribution of medical gases.

(4) False or fraudulent material provided by the applicant in an application made in connection with the manufacturing, retailing, or distribution of prescription drugs.

(5) Any 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 prescription drugs.

(6) Compliance with previously granted licenses or permits.


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

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

Section 20. Section 499.84, Florida Statutes, is created to read:

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

(1) A facility where a medical gas is received, stored, warehoused, handled, held, offered, marketed, displayed, or transported, to avoid any negative effect on the identity, strength, quality, or purity of the medical gas, must:

(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 permitted 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 located in a commercial location and not in a personal dwelling or residence location, except that a personal dwelling location used for on-call delivery of oxygen USP for

homecare use if the person providing on-call delivery is employed by or acting under a written contract with an entity that holds a medical oxygen retailer permit;

(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 patient information; and

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

(2) Medical gas shall be stored under appropriate conditions in accordance with the manufacturer's recommendations on product labeling and department rules or, in the absence of rules, in accordance with applicable industry standards.

(3) Medical gas shall be packaged in accordance with official compendium standards, such as the USP-NF.

Section 21. Section 499.85, Florida Statutes, is created to read:

499.85 Security.—

(1) A permitholder that has a facility used for the distribution or retailing of medical gases shall protect such gases from unauthorized access by implementing all of the following security measures:

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

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

(c) Limiting access into areas where medical gases are held to authorized personnel.

(d) Equipping all facilities with a fence or other system

to detect or deter entry after hours.

(2) A facility used for distributing or retailing medical gases shall be equipped with a system that provides suitable protection against theft, including if appropriate, protection against theft of computers or electronic records and the protection of 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) If a wholesale distributor 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.

(6) The department shall adopt rules that govern the distribution of 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 regulations, including the labeling requirements of oxygen under the federal act.

Section 22. Section 499.86, Florida Statutes, is created to read:

499.86 Examination of materials.—

(1) A wholesale distributor must visually examine a medical

gas container upon receipt from the manufacturer in order to identify the medical gas stored within and to determine if the container has been damaged or is otherwise unfit for 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 found to be damaged or otherwise unfit pursuant to subsection (1) must be quarantined from the stock of medical gas until a determination is made that the medical gas in question is not misbranded or adulterated.

(3) An outgoing shipment must be inspected to identify the medical gases in the shipment to ensure that medical gas containers that have been damaged in storage or held under improper conditions are not distributed or dispensed.

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

Section 23. Section 499.87, Florida Statutes, is created to read:

499.87 Returned, damaged, and outdated medical gas.—

(1) A 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 a manufacturer using proper and adequate controls to ensure the identity, strength, quality, and purity of the reprocessed medical gas.

(2) A medical gas that has been subjected to improper conditions, such as a fire, accident, or natural disaster, may


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not be salvaged or reprocessed.

(3) A 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 of a medical gas container or closure system which does not impact the integrity of the medical gas is not considered damaged or adulterated for purposes of this subsection. If a 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.

(4) 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.

(5) A 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 24. 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 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 legally authorized to distribute medical gas within or into the state;

(c) The name of the responsible facility 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 United States Food and Drug Administration in accordance with s. 510 of the federal act and the manufacturer provides:

(a) Proof of such registration; and

(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.

(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 25. Section 499.89, Florida Statutes, is created to read:

499.89 Recordkeeping.—

(1) A permitholder under this part shall establish and maintain a record of transactions regarding the receipt and the distribution, or other disposition, of medical gases, as applicable. 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 of the following information, which may be kept in two separate documents one related to the distribution of medical gas and the other related to the receipt of medical gas:

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

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

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

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

(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 distribution date of high pressure medical gases.

(b) Two years following the distribution 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 pedigree paper is not required for distributing or dispensing medical gas.

(5) A wholesale distributor 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.

Section 26. 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 distribution of medical gases 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 United States

Food and Drug Administration or any federal, state, or local law enforcement or other government agency, including the department; or

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

(2) A procedure that includes preparation for, protection against, and responding to a crisis that affects the security or operation of a facility that stores medical gases in the event of a strike; a fire, flood, or other natural disaster; or other 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 27. 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 a medical gas that is adulterated, misbranded, or is otherwise unfit for distribution.

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

(3) The receipt of a 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.


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

(5) The purchase or receipt of a medical gas from a person not authorized to distribute or dispense medical gas or who is not exempted from permitting requirements to wholesale distribute medical gas to such purchaser or recipient.

(6) The knowing and willful sale or transfer of a medical gas to a recipient who is not legally authorized to receive a medical gas, except that a violation does not exist if a permitted wholesale distributor provides oxygen to a permitted medical oxygen retail establishment that is out of compliance with the notice of location change requirements of s. 499.834, provided that 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 required under this part and the rules adopted under this part.

(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 or the rules adopted under this part.

(9) The distribution of a 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 license or permit or operating without a valid license or permit, if one is required.

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

(12) Except for emergency use oxygen, the distribution of a medical gas to a patient without a prescription from a practitioner authorized by law to prescribe a medical gas.

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

(14) The distribution or dispensing of a 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 the medical gas.

(15) Failure to report an act prohibited under this part or the rules adopted under this part.

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

Section 28. 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) Adulterates or misbrands a medical gas with intent to defraud or deceive;

(b) Knowingly purchases or receives a medical gas from a person not legally authorized to distribute or dispense medical gas;

(c) Knowingly engages in the wholesale distribution of, or sells, barters, brokers, or transfers, a medical gas to a person not legally authorized to purchase or receive medical gas in the jurisdiction in which the person receives the medical gas. A permitted wholesale distributor that, at its location, provides oxygen to a permitted medical oxygen retail establishment that is out of compliance with only the change of location notice requirement under s. 499.834, does not commit a violation of this subsection if the wholesale distributor notifies the department of the transaction no later than the next business day; or

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

(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.

(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 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.

Section 29. 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, including inspections for initial permitting, permit renewal, and a permitholder’s change of location. The department may recognize a third party to inspect wholesale distributors in this state or other states pursuant to a schedule to be determined by the department.

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

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

(a) The manufacturing facility is currently registered with


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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; and

(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 in that state within the past 3 years, which demonstrates substantial compliance with current good manufacturing practices applicable to medical gases.

(4) A permitholder under this part shall exhibit or have readily available its state permits and its most recent inspection report administered by the department.

Section 30. 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 permitholder must be maintained as required under s. 499.051.

Section 31. 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 32. Paragraph (a) of subsection (1) of section


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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. 499.82(10).

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 33. 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


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surgery except as stated herein, or from practicing obstetrics.

2. Notwithstanding the prohibition against prescribing and administering legend drugs under subparagraph 1. or s. 499.83(2)(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 34. 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 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 35. 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


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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.

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Section 36. 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 37. 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

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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 38. This act shall take effect October 1, 2014.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to medical gas; amending s. 499.001, F.S.; conforming provisions to changes made by this act; amending s. 499.003, F.S.; revising terms; amending ss. 499.01 and 499.0121, F.S.; conforming provisions to changes made by this act; amending s. 499.01211, F.S.; adding a member of to the Drug Wholesale Distributor Advisory Council; authorizing the Compressed Gas Association to recommend one person to the council for appointment; amending ss. 499.041, 499.05, 499.051, 499.066, 499.0661, and 499.067, F.S.; conforming provisions to changes made by this act; creating part III of ch. 499, F.S., entitled "Medical Gas"; creating s. 499.81, F.S.; providing for the administration and enforcement of this part; creating s. 499.82, F.S.; defining terms; creating s. 499.83, F.S.; requiring a person or entity that intends to distribute medical gas within or into this state to obtain an applicable permit before operating; establishing categories of permits and setting

requirements for each; creating s. 499.831, F.S.; requiring the Department of Business and Professional Regulation to establish the form and content of an application; authorizing the department to set fees within certain parameters; creating s. 499.832, F.S.; providing that a permit expires 2 years after the last day of the month in which the permit was originally issued; providing requirements for the renewal of a permit; requiring the department to adopt rules for the renewal of permits; creating s. 499.833, F.S.; authorizing the department to approve certain permitholder changes; creating s. 499.834, F.S.; authorizing the department to consider certain factors in determining the eligibility of an applicant; creating s. 499.84, F.S.; setting the minimum requirements for the storage and handling of medical gas; creating s. 499.85, F.S.; 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 distribution of medical oxygen; creating s. 499.86, F.S.; requiring a wholesale distributor of medical gases to visually examine a medical gas container upon receipt in order to identify the medical gas stored within and to determine if the 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 of medical gas 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 a 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 a medical gas; providing certain exemptions; creating s. 499.89, F.S.; requiring a permitholder under this part to establish and maintain transactional records; providing a retention period for certain records and requiring that such 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 in the manufacture, retail sale, or wholesale distribution of medical to undergo an inspection; authorizing the department to authorize a third party to inspect such


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facilities; creating s. 499.931, F.S.; providing that trade secret information required to be 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; amending ss. 409.9201, 460.403, 465.0265, 499.01212, 499.015, and 499.024, F.S.; conforming cross references; providing an effective date.