CHAPTER 499

FLORIDA DRUG AND COSMETIC ACT

PART I DRUGS; DEVICES; COSMETICS; HOUSEHOLD PRODUCTS (ss. 499.001-499.067)

PART II ETHER (ss. 499.601-499.79)

PART III MEDICAL GAS (ss. 499.81-499.94)

PART I

DRUGS; DEVICES; COSMETICS; HOUSEHOLD PRODUCTS

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

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; s. 1, ch. 86-133; ss. 1, 52, ch. 92-69; s. 122, ch. 2014-17; s. 1, ch. 2014-89.

499.002 Purpose, administration, and enforcement of and exemption from this part.—

(1) This part is intended to:

(a) Safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics.

(b) Provide uniform legislation to be administered so far as practicable in conformity with the provisions of, and regulations issued under the authority of, the Federal Food, Drug, and Cosmetic Act and that portion of the Federal Trade Commission Act which expressly prohibits the false advertisement of drugs, devices, and cosmetics.

(c) Promote thereby uniformity of such state and federal laws, and their administration and enforcement, throughout the United States.

(2) The department shall administer and enforce this part to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics.

(3) For the purpose of any investigation or proceeding conducted by the department under this part, the department may administer oaths, take depositions, issue and serve subpoenas, and compel the attendance of witnesses and the production of books, papers, documents, or other evidence. The department shall exercise this power on its own initiative. Challenges to, and enforcement of, the 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 any violation of this part shall cause appropriate proceedings to be instituted in the proper courts without delay and to be 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 it believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning.

(6) Common carriers engaged in interstate commerce are not subject to this part if they are engaged in the usual course of business as common carriers.

(7) Notwithstanding any other law or local ordinance or regulation to the contrary, the regulation of over-the-counter proprietary drugs and cosmetics is expressly preempted to the state.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 2, 3, ch. 86-133; s. 2, ch. 87-50; ss. 2, 4, 6, 48, 49, 50, 52, ch. 92-69; s. 240, ch. 96-410; s. 236, ch. 99-8; s. 1, ch. 2008-207; s. 1, ch. 2020-118.

Note.—Subsection (2) former s. 499.004; subsection (3) former s. 499.0053; subsection (4) former s. 499.07; subsection (5) former s. 499.071; subsection (6) former s. 499.081.

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

(1) "Active pharmaceutical ingredient" includes any substance or mixture of substances intended, represented, or labeled for use in drug manufacturing that furnishes or is intended to furnish, in a finished dosage form, any pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or to affect the structure or any function of the body of humans or animals.

(2) "Advertisement" means any representation disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of drugs, devices, or cosmetics.

(3) "Affiliate" means a business entity that has a relationship with another business entity in which, directly or indirectly:

(a) The business entity controls, or has the power to control, the other business entity; or

(b) A third party controls, or has the power to control, both business entities.

(4) "Affiliated party" means:

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

(b) A person who, directly or indirectly, manages, controls, or oversees the operation of a permittee or applicant, regardless of whether such person is a partner, shareholder, manager, member, officer, director, independent contractor, or employee of the permittee or applicant;

(c) A person who has filed or is required to file a personal information statement pursuant to s. 499.012(9) or is required to be identified in an application for a permit or to renew a permit pursuant to s. 499.012(8); or

(d) The five largest natural shareholders that own at least 5 percent of the permittee or applicant.

(5) "Applicant" means a person applying for a permit or certification under this part.

(6) "Certificate of free sale" means a document prepared by the department which certifies a drug or device that is registered with the department as one that can be legally sold in the state.

(7) "Chain pharmacy warehouse" means a distributor permitted pursuant to s. 499.01 that maintains a physical location for prescription drugs that functions solely as a central warehouse to perform intracompany transfers of such drugs between members of an affiliate.

(8) "Closed pharmacy" means a pharmacy that is licensed under chapter 465 and purchases prescription drugs for use by a limited patient population and not for wholesale distribution or sale to the public. The term does not include retail pharmacies.

(9) "Color" includes black, white, and intermediate grays.

(10) "Color additive" means, with the exception of any material that has been or hereafter is exempt under the federal act, a material that:

(a) Is a dye pigment, or other substance, made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity from a vegetable, animal, mineral, or other source; or

(b) When added or applied to a drug or cosmetic or to the human body, or any part thereof, is capable alone, or through reaction with other substances, of imparting color thereto.

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

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

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

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

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

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

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

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

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

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

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

(16) "Distribute" or "distribution" means to sell, purchase, trade, deliver, handle, store, or receive. The term does not mean to administer or dispense.

(17) "Drug" means an article that is:

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

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

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

(d) Intended for use as a component of any article specified in paragraph (a), paragraph (b), or paragraph (c), and includes active pharmaceutical ingredients, but does not include devices or their nondrug components, parts, or accessories.

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

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

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

(21) "Health care entity" means a closed pharmacy or any person, organization, or business entity that provides diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care, but does not include any wholesale distributor or retail pharmacy licensed under state law to deal in prescription drugs. However, a blood establishment is a health care entity that may engage in the wholesale distribution of prescription drugs under s. 499.01(2)(h)1.c.

(22) "Health care facility" means a health care facility licensed under chapter 395.

(23) "Hospice" means a corporation licensed under part IV of chapter 400.

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

(25) "Immediate container" does not include package liners.

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

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

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

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

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

(29) "Manufacturer" means:

(a) A person who holds a New Drug Application, an Abbreviated New Drug Application, a Biologics License Application, or a New Animal Drug Application approved under the federal act or a license issued under s. 351 of the Public Health Service Act, 42 U.S.C. s. 262, for such drug or biologics, or if such drug or biologics are not the subject of an approved application or license, the person who manufactured the drug or biologics;

(b) A co-licensed partner of the person described in paragraph (a) who obtains the drug or biologics directly from a person described in paragraph (a), paragraph (c), or this paragraph;

(c) An affiliate of a person described in paragraph (a), paragraph (b), or this paragraph that receives the drug or biologics directly from a person described in paragraph (a), paragraph (b), or this paragraph; or

(d) A person who manufactures a device or a cosmetic.

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

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

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

(32) "New drug" means:

(a) Any drug the composition of which is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling of that drug; or

(b) Any drug the composition of which is such that the drug, as a result of investigations to determine its safety and effectiveness for use under certain conditions, has been recognized for use under such conditions, but which drug has not, other than in those investigations, been used to a material extent or for a material time under such conditions.

(33) "Nursing home" means a facility licensed under part II of chapter 400.

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

(35) "Permittee" means any person holding a permit issued under this chapter.

(36) "Person" means any individual, child, joint venture, syndicate, fiduciary, partnership, corporation, division of a corporation, firm, trust, business trust, company, estate, public or private institution, association, organization, group, city, county, city and county, political subdivision of this state, other governmental agency within this state, and any representative, agent, or agency of any of the foregoing, or any other group or combination of the foregoing.

(37) "Pharmacist" means a person licensed under chapter 465.

(38) "Pharmacy" means an entity licensed under chapter 465.

(39) "Prepackaged drug product" means a drug that originally was in finished packaged form sealed by a manufacturer and that is placed in a properly labeled container by a pharmacy or practitioner authorized to dispense pursuant to chapter 465 for the purpose of dispensing or by a facility holding a Class III institutional pharmacy permit.

(40) "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 act or s. 465.003(8), s. 499.007(13), subsection (31), or subsection (47), 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.

(41) "Prescription drug label" means any display of written, printed, or graphic matter upon the immediate container of any prescription drug before it is dispensed to an individual patient pursuant to a prescription of a practitioner authorized by law to prescribe.

(42) "Prescription label" means any display of written, printed, or graphic matter upon the immediate container of any prescription drug dispensed pursuant to a prescription of a practitioner authorized by law to prescribe.

(43) "Proprietary drug," or "OTC drug," means a patent or over-the-counter drug in its unbroken, original package, which drug is sold to the public by, or under the authority of, the manufacturer or primary distributor thereof, is not misbranded under the provisions of this part, and can be purchased without a prescription.

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

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

(46) "Retail pharmacy" means a community pharmacy licensed under chapter 465 that purchases prescription drugs at fair market prices and provides prescription services to the public.

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

(48) "Wholesale distribution" means the distribution of a prescription drug to a person other than a consumer or patient, or the receipt of a prescription drug by a person other than the consumer or patient, but does not include:

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

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

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

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

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

a. The agency or entity must obtain written authorization for the distribution of a prescription drug under this subparagraph from the Secretary of Business and Professional Regulation or his or her designee.

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

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

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

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

f. In addition to the departmental inspection authority set forth in s. 499.051, the establishment of the contract provider and subcontractor and all records pertaining to prescription drugs subject to this subparagraph shall be subject to inspection by the agency or entity. All records relating to prescription drugs of a manufacturer under this subparagraph shall be subject to audit by the manufacturer of those drugs, without identifying individual patient information.

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

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

2. The distribution of a prescription drug or offer to distribute a prescription drug for emergency medical reasons, which may include transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage. For purposes of this subparagraph, a drug shortage not caused by a public health emergency does not constitute an emergency medical reason.

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

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

5. The distribution of a prescription drug by a person authorized to purchase or receive prescription drugs to a person licensed or permitted to handle reverse distributions or destruction under the laws of the jurisdiction in which the person handling the reverse distribution or destruction receives the drug.

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

(c) Intracompany distribution of any drug between members of an affiliate or within a manufacturer.

(d) The distribution of a prescription drug by the manufacturer of the prescription drug.

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

(f) The distribution of a prescription drug by a third-party logistics provider permitted or licensed pursuant to and operating in compliance with the laws of this state and federal law if such third-party logistics provider does not take ownership of the prescription drug.

(g) The distribution of a prescription drug, or an offer to distribute a prescription drug by a repackager registered as a drug establishment with the United States Food and Drug Administration that has taken ownership or possession of the prescription drug and repacks it in accordance with this part.

(h) The purchase or other acquisition by a dispenser, hospital, or other health care entity of a prescription drug for use by such dispenser, hospital, or other health care entity.

(i) The distribution of a prescription drug by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager for the purpose of repackaging the prescription drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the prescription drug remains with the hospital or other health care entity at all times.

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

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

(l) The distribution of a prescription drug between pharmacies as a result of a sale, transfer, merger, or consolidation of all or part of the business of the pharmacies from or with another pharmacy, whether accomplished as a purchase and sale of stock or of business assets.

(m) The distribution of minimal quantities of prescription drugs by a licensed retail pharmacy to a licensed practitioner for office use in compliance with chapter 465 and rules adopted thereunder. The department shall adopt rules specifying the quantities of prescription drugs which are considered to be minimal quantities. However, until such rules are adopted, minimal quantities distributed may not exceed 3 percent of the retail pharmacy's total annual purchases of prescription drugs.

(n) The distribution of an intravenous prescription drug that, by its formulation, is intended for the replenishment of fluids and electrolytes, such as sodium, chloride, and potassium or calories, such as dextrose and amino acids.

(o) The distribution of an intravenous prescription drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions.

(p) The distribution of a prescription drug that is intended for irrigation or sterile water, whether intended for such purposes or for injection.

(q) The distribution of an exempt medical convenience kit pursuant to 21 U.S.C. s. 353(e)(4)(M).

(r) A common carrier that transports a prescription drug, if the common carrier does not take ownership of the prescription drug.

(s) Saleable drug returns when conducted by a dispenser.

(t) Facilitating the distribution of a prescription drug by providing solely administrative services, including processing of orders and payments.

(u) The distribution by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of prescription drugs donated to or supplied at a reduced price to the charitable organization to:

1. A licensed health care practitioner, as defined in s. 456.001, who is authorized under the appropriate practice act to prescribe and administer prescription drugs;

2. A health care clinic establishment permitted pursuant to this chapter; or

3. The Department of Health or the licensed medical director of a government agency health care entity, authorized to possess prescription drugs, for storage and use in the treatment of persons in need of emergency medical services, including controlling communicable diseases or providing protection from unsafe conditions that pose an imminent threat to public health, if the distributor and the receiving entity receive no direct or indirect financial benefit other than tax benefits related to charitable contributions. Distributions under this section that involve controlled substances must comply with all state and federal regulations pertaining to the handling of controlled substances.

(v) The distribution of medical gas pursuant to part III of this chapter.

(w) A hospital covered by s. 340B of the Public Health Service Act, 42 U.S.C. s. 256b, that arranges for a prescription drug wholesale distributor to distribute prescription drugs covered under that act directly to a contract pharmacy. Such hospital is exempt from obtaining a restricted prescription drug distributor permit under s. 499.01(2)(h).

(x) The dispensing or distribution of a medicinal drug by a Class III institutional pharmacy pursuant to s. 465.019.

(49) "Wholesale distributor" means a person, other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or a repackager, who is engaged in wholesale distribution.

History.—s. 34, ch. 82-225; s. 105, ch. 83-218; s. 1, ch. 83-265; s. 1, ch. 84-115; s. 1, ch. 87-57; s. 3, ch. 88-159; ss. 3, 15, 52, ch. 92-69; s. 584, ch. 97-103; s. 31, ch. 98-151; s. 235, ch. 99-8; ss. 124, 172, ch. 99-397; s. 34, ch. 2000-242; s. 10, ch. 2000-326; s. 38, ch. 2002-400; ss. 3, 13, 14, 25, ch. 2003-155; s. 1, ch. 2004-328; ss. 1, 2, ch. 2005-248; ss. 1, 3, ch. 2006-310; s. 122, ch. 2007-5; s. 20, ch. 2007-6; s. 104, ch. 2008-6; s. 2, ch. 2008-207; s. 60, ch. 2009-21; s. 1, ch. 2009-221; s. 22, ch. 2010-161; s. 2, ch. 2012-37; s. 33, ch. 2012-61; s. 3, ch. 2012-143; s. 122, ch. 2012-184; s. 2, ch. 2014-89; s. 15, ch. 2016-145; s. 2, ch. 2016-212; s. 2, ch. 2017-51; s. 5, ch. 2018-95.

Note.—Subsection (24) former s. 499.029(3)(f); subsection (25) former s. 499.029(3)(h); subsection (26) former s. 499.029(3)(i); subsection (34) former s. 499.029(3)(j); subsection (37) former s. 499.0661(1); subsection (39) former s. 499.029(3)(l); subsection (40) former s. 499.029(3)(m); subsection (46) intro., paragraphs (a), (b) former s. 499.012(1)(d); paragraph (46)(c) former s. 499.012(1)(e); subsection (50) former s. 499.012(1)(c); subsection (51) former s. 499.012(1)(f); subsection (53) former s. 499.012(1)(a); subsection (54) former s. 499.012(1)(b).

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

(1) The manufacture, repackaging, sale, delivery, or holding or offering for sale of any drug, device, or cosmetic that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use.

(2) The adulteration or misbranding of any drug, device, or cosmetic.

(3) The receipt of any drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery of such drug, device, or cosmetic, for pay or otherwise.

(4) The sale, distribution, purchase, trade, holding, or offering of any drug, device, or cosmetic in violation of this part.

(5) The dissemination of any false or misleading advertisement of a drug, device, or cosmetic.

(6) The refusal or constructive refusal:

(a) To allow the department to enter or inspect an establishment in which drugs, devices, or cosmetics are manufactured, processed, repackaged, sold, brokered, or held;

(b) To allow inspection of any record of that establishment;

(c) To allow the department to enter and inspect any vehicle that is being used to transport drugs, devices, or cosmetics; or

(d) To allow the department to take samples of any drug, device, or cosmetic.

(7) The purchase or sale of prescription drugs for wholesale distribution in exchange for currency, as defined in s. 560.103.

(8) Committing any act that causes a drug, device, or cosmetic to be a counterfeit drug, device, or cosmetic; or selling, dispensing, or holding for sale a counterfeit drug, device, or cosmetic.

(9) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of a drug, device, or cosmetic, or the doing of any other act with respect to a drug, device, or cosmetic, if the act is done while the drug, device, or cosmetic is held for sale and the act results in the drug, device, or cosmetic being misbranded.

(10) Forging; counterfeiting; simulating; falsely representing any drug, device, or cosmetic; or, without the authority of the manufacturer, using any mark, stamp, tag, label, or other identification device authorized or required by rules adopted under this part.

(11) The use, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application of the drug is effective when it is not or that the drug complies with this part when it does not.

(12) The possession of any drug in violation of this part.

(13) The sale, delivery, holding, or offering for sale of any self-testing kits designed to tell persons their status concerning human immunodeficiency virus or acquired immune deficiency syndrome or related disorders or conditions. This prohibition shall not apply to home access HIV test kits approved for distribution and sale by the United States Food and Drug Administration.

(14) The purchase or receipt of a prescription drug from a person that is not authorized under this chapter to distribute prescription drugs to that purchaser or recipient.

(15) The sale or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug to purchase or possess prescription drugs from the person selling or transferring the prescription drug.

(16) The purchase or receipt of a compressed medical gas from a person that is not authorized under this chapter to distribute compressed medical gases.

(17) The sale, purchase, or trade, or the offer to sell, purchase, or trade, a drug sample as defined in s. 499.028; the distribution of a drug sample in violation of s. 499.028; or the failure to otherwise comply with s. 499.028.

(18) Failure to maintain records as required by this part and rules adopted under this part.

(19) Providing the department with false or fraudulent records, or making false or fraudulent statements, regarding any matter within the provisions of this part.

[1](20) The importation of a prescription drug except as provided by s. 801(d) of the Federal Food, Drug, and Cosmetic Act.

(21) The wholesale distribution of any prescription drug that was:

(a) Purchased by a public or private hospital or other health care entity; or

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

unless the wholesale distribution of the prescription drug is authorized in s. 499.01(2)(h)1.c.

(22) Failure to obtain a permit or registration, or operating without a valid permit when a permit or registration is required by this part for that activity.

(23) Obtaining or attempting to obtain a prescription drug or device by fraud, deceit, misrepresentation or subterfuge, or engaging in misrepresentation or fraud in the distribution of a drug or device.

(24) The distribution of a prescription device to the patient or ultimate consumer without a prescription or order from a practitioner licensed by law to use or prescribe the device.

(25) Charging a dispensing fee for dispensing, administering, or distributing a prescription drug sample.

(26) Removing a pharmacy's dispensing label from a dispensed prescription drug with the intent to further distribute the prescription drug.

(27) Distributing a prescription drug that was previously dispensed by a licensed pharmacy, unless such distribution was authorized in chapter 465 or the rules adopted under chapter 465.

(28) Failure to acquire or deliver a transaction history, transaction information, or transaction statement as required under this part and rules adopted under this part.

History.—s. 34, ch. 82-225; s. 106, ch. 83-218; s. 1, ch. 83-265; s. 24, ch. 88-380; ss. 5, 52, ch. 92-69; s. 3, ch. 95-308; s. 585, ch. 97-103; s. 29, ch. 98-151; s. 37, ch. 99-397; s. 35, ch. 2000-242; s. 17, ch. 2001-63; s. 32, ch. 2001-89; s. 4, ch. 2003-155; s. 4, ch. 2006-310; s. 21, ch. 2007-6; s. 48, ch. 2008-177; s. 3, ch. 2008-207; s. 3, ch. 2012-37; s. 3, ch. 2016-212; s. 4, ch. 2019-99.

[1]**Note.**—

A. Section 11, ch. 2019-99, provides in part that "[i]mplementation of sections 2 through 10 of this act is contingent upon authorization granted under federal law, rule, or approval." Section 11, ch. 2019-99, was codified as s. 499.02851. Section 12, ch. 2019-99, provides that "[t]his act shall take effect July 1, 2019."

B. Subject to the contingency as to implementation in s. 11, ch. 2019-99, s. 4, ch. 2019-99, amends subsection (20), to read:

(20) The importation of a prescription drug except as provided by s. 801(d) of the Federal Food, Drug, and Cosmetic Act or s. 499.0285.

499.0051 Criminal acts.—

(1) FAILURE TO MAINTAIN OR DELIVER TRANSACTION HISTORY, TRANSACTION INFORMATION, OR TRANSACTION STATEMENT.—

(a) A person engaged in the distribution of prescription drugs who fails to deliver to another person a complete and accurate transaction history, transaction information, or transaction statement concerning a prescription drug or contraband prescription drug, as required by this chapter and rules adopted under this chapter, before, or simultaneous with, the transfer of the prescription drug or contraband prescription drug to another person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b) A person engaged in the distribution of prescription drugs who fails to acquire a complete and accurate transaction history, transaction information, or transaction statement concerning a prescription drug or contraband prescription drug, as required by this chapter and rules adopted under this chapter, before, or simultaneous with, the receipt of the prescription drug or

contraband prescription drug from another person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(c) Any person who knowingly destroys, alters, conceals, or fails to maintain a complete and accurate transaction history, transaction information, or transaction statement concerning any prescription drug or contraband prescription drug, as required by this chapter and rules adopted under this chapter, in his or her possession commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(2) KNOWING FORGERY OF TRANSACTION HISTORY, TRANSACTION INFORMATION, OR TRANSACTION STATEMENT.—A person who knowingly forges, counterfeits, or falsely creates any transaction history, transaction information, or transaction statement; who falsely represents any factual matter contained on any transaction history, transaction information, or transaction statement; or who knowingly omits to record material information required to be recorded in a transaction history, transaction information, or transaction statement, commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(3) KNOWING PURCHASE OR RECEIPT OF PRESCRIPTION DRUG FROM UNAUTHORIZED PERSON.—A person who knowingly purchases or receives from a person not authorized to distribute prescription drugs under this chapter a prescription drug in a wholesale distribution transaction commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(4) KNOWING SALE OR TRANSFER OF PRESCRIPTION DRUG TO UNAUTHORIZED PERSON. A person who knowingly sells or transfers to a person not authorized to purchase or possess prescription drugs, under the law of the jurisdiction in which the person receives the drug, a prescription drug in a wholesale distribution transaction commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(5) KNOWING SALE OR DELIVERY, OR POSSESSION WITH INTENT TO SELL, CONTRABAND PRESCRIPTION DRUGS.—A person who is knowingly in actual or constructive possession of any amount of contraband prescription drugs, who knowingly sells or delivers, or who possesses with intent to sell or deliver any amount of contraband prescription drugs, commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(6) KNOWING TRAFFICKING IN CONTRABAND PRESCRIPTION DRUGS.—A person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of any amount of contraband prescription drugs valued at $25,000 or more commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(a) Upon conviction, each defendant shall be ordered to pay a mandatory fine according to the following schedule:

1. If the value of contraband prescription drugs involved is $25,000 or more, but less than $100,000, the defendant shall pay a mandatory fine of $25,000. If the defendant is a corporation or other person that is not a natural person, it shall pay a mandatory fine of $75,000.

2. If the value of contraband prescription drugs involved is $100,000 or more, but less than $250,000, the defendant shall pay a mandatory fine of $100,000. If the defendant is a corporation or other person that is not a natural person, it shall pay a mandatory fine of $300,000.

3. If the value of contraband prescription drugs involved is $250,000 or more, the defendant shall pay a mandatory fine of $200,000. If the defendant is a corporation or other person that is not a natural person, it shall pay a mandatory fine of $600,000.

(b) As used in this subsection, the term "value" means the market value of the property at the time and place of the offense or, if such cannot be satisfactorily ascertained, the cost of replacement of the property within a reasonable time after the offense. Amounts of value of separate contraband prescription drugs involved in distinct transactions for the distribution of the contraband prescription drugs committed pursuant to one scheme or course of conduct, whether involving the same person or several persons, may be aggregated in determining the punishment of the offense.

(7) KNOWING FORGERY OF PRESCRIPTION OR PRESCRIPTION DRUG LABELS.—A person who knowingly forges, counterfeits, or falsely creates any prescription label or prescription drug label, or who falsely represents any factual matter contained on any prescription label or prescription drug label, commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(8) KNOWING SALE OR PURCHASE OF CONTRABAND PRESCRIPTION DRUGS RESULTING IN GREAT BODILY HARM.—A person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of any amount of contraband prescription drugs, and whose acts in violation of this subsection result in great bodily harm to a person, commits a felony of the first degree, as provided in s. 775.082, s. 775.083, or s. 775.084.

(9) KNOWING SALE OR PURCHASE OF CONTRABAND PRESCRIPTION DRUGS RESULTING IN DEATH.—A person who knowingly manufactures, sells, purchases, delivers, or brings into this state, or who is knowingly in actual or constructive possession of any amount of contraband prescription drugs, and whose acts in violation of this subsection result in the death of a person, commits a felony of the first degree, punishable by a term of years not exceeding life, as provided in s. 775.082, s. 775.083, or s. 775.084.

(10) VIOLATIONS OF S. 499.005 RELATED TO DEVICES AND COSMETICS; DISSEMINATION OF FALSE ADVERTISEMENT.—

(a) Any person who violates any of the provisions of s. 499.005 with respect to a device or cosmetic commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083; but, if the violation is committed after a conviction of such person under this

subsection has become final, such person is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083 or as otherwise provided in this part, except that any person who violates s. 499.005(8) or (10) with respect to a device or cosmetic commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in this part.

(b) A publisher, radio broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, wholesaler, or seller of the article to which a false advertisement relates, is not liable under this subsection by reason of the dissemination by him or her of such false advertisement, unless he or she has refused, on the request of the department, to furnish to the department the name and post office address of the manufacturer, wholesaler, seller, or advertising agency that asked him or her to disseminate such advertisement.

(11) ADULTERATED AND MISBRANDED DRUGS; FALSE ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS.—Any person who violates any of the following provisions commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083; but, if the violation is committed after a conviction of such person under this subsection has become final, such person commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, or as otherwise provided in this part:

(a) The manufacture, repackaging, sale, delivery, or holding or offering for sale of any drug that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use.

(b) The adulteration or misbranding of any drug intended for further distribution.

(c) The receipt of any drug that is adulterated or misbranded, and the delivery or proffered delivery of such drug, for pay or otherwise.

(d) The dissemination of any false or misleading advertisement of a drug.

(e) The use, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application of the drug is effective when it is not or that the drug complies with this part when it does not.

(f) The purchase or receipt of a compressed medical gas from a person that is not authorized under this chapter to distribute compressed medical gases.

(g) Charging a dispensing fee for dispensing, administering, or distributing a prescription drug sample.

(h) The failure to maintain records related to a drug as required by this part and rules adopted under this part, except for transaction histories, transaction information, or transaction statements, invoices, or shipping documents related to prescription drugs.

(i) The possession of any drug in violation of this part, except if the violation relates to a deficiency in transaction histories, transaction information, or transaction statements.

(12) REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING, OR TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO PRESCRIPTION DRUGS.—Any person who violates any of the following provisions commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in this part:

(a) The refusal or constructive refusal to allow:

1. The department to enter or inspect an establishment in which drugs are manufactured, processed, repackaged, sold, brokered, or held;

2. Inspection of any record of that establishment;

3. The department to enter and inspect any vehicle that is being used to transport drugs; or

4. The department to take samples of any drug.

(b) The sale, purchase, or trade, or the offer to sell, purchase, or trade, a drug sample as defined in s. 499.028; the distribution of a drug sample in violation of s. 499.028; or the failure to otherwise comply with s. 499.028.

(c) Providing the department with false or fraudulent records, or making false or fraudulent statements, regarding any matter within the provisions of this part related to a drug.

(d) The failure to receive, maintain, or provide invoices and shipping documents if applicable, related to the distribution of a prescription drug.

[1](e) The importation of a prescription drug for wholesale distribution, except as provided by s. 801(d) of the Federal Food, Drug, and Cosmetic Act.

(f) The wholesale distribution of a prescription drug that was:

1. Purchased by a public or private hospital or other health care entity; or

2. Donated or supplied at a reduced price to a charitable organization.

(g) The failure to obtain a permit as a prescription drug wholesale distributor when a permit is required by this part for that activity.

(h) Knowingly possessing any adulterated or misbranded prescription drug outside of a designated quarantine area.

(i) The purchase or sale of a prescription drug for wholesale distribution in exchange for currency, as defined in s. 560.103.

(13) OTHER VIOLATIONS.—Any person who violates any of the following provisions commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in this part:

(a) Knowingly manufacturing, repackaging, selling, delivering, or holding or offering for sale any drug that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use.

(b) Knowingly adulterating a drug that is intended for further distribution.

(c) Knowingly receiving a drug that is adulterated and delivering or proffering delivery of such drug for pay or otherwise.

(d) Committing any act that causes a drug to be a counterfeit drug, or selling, dispensing, or knowingly holding for sale a counterfeit drug.

(e) Forging, counterfeiting, simulating, or falsely representing any drug, or, without the authority of the

manufacturer, using any mark, stamp, tag, label, or other identification device authorized or required by rules adopted under this part.

(f) Knowingly obtaining or attempting to obtain a prescription drug for wholesale distribution by fraud, deceit, misrepresentation, or subterfuge, or engaging in misrepresentation or fraud in the distribution of a drug.

(g) Removing a pharmacy's dispensing label from a dispensed prescription drug with the intent to further distribute the prescription drug.

(h) Knowingly distributing a prescription drug that was previously dispensed by a licensed pharmacy, unless such distribution was authorized in chapter 465 or the rules adopted under chapter 465.

(14) FALSE ADVERTISEMENT.—A publisher, radio broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, repackager, wholesale distributor, or seller of the article to which a false advertisement relates, is not liable under subsection (11), subsection (12), or subsection (13) by reason of the dissemination by him or her of such false advertisement, unless he or she has refused, on the request of the department, to furnish to the department the name and post office address of the manufacturer, repackager, wholesale distributor, seller, or advertising agency that asked him or her to disseminate such advertisement.

(15) FALSE REPORT.—Any person who submits a report required by s. 499.0121(14) knowing that such report contains a false statement commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(16) CONTROLLED SUBSTANCE DISTRIBUTION. Any person who engages in the wholesale distribution of prescription drugs and who knowingly distributes controlled substances in violation of s. 499.0121(14) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. In addition to any other fine that may be imposed, a person convicted of such a violation may be sentenced to pay a fine that does not exceed three times the gross monetary value gained from such violation, plus court costs and the reasonable costs of investigation and prosecution.

History.—s. 34, ch. 82-225; s. 118, ch. 83-218; s. 1, ch. 83-265; ss. 47, 52, ch. 92-69; s. 595, ch. 97-103; s. 40, ch. 99-397; ss. 5, 6, 7, 8, 27, 28, ch. 2003-155; s. 16, ch. 2007-6; s. 49, ch. 2008-177; s. 4, ch. 2008-207; s. 16, ch. 2011-141; s. 4, ch. 2016-212; s. 5, ch. 2019-99.

[1]**Note.**—

A. Section 11, ch. 2019-99, provides in part that "[i]mplementation of sections 2 through 10 of this act is contingent upon authorization granted under federal law, rule, or approval." Section 11, ch. 2019-99, was codified as s. 499.02851. Section 12, ch. 2019-99, provides that "[t]his act shall take effect July 1, 2019."

B. Subject to the contingency as to implementation in s. 11, ch. 2019-99, s. 5, ch. 2019-99, amends paragraph (12)(e), to read:

(e) The importation of a prescription drug for wholesale distribution, except as provided by s. 801(d) of the Federal Food, Drug, and Cosmetic Act or s. 499.0285.

Note.—Subsection (7) former s. 499.0052; subsection (9) former s. 499.00535; subsection (10) former s. 499.00545; subsection (11) former s. 499.069; subsections (12)-(15) former s. 499.0691.

499.0054 Advertising and labeling of drugs, devices, and cosmetics; exemptions.—

(1) It is a violation of the Florida Drug and Cosmetic Act to perform or cause the performance of any of the following acts:

(a) The dissemination of any false advertisement of any drug, device, or cosmetic. An advertisement is false if it is false or misleading in any way.

(b) The distribution in commerce of any drug, device, or cosmetic, if its labeling or advertising is in violation of this part.

(c) The manufacturing, repackaging, packaging, selling, delivery, holding, or offering for sale of any drug, device, or cosmetic for which the advertising or labeling is false or misleading.

(d) The advertising of any drug, device, or cosmetic that is adulterated or misbranded.

(e) The receiving in commerce of any drug, device, or cosmetic that is falsely advertised or labeled or the delivering or proffering for delivery of any such drug, device, or cosmetic.

(f) The advertising or labeling of any product containing ephedrine, a salt of ephedrine, an isomer of ephedrine, or a salt of an isomer of ephedrine, for the indication of stimulation, mental alertness, weight loss, appetite control, energy, or other indications not approved by the pertinent United States Food and Drug Administration Over-the-Counter Final or Tentative Final Monograph or approved new drug application under the federal act. In determining compliance with this requirement, the department may consider the following factors:

1. The packaging of the product.
2. The name and labeling of the product.
3. The manner of distribution, advertising, and promotion of the product, including verbal representations at the point of sale.
4. The duration, scope, and significance of abuse of the particular product.

(g) The advertising of any drug or device represented to have any effect in any of the following conditions, disorders, diseases, or processes:

1. Blood disorders.
2. Bone or joint diseases.
3. Kidney diseases or disorders.
4. Cancer.
5. Diabetes.
6. Gall bladder diseases or disorders.
7. Heart and vascular diseases.
8. High blood pressure.
9. Diseases or disorders of the ear or auditory apparatus, including hearing loss or deafness.
10. Mental disease or intellectual disability.
11. Paralysis.
12. Prostate gland disorders.
13. Conditions of the scalp affecting hair loss.
14. Baldness.
15. Endocrine disorders.
16. Sexual impotence.
17. Tumors.
18. Venereal diseases.
19. Varicose ulcers.
20. Breast enlargement.
21. Purifying blood.
22. Metabolic disorders.
23. Immune system disorders or conditions affecting the immune system.
24. Extension of life expectancy.

25. Stress and tension.
26. Brain stimulation or performance.
27. The body's natural defense mechanisms.
28. Blood flow.
29. Depression.
30. Human immunodeficiency virus or acquired immune deficiency syndrome or related disorders or conditions.

(h) The representation or suggestion in labeling or advertising that an article is approved under this part, when such is not the case.

(2) In determining whether an advertisement is false or misleading, the department shall review the representations made or suggested by statement, word, design, device, sound, or any combination thereof within the advertisement and the extent to which the advertisement fails to reveal material facts with respect to consequences that can result from the use of the drug, device, or cosmetic to which the advertisement relates under the conditions of use prescribed in the labeling or advertisement.

(3)(a) An advertisement that is not prohibited under paragraph (1)(a) is not prohibited under paragraph (1)(g) if it is disseminated:

1. To the public solely to advertise the product for those indications that are safe and effective indications and the product is safe and effective for self-medication, as established by the United States Food and Drug Administration; or

2. Only to members of the medical, dental, pharmaceutical, or veterinary professions or appears only in the scientific periodicals of these professions.

(b) Compliance with this part and the rules adopted under this part creates no legal presumption that a drug or device is safe or effective.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 1, 2, 4, ch. 86-271; s. 5, ch. 88-172; s. 25, ch. 88-380; ss. 7, 8, 9, 52, ch. 92-69; ss. 2, 3, ch. 95-415; s. 36, ch. 2000-242; s. 5, ch. 2008-207; s. 17, ch. 2013-162.

Note.—Subsection (2) former s. 499.0055; subsection (3) former s. 499.0057.

499.006 Adulterated drug or device.—A drug or device is adulterated, if any of the following apply:

(1) It consists in whole or in part of any filthy, putrid, or decomposed substance.

(2) It has been produced, prepared, packed, or held under conditions whereby it could have been contaminated with filth or rendered injurious to health.

(3) It is a drug and 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 assure that the drug meets the requirements of this part and that the drug has the identity and strength, and meets the standard of quality and purity, which it purports or is represented to possess.

(4) It is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which could render the contents injurious to health.

(5) It is a drug and it bears or contains, for the purpose of coloring only, a color additive that is unsafe within the meaning of the federal act; or, if it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, and it is unsafe within the meaning of the federal act.

(6) It purports to be, or is represented as, a drug the name of which is recognized in the official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. The determination as to strength, quality, or purity must be made in accordance with the tests or methods of assay set forth in such compendium, or, when such tests or methods of assay are absent or inadequate, in accordance with those tests or methods of assay prescribed under authority of the federal act. A drug defined in the official compendium is not adulterated under this subsection merely because it differs from the standard of strength, quality, or purity set forth for that drug in such compendium if its difference in strength, quality, or purity from such standard is plainly stated on its label.

(7) It is not subject to subsection (6) and its strength differs from, or its purity or quality falls below the standard of, that which it purports or is represented to possess.

(8) It is a drug:

(a) With which any substance has been mixed or packed so as to reduce the quality or strength of the drug; or

(b) For which any substance has been substituted wholly or in part.

(9) It is a drug or device for which the expiration date has passed.

(10) It is a prescription drug for which the required transaction history, transaction information, or transaction statement is nonexistent, fraudulent, or incomplete under the requirements of this part or applicable rules, or that has been purchased, held, sold, or distributed at any time by a person not authorized under federal or state law to do so.

(11) It is a prescription drug subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian to a limited prescription drug veterinary wholesale distributor.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 10, 52, ch. 92-69; s. 9, ch. 2003-155; s. 1, ch. 2006-92; s. 6, ch. 2008-207; s. 5, ch. 2016-212.

499.007 Misbranded drug or device.—A drug or device is misbranded:

(1) If its labeling is in any way false or misleading.

(2) If in package form, it does not bear a label containing:

(a) The name and place of business of the manufacturer, repackager, or distributor of the finished dosage form of the drug. For the purpose of this paragraph, the finished dosage form of a prescription drug is that form of the drug which is, or is intended to be, dispensed or administered to the patient and requires no further manufacturing or processing other than packaging, reconstitution, and labeling; and

(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. However, under this section, reasonable variations are permitted, and the department shall establish by rule exemptions for small packages.

(3) If it is an active pharmaceutical ingredient in bulk form and does not bear a label containing:

(a) The name and place of business of the manufacturer, repackager, or distributor; and

(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

(4) If any word, statement, or other information required by or under this part to appear on the label or labeling is not prominently placed thereon with such conspicuousness as compared with other words, statements, designs, or devices in the labeling, and in such terms, as to render the word, statement, or other information likely to be read and understood under customary conditions of purchase and use.

(5) If it is a drug and is not designated solely by a name recognized in an official compendium and its label does not bear:

(a) The common or usual name of the drug, if any; and

(b) In case it is fabricated from two or more ingredients, the common or usual name and quantity of each active ingredient.

(6) If its labeling does not bear:

(a) Adequate directions for use; and

(b) Adequate warnings against use in those pathological conditions in which its use may be dangerous to health or against use by children if its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.

(7) If it purports to be a drug the name of which is recognized in the official compendium and it is not packaged and labeled as prescribed therein. However, the method of packaging may be modified with the consent of the department.

(8) If it has been found by the department to be a drug liable to deterioration and it is not packaged in such form and manner, and its label bears a statement of such precautions, as the department by rule requires as necessary to protect the public health. Such rule may not be established for any drug recognized in an official compendium until the department has informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and that body has failed within a reasonable time to prescribe such requirements.

(9) If it is:

(a) A drug and its container or finished dosage form is so made, formed, or filled as to be misleading;

(b) An imitation of another drug; or

(c) Offered for sale under the name of another drug.

(10) If it is dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling of the drug.

(11) If it is, purports to be, or is represented as a drug composed wholly or partly of insulin and it is not from a batch with respect to which a certificate has been issued pursuant to s. 506 of the federal act, which certificate is in effect with respect to the drug.

(12) If it is, purports to be, or is represented as a drug composed wholly or partly of any kind of antibiotic requiring certification under the federal act and it is not from a batch with respect to which a certificate has been issued pursuant to s. 507 of the federal act, which certificate is in effect with respect to the drug. However, this subsection does not apply to any drug or class of drugs exempted by regulations adopted under s. 507(c) or (d) of the federal act.

(13) If it is a drug intended for use by humans which is a habit-forming drug or which, because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drugs, or which is limited by an effective application under s. 505 of the federal act to use under the professional supervision of a practitioner licensed by law to prescribe such drug, if it is not dispensed only:

(a) Upon the written prescription of a practitioner licensed by law to prescribe such drug;

(b) Upon an oral prescription of such practitioner, which is reduced promptly to writing and filled by the pharmacist; or

(c) By refilling any such written or oral prescription, if such refilling is authorized by the prescriber in the original prescription or by oral order which is reduced promptly to writing and filled by the pharmacist.

This subsection does not relieve any person from any requirement prescribed by law with respect to controlled substances as defined in the applicable federal and state laws.

(14) If it is a drug that is subject to paragraph (13)(a), and if, at any time before it is dispensed, its label does not bear the statement:

(a) “Caution: Federal Law Prohibits Dispensing Without Prescription”;

(b) “Rx Only”;

(c) The prescription symbol followed by the word “Only”; or

(d) “Caution: State Law Prohibits Dispensing Without Prescription.”

(15) If it is a drug that is not subject to paragraph (13)(a), if at any time before it is dispensed its label bears the statement of caution required in subsection (14).

(16) If it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only and its packaging and labeling are not in conformity with the packaging and labeling requirements that apply to such color additive and are prescribed under the federal act.

(17) A drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to prescribe such drug is exempt from the requirements of this section, except subsections (1), (9), (11), and (12) and the packaging requirements of subsections (7) and (8), if the drug bears a label that contains the name and address of the dispenser or seller, the prescription number and the date the prescription was written or filled, the name of the prescriber and the name of the patient, and the directions for use and cautionary statements. This exemption does not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail or to any drug dispensed in violation of subsection (13). The department may, by rule, exempt

drugs subject to s. 499.062 from subsection (13) if compliance with that subsection is not necessary to protect the public health, safety, and welfare.

History.—s. 34, ch. 82-225; s. 107, ch. 83-218; s. 1, ch. 83-265; s. 2, ch. 84-115; ss. 11, 52, ch. 92-69; s. 586, ch. 97-103; s. 38, ch. 99-397; s. 10, ch. 2003-155; s. 84, ch. 2004-5; s. 7, ch. 2008-207.

499.008 Adulterated cosmetics.—A cosmetic is adulterated:

(1) If it bears or contains any poisonous or deleterious substance that is injurious to users under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual; however, this subsection does not apply to coal-tar hair dye:

(a) The label of which bears the following legend conspicuously displayed thereon: "Caution: This product contains ingredients which may cause skin irritation on certain individuals, and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness"; and

(b) The labeling of which bears adequate directions for such preliminary testing.

(2) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(3) If it has been produced, prepared, packed, or held under conditions whereby it could have become contaminated with filth or whereby it could have been rendered injurious to health.

(4) If it is not a hair dye and it is, or it bears or contains, a color additive that is unsafe within the meaning of the federal act.

(5) For the purposes of subsections (1) and (4), the term "hair dye" does not include eyelash dyes or eyebrow dyes.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 12, 52, ch. 92-69; s. 8, ch. 2008-207.

499.009 Misbranded cosmetics.—A cosmetic is misbranded:

(1) If its labeling is false or misleading in any particular.

(2) If in package form, it does not bear a label containing:

(a) The name and place of business of the manufacturer, packer, or distributor;

(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; however, under this paragraph reasonable variations are permitted, and the department shall establish by rule exemptions for small packages; and

(c) A declaration of ingredients in descending order of predominance, or as otherwise required by federal law.

(3) If any word, statement, or other information required by or under authority of this part to appear on the label or labeling is not prominently placed thereon with such conspicuousness as compared with other words, statements, designs, or devices in the labeling, and in such terms, as to render the word, statement, or other information likely to be read and understood by an individual under customary conditions of purchase and use.

(4) If its container is so made, formed, or filled as to be misleading.

(5) If it is a color additive, its packaging and labeling are not in conformity with the packaging and labeling requirements applicable to that color additive prescribed under the federal act. This subsection does not apply to packages of color additives that, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 13, 52, ch. 92-69; s. 9, ch. 2008-207.

499.01 Permits.—

[1](1) Before 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 nonresident prescription drug repackager;

(e) A prescription drug wholesale distributor;

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

(g) A retail pharmacy drug wholesale distributor;

(h) A restricted prescription drug distributor;

(i) A complimentary drug distributor;

(j) A freight forwarder;

(k) A veterinary prescription drug retail establishment;

(l) A veterinary prescription drug wholesale distributor;

(m) A limited prescription drug veterinary wholesale distributor;

(n) An over-the-counter drug manufacturer;

(o) A device manufacturer;

(p) A cosmetic manufacturer;

(q) A third party logistics provider; or

(r) A health care clinic establishment.

[1](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 distribution of prescription drugs for which the person is the manufacturer and must comply with s. 499.0121 and all other provisions of this part and rules adopted under this part. The department shall adopt rules for issuing a virtual prescription drug manufacturer permit to a person who engages in the manufacture of prescription drugs but does not make or take physical possession of any prescription drugs. The rules adopted by the department under this section may exempt virtual manufacturers from certain establishment, security, and storage requirements set forth in s. 499.0121.

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(48)(j) is not required to be permitted as a prescription drug manufacturer under this paragraph or to register products under s. 499.015.

(b) *Prescription drug repackager permit.*—A prescription drug repackager permit is required for any person that repackages a prescription drug in this state.

1. A person that operates an establishment permitted as a prescription drug repackager may engage in distribution of prescription drugs repackaged at that establishment and must comply with all of the provisions of this part and the rules adopted under this part that apply to a prescription drug manufacturer.

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

3. A prescription drug repackager permit is not required for distributing medicinal drugs or prepackaged drug products between entities under common control which each hold either an active Class III institutional pharmacy permit under chapter 465 or an active health care clinic establishment permit under paragraph (r). For purposes of this subparagraph, the term "common control" has the same meaning as in s. 499.003(48)(a)3.

[1](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 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 prescription drug manufacturer under this part. The department shall adopt rules for issuing a virtual nonresident prescription drug manufacturer permit to a person who engages in the manufacture of prescription drugs but does not make or take physical possession of any prescription drugs. The rules adopted by the department under this section may exempt virtual nonresident manufacturers from certain establishment, security, and storage requirements set forth in s. 499.0121.

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 distribution of such prescription drugs when required by this part. This subparagraph does not apply to a manufacturer that distributes prescription drugs only for the manufacturer of the prescription drugs where both manufacturers are affiliates.

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 prescription drug distributed 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.

(d) *Nonresident prescription drug repackager permit.*—A nonresident prescription drug repackager permit is required for any person located outside of this state, but within the United States or its territories, that repackages prescription drugs and engages in the distribution of such prescription drugs into this state.

1. A nonresident prescription drug repackager must comply with all of the provisions of this section and the rules adopted under this section that apply to a prescription drug manufacturer.

2. A nonresident prescription drug repackager must be permitted by the department and comply with all appropriate state and federal good manufacturing practices.

3. A nonresident prescription drug repackager must be registered as a drug establishment with the United States Food and Drug Administration.

(e) *Prescription drug wholesale distributor permit.* A prescription drug wholesale distributor permit is required for any person who is a wholesale distributor of prescription drugs and that wholesale distributes such prescription drugs in this state. The department may adopt rules for issuing a prescription drug wholesale distributor-broker permit to a person who engages in the wholesale distribution of prescription drugs and does not take physical possession of any prescription drugs.

(f) *Out-of-state prescription drug wholesale distributor permit.*—An out-of-state prescription drug wholesale distributor permit is required for any person that is a wholesale distributor located outside this state, but within the United States or its territories, which engages in the wholesale distribution of prescription drugs into this state. The out-of-state prescription drug wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident. If the state from which the wholesale distributor distributes prescription drugs does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor as required by the federal act.

(g) *Retail pharmacy drug wholesale distributor permit.*—A retail pharmacy drug wholesale distributor is a retail pharmacy engaged in wholesale distribution of prescription drugs within this state under the following conditions:

1. The pharmacy must obtain a retail pharmacy drug wholesale distributor permit pursuant to this part and rules adopted under this part.

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

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

4. The transfer is between a retail pharmacy and another retail pharmacy, or a Modified Class II

institutional pharmacy, or a health care practitioner licensed in this state and authorized by law to dispense or prescribe prescription drugs.

5. All records of sales of prescription drugs subject to this section must be maintained separate and distinct from other records and comply with the recordkeeping requirements of this part.

(h) *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(48)(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(48)(j) 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.

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.

5. A restricted prescription drug distributor permit is not required for distributions between pharmacies that each hold an active permit under chapter 465, have a common ownership, and are operating in a freestanding end-stage renal dialysis clinic, if such distributions are made to meet the immediate emergency medical needs of specifically identified patients and do not occur with such frequency as to amount to the regular and systematic supplying of that drug between the pharmacies. The department shall adopt rules establishing when the distribution of a prescription drug under this subparagraph amounts to the regular and systematic supplying of that drug.

6. A restricted prescription drug distributor permit is not required for distributing medicinal drugs or prepackaged drug products between entities under common control that each hold either an active Class III institutional pharmacy permit under chapter 465 or an active health care clinic establishment permit under paragraph (r). For purposes of this subparagraph, the term "common control" has the same meaning as in s. 499.003(48)(a)3.

(i) *Complimentary drug distributor permit.*—A complimentary drug distributor permit is required for any person that engages in the distribution of a complimentary drug, subject to the requirements of s. 499.028.

(j) *Freight forwarder permit.*—A freight forwarder permit is required for any person that engages in the distribution of a prescription drug as a freight forwarder unless the person is a common carrier. The storage, handling, and recordkeeping of such distributions must comply with the requirements for wholesale distributors under s. 499.0121. A freight forwarder must provide the source of the prescription drugs with a validated airway bill, bill of lading, or other appropriate documentation to evidence the exportation of the product.

(k) *Veterinary prescription drug retail establishment permit.*—A veterinary prescription drug retail establishment permit is required for any person that sells veterinary prescription drugs to the public but does not include a pharmacy licensed under chapter 465.

1. The sale to the public must be based on a valid written order from a veterinarian licensed in this state

who has a valid client-veterinarian relationship with the purchaser's animal.

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

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

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

5. A veterinary prescription drug retail establishment must sell a veterinary prescription drug in the original, sealed manufacturer's container with all labeling intact and legible. The department may adopt by rule additional labeling requirements for the sale of a veterinary prescription drug.

6. A veterinary prescription drug retail establishment must comply with all of the wholesale distribution requirements of s. 499.0121.

7. Prescription drugs sold by a veterinary prescription drug retail establishment pursuant to a practitioner's order may not be returned into the retail establishment's inventory.

(l) *Veterinary prescription drug wholesale distributor permit.*—A veterinary prescription drug wholesale distributor permit is required for any person that engages in the distribution of veterinary prescription drugs in or into this state. A veterinary prescription drug wholesale distributor that also distributes prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which it did not manufacture must obtain a permit as a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, or a limited prescription drug veterinary wholesale distributor in lieu of the veterinary prescription drug wholesale distributor permit. A veterinary prescription drug wholesale distributor must comply with the requirements for wholesale distributors under s. 499.0121.

(m) *Limited prescription drug veterinary wholesale distributor permit.*—Unless engaging in the activities of and permitted as a prescription drug manufacturer, nonresident prescription drug manufacturer, prescription drug wholesale distributor, or out-of-state prescription drug wholesale distributor, a limited prescription drug veterinary wholesale distributor permit is required for any person that engages in the distribution in or into this state of veterinary prescription drugs and prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act under the following conditions:

1. The person is engaged in the business of wholesaling prescription and veterinary prescription drugs to persons:

a. Licensed as veterinarians practicing on a full-time basis;

b. Regularly and lawfully engaged in instruction in veterinary medicine;

c. Regularly and lawfully engaged in law enforcement activities;

d. For use in research not involving clinical use; or

e. For use in chemical analysis or physical testing or for purposes of instruction in law enforcement activities, research, or testing.

2. No more than 30 percent of total annual prescription drug sales may be prescription drugs approved for human use which are subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.

3. The person does not distribute in any jurisdiction prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act to any person who is authorized to sell, distribute, purchase, trade, or use these drugs on or for humans.

4. A limited prescription drug veterinary wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $20,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Professional Regulation Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later.

5. A limited prescription drug veterinary wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident.

6. A limited prescription drug veterinary wholesale distributor must comply with the requirements for wholesale distributors under s. 499.0121.

7. A limited prescription drug veterinary wholesale distributor may not return to inventory for subsequent wholesale distribution any prescription drug subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian.

8. A limited prescription drug veterinary wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed to engage in the wholesale distribution of prescription drugs in its state of residence to a licensed limited prescription drug veterinary wholesale distributor in this state if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of s. 499.0121(6) must be followed for this transaction.

(n) *Over-the-counter drug manufacturer permit.*—An over-the-counter drug manufacturer permit is required for any person that engages in the manufacture or repackaging of an over-the-counter drug.

1. An over-the-counter drug manufacturer may not possess or purchase prescription drugs.

2. A pharmacy is exempt from obtaining an over-the-counter drug manufacturer permit if it is operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.

3. An over-the-counter drug manufacturer must comply with all appropriate state and federal good manufacturing practices.

(o) *Device manufacturer permit.*—

1. A device manufacturer permit is required for any person that engages in the manufacture, repackaging, or assembly of medical devices for human use in this state, except that a permit is not required if:

a. The person is engaged only in manufacturing, repackaging, or assembling a medical device pursuant to a practitioner's order for a specific patient; or

b. The person does not manufacture, repackage, or assemble any medical devices or components for such devices, except those devices or components which are exempt from registration pursuant to s. 499.015(8).

2. A manufacturer or repackager of medical devices in this state must comply with all appropriate state and federal good manufacturing practices and quality system rules.

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

(p) *Cosmetic manufacturer permit.*—A cosmetic manufacturer permit is required for any person that manufactures or repackages cosmetics in this state. A person that only labels or changes the labeling of a cosmetic but does not open the container sealed by the manufacturer of the product is exempt from obtaining a permit under this paragraph.

(q) *Third party logistics provider permit.*—A third party logistics provider permit is required for any person that contracts with a prescription drug wholesale distributor or prescription drug manufacturer to provide warehousing, distribution, or other logistics services on behalf of a manufacturer, wholesale distributor, or dispenser, but who does not take title to the prescription drug or have responsibility to direct the sale or disposition of the prescription drug. A third party logistics provider located outside of this state must be licensed in the state or territory from which the prescription drug is distributed by the third party logistics provider. If the state or territory from which the third party logistics provider originates does not require a license to operate as a third party logistics provider, the third party logistics provider must be licensed as a third party logistics provider as required by the federal act. Each third party logistics provider permittee shall comply with s. 499.0121 and other rules that the department requires.

(r) *Health care clinic establishment permit.*—A health care clinic establishment permit is required for the purchase of a prescription drug by a place of business at one general physical location that provides health care or veterinary services, which is owned and operated by a business entity that has been issued a federal employer tax identification number. For the purpose of this paragraph, the term "qualifying practitioner" means a licensed health care practitioner defined in s. 456.001, or a veterinarian licensed under chapter 474, who is authorized under the appropriate practice act to prescribe and administer a prescription drug.

1. An establishment must provide, as part of the application required under s. 499.012, designation of a qualifying practitioner who will be responsible for complying with all legal and regulatory requirements related to the purchase, recordkeeping, storage, and handling of the prescription drugs. In addition, the designated qualifying practitioner shall be the practitioner whose name, establishment address, and license number is used on all distribution documents for prescription drugs purchased or returned by the health care clinic establishment. Upon initial appointment of a qualifying practitioner, the qualifying practitioner and the health care clinic establishment shall notify the department on a form furnished by the department within 10 days after such employment. In addition, the qualifying practitioner and health care clinic establishment shall notify the department within 10 days after any subsequent change.

2. The health care clinic establishment must employ a qualifying practitioner at each establishment.

3. In addition to the remedies and penalties provided in this part, a violation of this chapter by the health care clinic establishment or qualifying practitioner constitutes grounds for discipline of the qualifying practitioner by the appropriate regulatory board.

4. The purchase of prescription drugs by the health care clinic establishment is prohibited during any period of time when the establishment does not comply with this paragraph.

5. A health care clinic establishment permit is not a pharmacy permit or otherwise subject to chapter 465. A health care clinic establishment that meets the criteria of a modified Class II institutional pharmacy under s. 465.019 is not eligible to be permitted under this paragraph.

6. This paragraph does not apply to the purchase of a prescription drug by a licensed practitioner under his or her license.

(3) A nonresident prescription drug manufacturer permit is not required for a manufacturer to distribute a prescription drug active pharmaceutical ingredient that it manufactures to a prescription drug manufacturer permitted in this state intended for research and development and not for resale or human use other than lawful clinical trials and biostudies authorized and regulated by federal law. A manufacturer claiming to be exempt from the permit requirements of this subsection and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6). The prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall maintain on file a record of the FDA registration number; if available, the out-of-state license, permit, or registration number; and, if available, a copy of the most current FDA inspection report, for all manufacturers from whom they purchase active pharmaceutical ingredients under this section. The failure to comply with the requirements of this subsection, or rules

adopted by the department to administer this subsection, for the purchase of prescription drug active pharmaceutical ingredients is a violation of s. 499.005(14), and a knowing failure is a violation of s. 499.0051(3).

(a) The immediate package or container of a prescription drug active pharmaceutical ingredient distributed into the state that is intended for research and development under this subsection shall bear a label prominently displaying the statement: "Caution: Research and Development Only—Not for Manufacturing, Compounding, or Resale."

(b) A prescription drug manufacturer that obtains a prescription drug active pharmaceutical ingredient under this subsection for use in clinical trials and or biostudies authorized and regulated by federal law must create and maintain records detailing the specific clinical trials or biostudies for which the prescription drug active pharmaceutical ingredient was obtained.

(4)(a) A permit issued under this part is not required to distribute a prescription drug active pharmaceutical ingredient from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for use by the recipient in preparing, deriving, processing, producing, or fabricating a prescription drug finished dosage form at the establishment in this state where the product is received under an approved and otherwise valid New Drug Approval Application, Abbreviated New Drug Application, New Animal Drug Application, or Therapeutic Biologic Application, provided that the application, active pharmaceutical ingredient, or finished dosage form has not been withdrawn or removed from the market in this country for public health reasons.

1. Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit, or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed. If the state from which the prescription drugs are distributed does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor as required by the federal act.

2. Any distributor claiming exemption from permitting requirements pursuant to this paragraph and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6).

(b) A permit issued under this part is not required to distribute a prescription drug that has not been repackaged from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for research and development or to a holder of a letter of exemption issued by the department under s. 499.03(4) for research, teaching, or testing.

1. Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit, or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed. If the state from which the prescription drugs are distributed does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor as required by the federal act.

2. All purchasers and recipients of any prescription drugs distributed pursuant to this paragraph shall ensure that the products are not resold or used, directly or indirectly, on humans except in lawful clinical trials and biostudies authorized and regulated by federal law.

3. Any distributor claiming exemption from permitting requirements pursuant to this paragraph, and the purchaser and recipient of the prescription drug, shall comply with the recordkeeping requirements of s. 499.0121(6).

4. The immediate package or container of any active pharmaceutical ingredient distributed into the state that is intended for teaching, testing, research, and development shall bear a label prominently displaying the statement: "Caution: Research, Teaching, or Testing Only – Not for Manufacturing, Compounding, or Resale."

(c) An out-of-state prescription drug wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed as a prescription drug wholesale distributor in its state of residence to a licensed prescription drug wholesale distributor in this state, if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of s. 499.0121(6) must be followed for such transactions.

(d) Persons receiving prescription drugs from a source claimed to be exempt from permitting requirements under this subsection shall maintain on file:

1. A record of the FDA establishment registration number, if any;

2. The resident state or federal license, registration, or permit that authorizes the source to distribute prescription drugs; and

3. A copy of the most recent resident state or FDA inspection report, for all distributors and establishments from whom they purchase or receive prescription drugs under this subsection.

(e) All persons claiming exemption from permitting requirements pursuant to this subsection who engage in the distribution of prescription drugs within or into the state are subject to this part, including ss. 499.005 and 499.0051, and shall make available, within 48 hours, to the department on request all records related to any prescription drugs distributed under this subsection, including those records described in s. 499.051(4), regardless of the location where the records are stored.

(f) A person purchasing and receiving a prescription drug from a person claimed to be exempt from licensing requirements pursuant to this subsection shall report to the department in writing within 14 days after receiving any product that is misbranded or adulterated or that fails to meet minimum standards set forth in the official compendium or state or federal good manufacturing practices for identity, purity, potency, or sterility, regardless of whether the product is thereafter rehabilitated, quarantined, returned, or destroyed.

(g) The department may adopt rules to administer this subsection which are necessary for the protection of the public health, safety, and welfare. Failure to comply with the requirements of this subsection, or rules adopted by the department to administer this subsection, is a violation of s. 499.005(14), and a knowing failure is a violation of s. 499.0051(3).

(h) This subsection does not relieve any person from any requirement prescribed by law with respect to controlled substances as defined in the applicable federal and state laws.

History.—s. 34, ch. 82-225; s. 108, ch. 83-218; s. 1, ch. 83-265; ss. 14, 15, 18, 19, 52, ch. 92-69; ss. 30, 31, 34, 35, ch. 98-151; ss. 37, 40, ch. 2000-242; s. 20, ch. 2001-53; s. 138, ch. 2001-277; ss. 11, 12, 13, 14, 18, 19, ch. 2003-155; s. 85, ch. 2004-5; ss. 2, 3, ch. 2004-328; ss. 2, 3, ch. 2006-92; ss. 22, 25, ch. 2007-6; ss. 10, 11, ch. 2008-207; s. 2, ch. 2009-221; ss. 23, 39, ch. 2010-161; s. 4, ch. 2012-37; s. 34, ch. 2012-61; s. 11, ch. 2012-143; s. 88, ch. 2013-15; s. 3, ch. 2014-89; s. 6, ch. 2016-212; s. 6, ch. 2018-95; s. 6, ch. 2019-99.

[1]**Note.**—

A. Section 11, ch. 2019-99, provides in part that "[i]mplementation of sections 2 through 10 of this act is contingent upon authorization granted under federal law, rule, or approval." Section 11, ch. 2019-99, was codified as s. 499.02851. Section 12, ch. 2019-99, provides that "[t]his act shall take effect July 1, 2019."

B. Subject to the contingency as to implementation in s. 11, ch. 2019-99, s. 6, ch. 2019-99, amends subsection (1) and paragraph (2)(c) and adds paragraph (2)(s), to read:

(1) Before 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 nonresident prescription drug repackager;
(e) A prescription drug wholesale distributor;
(f) An out-of-state prescription drug wholesale distributor;
(g) A retail pharmacy drug wholesale distributor;
(h) A restricted prescription drug distributor;
(i) A complimentary drug distributor;
(j) A freight forwarder;
(k) A veterinary prescription drug retail establishment;
(l) A veterinary prescription drug wholesale distributor;
(m) A limited prescription drug veterinary wholesale distributor;
(n) An over-the-counter drug manufacturer;
(o) A device manufacturer;
(p) A cosmetic manufacturer;
(q) A third party logistics provider;
(r) A health care clinic establishment; or
(s) An international prescription drug wholesale distributor.

* * * * *

(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 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 prescription drug manufacturer under this part. The department shall adopt rules for issuing a virtual nonresident prescription drug manufacturer permit to a person who engages in the manufacture of prescription drugs but does not make or take physical possession of any prescription drugs. The rules adopted by the department under this section may exempt virtual nonresident manufacturers from certain establishment, security, and storage requirements set forth in s. 499.0121.

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, an international prescription drug wholesale distributor permit, or third party logistics provider permit pursuant to this section to engage in the distribution of such prescription drugs when required by this part. This subparagraph does not apply to a manufacturer that distributes prescription drugs only for the manufacturer of the prescription drugs where both manufacturers are affiliates.

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 prescription drug distributed 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.

3.a. A nonresident prescription drug manufacturer that has registered to participate in the International Prescription Drug Importation Program pursuant to this section is not required to provide the list and approval required by subparagraph 2. for prescription drugs imported under that program.

b. To participate as an exporter of prescription drugs into this state under the International Prescription Drug Importation Program established under s. 499.0285, a nonresident prescription drug manufacturer located outside of the United States must register with the Department of Business and Professional Regulation before engaging in any activities under that section. Such manufacturer must be licensed or permitted in a country with which the United States has a current mutual recognition agreement, cooperation agreement, memorandum of understanding, or other federal mechanism recognizing the country's adherence to current good manufacturing practices for pharmaceutical products.

c. The department shall adopt rules governing the financial responsibility of a nonresident prescription drug manufacturer licensee or permittee. The rules will establish, at a minimum, financial reporting requirements, standards for financial capability to perform the functions governed by the permit, and requirements for ensuring permittees and their contractors can be held accountable for the financial consequences of any act of malfeasance or misfeasance or fraudulent or dishonest act or acts committed by the permittee or its contractors.

* * * * *

(s) *International prescription drug wholesale distributor.*—

1. A wholesale distributor located outside of the United States must obtain an international prescription drug wholesale distributor permit to engage in the wholesale exportation and distribution of prescription drugs in the state under the International Prescription Drug Importation Program established in s. 499.0285. The wholesale distributor must be licensed or permitted to operate in a country with which the United States has a mutual recognition agreement, cooperation agreement, memorandum of understanding, or other federal mechanism recognizing the country's adherence to current good manufacturing practices for pharmaceutical products. The wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with the laws of the jurisdiction in which it operates. An international prescription drug wholesale distributor permit may not be issued to a wholesale distributor if the jurisdiction in which the wholesale distributor operates does not require a license to engage in the wholesale distribution of prescription drugs.

2. The department shall adopt rules governing the financial responsibility of an international prescription drug wholesale distributor permittee. The rules will establish, at a minimum, financial reporting requirements, standards for financial capability to perform the functions governed by the permit, and requirements for ensuring permittees and their contractors can be held accountable for the financial consequences of any act of malfeasance or misfeasance or fraudulent or dishonest act or acts committed by the permittee or its contractors.

Note.—Subsection (2) intro. former s. 499.012(2) intro.; paragraph (2)(c) former s. 499.012(2)(e); paragraph (2)(d) former s. 499.012(2)(a); paragraph (2)(e) former s. 499.012(2)(c); paragraph (2)(f) former s. 499.012(2)(d); paragraph (2)(g) former s. 499.014; paragraph (2)(i) former s. 499.012(2)(f); paragraph (2)(k) former s. 499.012(2)(g); paragraph (2)(l) former s. 499.012(2)(h); paragraph (2)(n) former s. 499.012(2)(b); paragraph (2)(o) former s. 499.013(2)(c); paragraph (2)(p) former s. 499.013(2)(b); paragraph (2)(q) former s. 499.013(2)(d); paragraph (2)(r) former s. 499.013(2)(e).

499.012 Permit application requirements.—

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

(b) An establishment that is a place of residence may not receive a permit and may not operate under this part.

(c) A person that applies for or renews a permit to manufacture or distribute prescription drugs may not use a name identical to the name used by any other establishment or licensed person authorized to purchase prescription drugs in this state, except that a restricted drug distributor permit issued to a health care entity will be issued in the name in which the institutional pharmacy permit is issued and a retail pharmacy drug wholesale distributor will be issued a permit in the name of its retail pharmacy permit.

(d) A permit for a prescription drug manufacturer, prescription drug repackager, prescription drug wholesale distributor, limited prescription drug veterinary wholesale distributor, or retail pharmacy drug wholesale distributor may not be issued to the address of a health care entity or to a pharmacy licensed under chapter 465, except as provided in this paragraph. The department may issue a prescription drug manufacturer permit to an applicant at the same address as a licensed nuclear pharmacy, which is a health care entity, even if the nuclear pharmacy holds a special sterile compounding permit under chapter 465, for the purpose of manufacturing prescription drugs used in positron emission

tomography or other radiopharmaceuticals, as listed in a rule adopted by the department pursuant to this paragraph. The purpose of this exemption is to assure availability of state-of-the-art pharmaceuticals that would pose a significant danger to the public health if manufactured at a separate establishment address from the nuclear pharmacy from which the prescription drugs are dispensed. The department may also issue a retail pharmacy drug wholesale distributor permit to the address of a community pharmacy licensed under chapter 465, even if the community pharmacy holds a special sterile compounding permit under chapter 465, as long as the community pharmacy does not meet the definition of a closed pharmacy in s. 499.003.

(e) A county or municipality may not issue an occupational license for any establishment that requires a permit pursuant to this part, unless the establishment exhibits a current permit issued by the department for the establishment. Upon presentation of the requisite permit issued by the department, an occupational license may be issued by the municipality or county in which application is made. The department shall furnish to local agencies responsible for issuing occupational licenses a current list of all establishments licensed pursuant to this part.

[1](2) Notwithstanding subsection (6), a permitted person in good standing may change the type of permit issued to that person by completing a new application for the requested permit, paying the amount of the difference in the permit fees if the fee for the new permit is more than the fee for the original permit, and meeting the applicable permitting conditions for the new permit type. The new permit expires on the expiration date of the original permit being changed; however, a new permit for a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, or a retail pharmacy drug wholesale distributor shall expire on the expiration date of the original permit or 1 year after the date of issuance of the new permit, whichever is earlier. A refund may not be issued if the fee for the new permit is less than the fee that was paid for the original permit.

(3)(a) A written application for a permit or to renew a permit must be filed with the department on forms furnished by the department. The department shall establish, by rule, the form and content of the application to obtain or renew a permit. The applicant must submit to the department with the application a statement that swears or affirms that the information is true and correct.

(b) Upon a determination that 2 years have elapsed since the department notified an applicant for permit, certification, or product registration of a deficiency in the application and that the applicant has failed to cure the deficiency, the application shall expire. The determination regarding the 2-year lapse of time shall be based on documentation that the department notified the applicant of the deficiency in accordance with s. 120.60.

(c) Information submitted by an applicant on an application required pursuant to this subsection which is a trade secret, as defined in s. 812.081, shall be maintained by the department as trade secret information pursuant to s. 499.051(7).

[1](4)(a) Except for a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor, an application for a permit must include:

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

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

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

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

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

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

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

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

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

e. If a limited liability company, the name of each member, the name of each manager, the name of the limited liability company, and the name of the state in which the limited liability company was organized; and

f. Any other relevant information that the department requires.

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

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

(d) The department shall consider, at a minimum, the following factors in reviewing the qualifications of persons to be permitted under this part:

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

2. The applicant's having been disciplined by a regulatory agency in any state for any offense that would constitute a violation of this part.

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

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

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

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

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

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

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

(5)(a) The department shall adopt rules for the biennial renewal of permits; however, the department may issue up to a 4-year permit to selected permittees notwithstanding any other provision of law. Fees for such renewal may not exceed the fee caps set forth in s. 499.041 on an annualized basis as authorized by law.

(b) The department shall renew a permit upon receipt of the renewal application and renewal fee if the applicant meets the requirements established under this part and rules adopted under this part.

(c) At least 90 days before the expiration date of a permit, the department shall forward a permit renewal notification to the permittee at the mailing address of the permitted establishment on file with the department. The permit renewal notification must state conspicuously the date on which the permit for the establishment will expire and that the establishment may not operate unless the permit for the establishment is renewed timely.

(d) A permit issued under this part may be renewed by making application for renewal on forms furnished by the department and paying the appropriate fees.

1. If a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor renewal application and fee are submitted and postmarked later than 45 days before the expiration date of the permit, the permit may be renewed only upon payment of a late renewal fee of $100, plus the required renewal fee.

2. If any other renewal application and fee are submitted and postmarked after the expiration date of the permit, the permit may be renewed only upon payment of a late renewal delinquent fee of $100, plus the required renewal fee, not later than 60 days after the expiration date.

3. A permittee who submits a renewal application in accordance with this paragraph may continue to operate under its permit, unless the permit is suspended or revoked, until final disposition of the renewal application.

4. 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, before an establishment may engage in activities that require a permit under this part, the 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.

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

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

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

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

(c) If an establishment permitted under this part closes, the owner must notify the department in writing before the effective date of closure and must:

1. Return the permit to the department;

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

The department may revoke the permit of any person that fails to comply with the requirements of this subsection.

(7) A permit must be posted in a conspicuous place on the licensed premises.

[1](8) An application for a permit or to renew a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor submitted to the department must include:

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

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

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

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

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

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

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

3. If a corporation:

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

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

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

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

5. If a limited liability company:

a. The name and address of each member.

b. The name and address of each manager.

c. The name and address of the limited liability company, the resident agent of the limited liability company, and the name of the state in which the limited liability company was organized.

(f) If applicable, the name and address of each affiliate of the applicant.

(g) The applicant's gross annual receipts attributable to prescription drug wholesale distribution activities for the previous tax year.

(h) The tax year of the applicant.

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

(j) A list of all licenses and permits issued to the applicant by any other state which authorize the applicant to purchase or possess prescription drugs.

(k) The name of the manager of the establishment that is applying for the permit or to renew the permit, the next four highest ranking employees responsible for prescription drug wholesale operations for the establishment, and the name of all affiliated parties for the establishment, together with the personal information statement and fingerprints required pursuant to subsection (9) for each of such persons.

(l) The name of each of the applicant's designated representatives as required by subsection (15), together with the personal information statement and fingerprints required pursuant to subsection (9) for each such person.

(m) Evidence of a surety bond in this state or any other state in the United States in the amount of $100,000. If the annual gross receipts of the applicant's previous tax year are $10 million or less, evidence of a surety bond in the amount of $25,000. The specific language of the surety bond must include the State of Florida as a beneficiary, payable to the Professional Regulation Trust Fund. In lieu of the surety bond, the applicant may provide other equivalent security such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, which includes the State of Florida as a beneficiary, payable to the Professional Regulation Trust Fund. The purpose of the bond or other security is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later.

(n) For establishments used in wholesale distribution, proof of an inspection conducted by the department, the United States Food and Drug Administration, or another governmental entity charged with the regulation of good manufacturing practices related to wholesale distribution of prescription drugs, within timeframes set forth by the department in departmental rules, which demonstrates substantial compliance with current good manufacturing practices applicable to wholesale distribution of prescription drugs. The department may recognize another state's inspection of a wholesale distributor located in that state if such state's laws are deemed to be substantially equivalent to the law of this state by the department. The department may accept an inspection by a third-party accreditation or inspection service which meets the criteria set forth in department rule.

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

(p) Documentation of the credentialing policies and procedures required by s. 499.0121(15).

(9)(a) Each person required by subsection (8) or subsection (15) to provide a personal information statement and fingerprints shall provide the following information to the department on forms prescribed by the department:

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

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

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

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

5. Whether the person has been, during the past 7 years, the subject of any proceeding for the revocation of any license and, if so, the nature of the proceeding and the disposition of the proceeding.

6. Whether, during the past 7 years, the person has been enjoined, temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs, together with details concerning any such event.

7. A description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past 4 years, which manufactured, administered, prescribed, distributed, or stored pharmaceutical products and any lawsuits in which such businesses were named as a party.

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

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

9. A photograph of the person taken in the previous 180 days.

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

11. The name, address, occupation, and date and place of birth for each member of the person's immediate family who is 18 years of age or older. As used in this subparagraph, the term "member of the person's immediate family" includes the person's spouse, children, parents, siblings, the spouses of the person's children, and the spouses of the person's siblings.

12. Any other relevant information that the department requires.

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

(c) The department shall submit the fingerprints provided by a person for initial licensure to the Department of Law Enforcement for a statewide criminal record check and for forwarding to the Federal Bureau of Investigation for a national criminal record check of the person. The department shall submit the fingerprints provided by a person as a part of a renewal application to the Department of Law Enforcement for a statewide criminal record check, and for forwarding to the Federal Bureau of Investigation for a national criminal record check, for the initial renewal of a permit after January 1, 2004; for any subsequent renewal of a permit, the department shall submit the required information for a statewide and national criminal record check of the person. Any person who as a part of an initial permit application or initial permit renewal after January 1, 2004, submits to the department a set of fingerprints required for the criminal record check required in this paragraph is not required to provide a subsequent set of fingerprints for a criminal record check to the department, if the person has undergone a criminal record check as a condition of the issuance of an initial permit or the initial renewal of a permit of an applicant after January 1, 2004. The department is authorized to contract with private vendors, or enter into interagency agreements, to collect electronic fingerprints where fingerprints are required for registration, certification, or the licensure process or where criminal history record checks are required.

(d) For purposes of applying for renewal of a permit under subsection (8) or certification under subsection (15), a person may submit the following in lieu of satisfying the requirements of paragraphs (a), (b), and (c):

1. A photograph of the individual taken within 180 days; and

2. A copy of the personal information statement form most recently submitted to the department and a certification under oath, on a form specified by the department, that the individual has reviewed the previously submitted personal information statement form and that the information contained therein remains unchanged.

[1](10) The department may deny an application for a permit or refuse to renew a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor if:

(a) The applicant has not met the requirements for the permit.

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

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

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

(e) The applicant is lacking in experience in the distribution of prescription drugs.

(f) The applicant's past experience in manufacturing or distributing prescription drugs indicates that the applicant poses a public health risk.

(g) The applicant is affiliated directly or indirectly through ownership, control, or other business relations, with any person or persons whose business operations are or have been detrimental to the public health.

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

(i) The applicant or any affiliated party has been charged with a felony in a state or federal court and the disposition of that charge is pending during the application review or renewal review period.

(j) The applicant has furnished false or fraudulent information or material in any application made in this state or any other state in connection with obtaining a permit or license to manufacture or distribute drugs, devices, or cosmetics.

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

(l) The applicant does not possess the financial or physical resources to operate in compliance with the permit being sought, this chapter, and the rules adopted under this chapter.

(m) The applicant or any affiliated party receives, directly or indirectly, financial support and assistance from a person who was an affiliated party of a permittee whose permit was subject to discipline or was suspended or revoked, other than through the ownership of stock in a publicly traded company or a mutual fund.

(n) The applicant or any affiliated party receives, directly or indirectly, financial support and assistance from a person who has been found guilty of any violation of this part or chapter 465, chapter 501, or chapter 893, any rules adopted under this part or those chapters, any

federal or state drug law, or any felony where the underlying facts related to drugs, regardless of whether the person has been pardoned, had her or his civil rights restored, or had adjudication withheld, other than through the ownership of stock in a publicly traded company or a mutual fund.

(o) The applicant for renewal of a permit under s. 499.01(2)(e) or (f) has not actively engaged in the wholesale distribution of prescription drugs, as demonstrated by the regular and systematic distribution of prescription drugs throughout the year as evidenced by not fewer than 12 wholesale distributions in the previous year and not fewer than three wholesale distributions in the previous 6 months.

(p) Information obtained in response to s. 499.01(2)(e) or (f) demonstrates it would not be in the best interest of the public health, safety, and welfare to issue a permit.

(q) The applicant does not possess the financial standing and business experience for the successful operation of the applicant.

(r) The applicant or any affiliated party has failed to comply with the requirements for manufacturing or distributing prescription drugs under this part, similar federal laws, similar laws in other states, or the rules adopted under such laws.

[1](11) Upon approval of the application by the department and payment of the required fee, the department shall issue or renew a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor permit to the applicant.

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

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

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

2. The pharmacy maintains its permit under chapter 465;

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

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

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

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

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

(c) A separate establishment permit is not required when a permitted prescription drug wholesale distributor operates temporary transit storage facilities for the sole purpose of storage, for up to 16 hours, of a delivery of prescription drugs when the wholesale distributor was temporarily unable to complete the delivery to the recipient.

(d) The department shall require information from each wholesale distributor as part of the permit and renewal of such permit, as required under this section.

(13) Personnel employed in wholesale distribution must have appropriate education and experience to enable them to perform their duties in compliance with state permitting requirements.

[1](14) The name of a permittee or establishment on a prescription drug wholesale distributor permit or an out-of-state prescription drug wholesale distributor permit may not include any indicia of attainment of any educational degree, any indicia that the permittee or establishment possesses a professional license, or any name or abbreviation that the department determines is likely to cause confusion or mistake or that the department determines is deceptive, including that of any other entity authorized to purchase prescription drugs.

(15)[1](a) Each establishment that is issued an initial or renewal permit as a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor must designate in writing to the department at least one natural person to serve as the designated representative of the wholesale distributor. Such person must have an active certification as a designated representative from the department.

[1](b) To be certified as a designated representative, a natural person must:

1. Submit an application on a form furnished by the department and pay the appropriate fees.

2. Be at least 18 years of age.

3. Have at least 2 years of verifiable full-time:

a. Work experience in a pharmacy licensed in this state or another state, where the person's responsibilities included, but were not limited to, recordkeeping for prescription drugs;

b. Managerial experience with a prescription drug wholesale distributor licensed in this state or in another state; or

c. Managerial experience with the United States Armed Forces, where the person's responsibilities included, but were not limited to, recordkeeping, warehousing, distributing, or other logistics services pertaining to prescription drugs.

4. Receive a passing score of at least 75 percent on an examination given by the department regarding federal laws governing distribution of prescription drugs and this part and the rules adopted by the department governing the wholesale distribution of prescription drugs. This requirement shall be effective 1 year after the results of the initial examination are mailed to the persons that took the examination. The department shall offer such examinations at least four times each calendar year.

5. Provide the department with a personal information statement and fingerprints pursuant to subsection (9).

(c) The department may deny an application for certification as a designated representative or may suspend or revoke a certification of a designated representative pursuant to s. 499.067.

(d) A designated representative:

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

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

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

4. May serve as a designated representative for only one wholesale distributor at any one time.

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

[1](f) A wholesale distributor may not operate under a prescription drug wholesale distributor permit or an out-of-state prescription drug wholesale distributor permit for more than 10 business days after the designated representative leaves the employ of the wholesale distributor, unless the wholesale distributor employs another designated representative and notifies the department within 10 business days of the identity of the new designated representative.

History.—s. 34, ch. 82-225; s. 108, ch. 83-218; s. 1, ch. 83-265; ss. 14, 15, 52, ch. 92-69; s. 187, ch. 97-264; ss. 30, 31, ch. 98-151; s. 172, ch. 99-397; s. 37, ch. 2000-242; s. 20, ch. 2001-53; s. 138, ch. 2001-277; s. 38, ch. 2002-400; ss. 11, 12, 13, 14, ch. 2003-155; s. 85, ch. 2004-5; s. 3, ch. 2004-328; s. 2, ch. 2005-248; ss. 2, 3, ch. 2006-92; s. 22, ch. 2007-6; ss. 2, 10, 11, 28, ch. 2008-207; s. 61, ch. 2009-21; s. 17, ch. 2011-141; s. 67, ch. 2012-5; s. 34, ch. 2014-1; s. 9, ch. 2016-6; s. 7, ch. 2016-212; s. 77, ch. 2018-110; s. 7, ch. 2019-99.

[1]**Note.**—

A. Section 11, ch. 2019-99, provides in part that "[i]mplementation of sections 2 through 10 of this act is contingent upon authorization granted under federal law, rule, or approval." Section 11, ch. 2019-99, was codified as s. 499.02851. Section 12, ch. 2019-99, provides that "[t]his act shall take effect July 1, 2019."

B. Subject to the contingency as to implementation in s. 11, ch. 2019-99, s. 7, ch. 2019-99, amends subsection (2), paragraph (4)(a), subsections (8), (10), (11), and (14), and paragraphs (15)(a), (b), and (f), to read:

(2) Notwithstanding subsection (6), a permitted person in good standing may change the type of permit issued to that person by completing a new application for the requested permit, paying the amount of the difference in the permit fees if the fee for the new permit is more than the fee for the original permit, and meeting the applicable permitting conditions for the new permit type. The new permit expires on the expiration date of the original permit being changed; however, a new permit for a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, an international prescription drug wholesale distributor, or a retail pharmacy drug wholesale distributor shall expire on the expiration date of the original permit or 1 year after the date of issuance of the new permit, whichever is earlier. A refund may not be issued if the fee for the new permit is less than the fee that was paid for the original permit.

* * * * *

(4)(a) Except for a permit for a prescription drug wholesale distributor, an international prescription drug wholesale distributor, or an out-of-state prescription drug wholesale distributor, an application for a permit must include:

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

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

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

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

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

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

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

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

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

e. If a limited liability company, the name of each member, the name of each manager, the name of the limited liability company, and the name of the state in which the limited liability company was organized; and

f. Any other relevant information that the department requires.

* * * * *

(8) An application for a permit or to renew a permit for a prescription drug wholesale distributor, an international prescription drug wholesale distributor, or an out-of-state prescription drug wholesale distributor submitted to the department must include:

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

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

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

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

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

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

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

3. If a corporation:

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

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

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

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

5. If a limited liability company:

a. The name and address of each member.

b. The name and address of each manager.

c. The name and address of the limited liability company, the resident agent of the limited liability company, and the name of the state in which the limited liability company was organized.

(f) If applicable, the name and address of each affiliate of the applicant.

(g) The applicant's gross annual receipts attributable to prescription drug wholesale distribution activities for the previous tax year.

(h) The tax year of the applicant.

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

(j) A list of all licenses and permits issued to the applicant by any other state or jurisdiction which authorize the applicant to purchase or possess prescription drugs.

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

statement and fingerprints required pursuant to subsection (9) for each of such persons.

(l) The name of each of the applicant's designated representatives as required by subsection (15), together with the personal information statement and fingerprints required pursuant to subsection (9) for each such person.

(m) Evidence of a surety bond in this state or any other state in the United States in the amount of $100,000. If the annual gross receipts of the applicant's previous tax year are $10 million or less, evidence of a surety bond in the amount of $25,000. The specific language of the surety bond must include the State of Florida as a beneficiary, payable to the Professional Regulation Trust Fund. In lieu of the surety bond, the applicant may provide other equivalent security such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, which includes the State of Florida as a beneficiary, payable to the Professional Regulation Trust Fund. The purpose of the bond or other security is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later.

(n) For establishments used in wholesale distribution, proof of an inspection conducted by the department, the United States Food and Drug Administration, or another governmental entity charged with the regulation of good manufacturing practices related to wholesale distribution of prescription drugs, within timeframes set forth by the department in departmental rules, which demonstrates substantial compliance with current good manufacturing practices applicable to wholesale distribution of prescription drugs. The department may recognize another state's or jurisdiction's inspection of a wholesale distributor located in that state or jurisdiction if such state's or jurisdiction's laws are deemed to be substantially equivalent to the law of this state by the department. The department may accept an inspection by a third-party accreditation or inspection service which meets the criteria set forth in department rule.

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

(p) Documentation of the credentialing policies and procedures required by s. 499.0121(15).

(q) For international prescription drug wholesale distributors and nonresident prescription drug manufacturers to participate in the International Prescription Drug Importation Program established under s. 499.0285, documentation demonstrating that the applicant is appropriately licensed or permitted by a country with which the United States has a mutual recognition agreement, cooperation agreement, memorandum of understanding, or other mechanism recognizing the country's adherence to current good manufacturing practices for pharmaceutical products.

* * * * *

(10) The department may deny an application for a permit or refuse to renew a permit for a prescription drug wholesale distributor, an international prescription drug wholesale distributor, or an out-of-state prescription drug wholesale distributor if:

(a) The applicant has not met the requirements for the permit.

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

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

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

(e) The applicant is lacking in experience in the distribution of prescription drugs.

(f) The applicant's past experience in manufacturing or distributing prescription drugs indicates that the applicant poses a public health risk.

(g) The applicant is affiliated directly or indirectly through ownership, control, or other business relations, with any person or persons whose business operations are or have been detrimental to the public health.

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

(i) The applicant or any affiliated party has been charged with a felony in a state or federal court and the disposition of that charge is pending during the application review or renewal review period.

(j) The applicant has furnished false or fraudulent information or material in any application made in this state or any other state in connection with obtaining a permit or license to manufacture or distribute drugs, devices, or cosmetics.

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

(l) The applicant does not possess the financial or physical resources to operate in compliance with the permit being sought, this chapter, and the rules adopted under this chapter.

(m) The applicant or any affiliated party receives, directly or indirectly, financial support and assistance from a person who was an affiliated party of a permittee whose permit was subject to discipline or was suspended or revoked, other than through the ownership of stock in a publicly traded company or a mutual fund.

(n) The applicant or any affiliated party receives, directly or indirectly, financial support and assistance from a person who has been found guilty of any violation of this part or chapter 465, chapter 501, or chapter 893, any rules adopted under this part or those chapters, any federal or state drug law, or any felony where the underlying facts related to drugs, regardless of whether the person has been pardoned, had her or his civil rights restored, or had adjudication withheld, other than through the ownership of stock in a publicly traded company or a mutual fund.

(o) The applicant for renewal of a permit under s. 499.01(2)(e) or (f) has not actively engaged in the wholesale distribution of prescription drugs, as demonstrated by the regular and systematic distribution of prescription drugs throughout the year as evidenced by not fewer than 12 wholesale distributions in the previous year and not fewer than three wholesale distributions in the previous 6 months.

(p) Information obtained in response to s. 499.01(2)(e) or (f) demonstrates it would not be in the best interest of the public health, safety, and welfare to issue a permit.

(q) The applicant does not possess the financial standing and business experience for the successful operation of the applicant.

(r) The applicant or any affiliated party has failed to comply with the requirements for manufacturing or distributing prescription drugs under this part, similar federal laws, similar laws in other states, or the rules adopted under such laws.

(11) Upon approval of the application by the department and payment of the required fee, the department shall issue or renew a prescription drug wholesale distributor, an international prescription drug wholesale distributor, or an out-of-state prescription drug wholesale distributor permit to the applicant.

* * * * *

(14) The name of a permittee or establishment on a prescription drug wholesale distributor permit, an international prescription drug wholesale distributor permit, or an out-of-state prescription drug wholesale distributor permit may not include any indicia of attainment of any educational degree, any indicia that the permittee or establishment possesses a professional license, or any name or abbreviation that the department determines is likely to cause confusion or mistake or that the department determines is deceptive, including that of any other entity authorized to purchase prescription drugs.

(15)(a) Each establishment that is issued an initial or renewal permit as a prescription drug wholesale distributor, an international prescription drug wholesale distributor, or an out-of-state prescription drug wholesale distributor must designate in writing to the department at least one natural person to serve as the designated representative of the wholesale distributor. Such person must have an active certification as a designated representative from the department.

(b) To be certified as a designated representative, a natural person must:

1. Submit an application on a form furnished by the department and pay the appropriate fees.

2. Be at least 18 years of age.

3. Have at least 2 years of verifiable full-time:

a. Work experience in a pharmacy licensed in this state or another state or jurisdiction, where the person's responsibilities included, but were not limited to, recordkeeping for prescription drugs;

b. Managerial experience with a prescription drug wholesale distributor licensed in this state or in another state or jurisdiction; or

c. Managerial experience with the United States Armed Forces, where the person's responsibilities included, but were not limited to, recordkeeping, warehousing, distributing, or other logistics services pertaining to prescription drugs.

4. Receive a passing score of at least 75 percent on an examination given by the department regarding federal laws governing distribution of prescription drugs and this part and the rules adopted by the department governing the wholesale distribution of prescription drugs. This requirement shall be effective 1 year after the results of the initial examination are mailed to the persons that took the examination. The department shall offer such examinations at least four times each calendar year.

5. Provide the department with a personal information statement and fingerprints pursuant to subsection (9).

* * * * *

(f) A wholesale distributor may not operate under a prescription drug wholesale distributor permit, an international prescription drug wholesale distributor permit, or an out-of-state prescription drug wholesale distributor permit for more than 10 business days after the designated representative leaves the employ of the wholesale distributor, unless the wholesale distributor employs another designated representative and notifies the department within 10 business days of the identity of the new designated representative.

Note.—Subsections (1)-(7) former s. 499.01(2)-(8).

499.01201 Agency for Health Care Administration review and use of statute and rule violation or compliance data.—Notwithstanding any other provision of law, the Agency for Health Care Administration may not:

(1) Review or use any violation or alleged violation of s. 499.0121(6), or any rules adopted under that section, as a ground for denying or withholding any payment of a Medicaid reimbursement to a pharmacy licensed under chapter 465; or

(2) Review or use compliance with s. 499.0121(6), or any rules adopted under that section, as the subject

of any audit of Medicaid-related records held by a pharmacy licensed under chapter 465.

History.—s. 4, ch. 2005-248; s. 12, ch. 2008-207; s. 8, ch. 2016-212.

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.

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

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

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

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

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

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

(2) SECURITY.—

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

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

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

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

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

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

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

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

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

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

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

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

(4) EXAMINATION OF MATERIALS AND RECORDS.—

(a) Upon receipt, each outside shipping container must be visually examined for identity and to prevent the acceptance of contaminated prescription drugs that are otherwise unfit for distribution. This examination must be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(b) Each outgoing shipment must be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have expired or been damaged in storage or held under improper conditions.

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

(d) Upon receipt, a wholesale distributor must review records required under this section for the acquisition of prescription drugs for accuracy and completeness, considering the total facts and circumstances surrounding the transactions and the wholesale distributors involved.

(5) RETURNED, DAMAGED, OR OUTDATED PRESCRIPTION DRUGS.—

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

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

(b) Any prescription drugs of which the immediate or sealed outer containers or sealed secondary containers have been opened or used must be identified as such and must be quarantined and physically separated from other prescription drugs until they are destroyed or returned to the supplier.

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

(d) The recordkeeping requirements in subsection (6) must be followed for all outdated, damaged,

deteriorated, misbranded, or adulterated prescription drugs.

(6) RECORDKEEPING.—The department shall adopt rules that require keeping such records of prescription drugs, including active pharmaceutical ingredients, as are necessary for the protection of the public health.

(a) The following persons must maintain business records that include the information specified in paragraph (b):

1. Persons permitted or required to be permitted under this chapter to engage in the manufacture, repackaging, or distribution of active pharmaceutical ingredients or prescription drugs.

2. Persons other than those set forth in subparagraph 1. that engage in the receipt of active pharmaceutical ingredients or prescription drugs.

(b) Business records for persons specified in paragraph (a) must include:

1. The name and address of the seller, and the Florida permit number of the seller if such seller is not exempt from Florida permitting requirements, of the active pharmaceutical ingredient or prescription drug.

2. The address of the location the active pharmaceutical ingredient or prescription drug was shipped from.

3. The distribution date of the active pharmaceutical ingredient or prescription drug.

4. The name, strength, and quantity, and the National Drug Code if such code has been assigned, of the distributed active pharmaceutical ingredient or prescription drug.

5. The name and Florida permit number of the person that purchased the active pharmaceutical ingredient or prescription drug.

6. The financial data, including the unit type and unit price, for the distributions involving active pharmaceutical ingredients or prescription drugs.

7. The date and method of disposition of the active pharmaceutical ingredient or prescription drug.

(c) Each manufacturer or repackager of medical devices, over-the-counter drugs, or cosmetics must maintain business records that include:

1. The name and address of the seller or transferor of the product.

2. The address of the location the product was shipped from.

3. The date of the sale or distribution of the product.

4. The name and quantity of the product involved.

5. The name and address of the person who purchased the product.

(d) Persons permitted, or required to be permitted, under this chapter to engage in the manufacture, repackaging, or distribution of active pharmaceutical ingredients or prescription drugs; or the manufacture or repackaging of medical devices, over-the-counter drugs, and cosmetics; must establish, maintain, or have the capability to create a current inventory of the active pharmaceutical ingredients, prescription drugs, over-the-counter drugs, cosmetics, and devices at an establishment where activities specified in this paragraph are undertaken and must be able to produce such inventory for inspection by the department within 2 business days.

(e) Business records required to be kept pursuant to this section, and that are kept at the inspection site or can be immediately retrieved by computer or other electronic means, must be readily available for authorized inspection during the retention period. Records kept at a central location outside of this state which are not electronically retrievable must be made available for inspection within 2 working days after a request by an authorized official of a federal, state, or local law enforcement agency. Records maintained at a central location within this state must be maintained at an establishment that is permitted pursuant to this part, and such records must be readily available for inspection.

(f) Records required to be kept pursuant to this subsection must be maintained as specified for a period of not less than 6 years from the date of disposition of the active pharmaceutical ingredients, prescription drugs, over-the-counter drugs, medical devices, or cosmetics.

(g) To the extent that prescription drugs are also products as defined in the federal act, as amended, and the information required by the business records requirements of this section are also included in the tracking and tracing requirements of the federal act, as amended, and departmental rules, the manufacturer, wholesale distributor, repackager, or dispenser must follow both the requirements of the federal act, as amended, and departmental rules.

(7) PRESCRIPTION DRUG PURCHASE LIST.—

(a) Each wholesale distributor, except for a manufacturer, shall annually provide the department with a written list of all wholesale distributors and manufacturers from whom the wholesale distributor purchases prescription drugs. A wholesale distributor, except a manufacturer, shall notify the department not later than 10 days after any change to either list.

(b) Such portions of the information required pursuant to this subsection which are a trade secret, as defined in s. 812.081, shall be maintained by the department as trade secret information is required to be maintained under s. 499.051. This paragraph is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2021, unless reviewed and saved from repeal through reenactment by the Legislature.

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

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

(b) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure

must be adequate to deal with recalls and withdrawals due to:

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

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

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

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

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

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

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

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

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

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

(12) SHIPPING AND TRANSPORTATION.—The person responsible for shipment and transportation of a prescription drug in a wholesale distribution may use a common carrier; its own vehicle or employee acting within the scope of employment if authorized under s. 499.03 for the possession of prescription drugs in this state; or, in the case of a prescription drug intended for domestic distribution, an independent contractor who must be the agent of the authorized seller or recipient responsible for shipping and transportation as set forth in a written contract between the parties. A person selling a prescription drug for export must obtain documentation, such as a validated airway bill, bill of lading, or other appropriate documentation that the prescription drug was exported. A person responsible for shipping or transporting prescription drugs is not required to maintain documentation from a common carrier that the designated recipient received the prescription drugs; however, the person must obtain such documentation from the common carrier and make it available to the department upon request of the department.

(13) DUE DILIGENCE OF SUPPLIERS.—Prior to purchasing any prescription drugs from another wholesale distributor, a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, or a prescription drug repackager must:

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

(b) Determine that the selling wholesale distributor has insurance coverage of not less than the greater of 1 percent of the amount of total dollar volume of the prescription drug sales reported to the department under s. 499.012(8)(g) or $500,000; however the coverage need not exceed $2 million.

(c) Obtain information from the selling wholesale distributor, including the length of time the selling wholesale distributor has been licensed in this state, a copy of the selling wholesale distributor's licenses or permits, and background information concerning the ownership of the selling wholesale distributor, including the experience of the wholesale distributor in the wholesale distribution of prescription drugs.

(d) Verify that the selling wholesale distributor's Florida permit is valid.

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

1. Before purchasing any drug from the wholesale distributor, and at least once each subsequent year; or

2. Before purchasing any drug from the wholesale distributor, and each subsequent year obtain a complete copy of the most recent inspection report for the establishment which was prepared by the department or the regulatory authority responsible for wholesale distributors in the state in which the establishment is located.

(14) DISTRIBUTION REPORTING.—Each prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, retail pharmacy drug

wholesale distributor, manufacturer, or repackager that engages in the wholesale distribution of controlled substances as defined in s. 893.02 shall submit a report to the department of its receipts and distributions of controlled substances listed in Schedule II, Schedule III, Schedule IV, or Schedule V as provided in s. 893.03. Wholesale distributor facilities located within this state shall report all transactions involving controlled substances, and wholesale distributor facilities located outside this state shall report all distributions to entities located in this state. If the prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, retail pharmacy drug wholesale distributor, manufacturer, or repackager does not have any controlled substance distributions for the month, a report shall be sent indicating that no distributions occurred in the period. The report shall be submitted monthly by the 20th of the next month, in the electronic format used for controlled substance reporting to the Automation of Reports and Consolidated Orders System division of the federal Drug Enforcement Administration. Submission of electronic data must be made in a secured Internet environment that allows for manual or automated transmission. Upon successful transmission, an acknowledgment page must be displayed to confirm receipt. The report must contain the following information:

(a) The federal Drug Enforcement Administration registration number of the wholesale distributing location.

(b) The federal Drug Enforcement Administration registration number of the entity to which the drugs are distributed or from which the drugs are received.

(c) The transaction code that indicates the type of transaction.

(d) The National Drug Code identifier of the product and the quantity distributed or received.

(e) The Drug Enforcement Administration Form 222 number or Controlled Substance Ordering System Identifier on all Schedule II transactions.

(f) The date of the transaction.

The department must share the reported data with the Department of Law Enforcement and local law enforcement agencies upon request and must monitor purchasing to identify purchasing levels that are inconsistent with the purchasing entity's clinical needs. The Department of Law Enforcement shall investigate purchases at levels that are inconsistent with the purchasing entity's clinical needs to determine whether violations of chapter 893 have occurred.

(15) DUE DILIGENCE OF PURCHASERS.—

(a) Each prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, and retail pharmacy drug wholesale distributor must establish and maintain policies and procedures to credential physicians licensed under chapter 458, chapter 459, chapter 461, or chapter 466 and pharmacies that purchase or otherwise receive from the wholesale distributor controlled substances listed in Schedule II or Schedule III as provided in s. 893.03. The prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, or retail pharmacy drug wholesale distributor shall maintain records of such credentialing and make the records available to the department upon request. Such credentialing must, at a minimum, include:

1. A determination of the clinical nature of the receiving entity, including any specialty practice area.

2. A review of the receiving entity's history of Schedule II and Schedule III controlled substance purchasing from the wholesale distributor.

3. A determination that the receiving entity's Schedule II and Schedule III controlled substance purchasing history, if any, is consistent with and reasonable for that entity's clinical business needs.

(b) A wholesale distributor must take reasonable measures to identify its customers, understand the normal and expected transactions conducted by those customers, and identify those transactions that are suspicious in nature. A wholesale distributor must establish internal policies and procedures for identifying suspicious orders and preventing suspicious transactions. A wholesale distributor must assess orders for more than 7,500 unit doses of any one controlled substance in any one month to determine whether the purchase is reasonable. In making such assessments, a wholesale distributor may consider the purchasing entity's clinical business needs, location, and population served, in addition to other factors established in the distributor's policies and procedures. A wholesale distributor must report to the department any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the law. The wholesale distributor shall maintain records that document the report submitted to the department in compliance with this paragraph.

(c) A wholesale distributor may not distribute controlled substances to an entity if any criminal history record check for any person associated with that entity shows that the person has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction related to controlled substances, the practice of pharmacy, or the dispensing of medicinal drugs.

History.—s. 16, ch. 92-69; s. 32, ch. 98-151; ss. 38, 40, ch. 2000-242; ss. 15, 16, 18, ch. 2003-155; s. 86, ch. 2004-5; s. 4, ch. 2004-328; s. 10, ch. 2004-387; s. 3, ch. 2005-248; s. 5, ch. 2006-310; s. 17, ch. 2007-6; s. 13, ch. 2008-207; s. 62, ch. 2009-21; s. 3, ch. 2009-221; s. 40, ch. 2010-161; s. 18, ch. 2011-141; s. 123, ch. 2014-17; s. 4, ch. 2014-89; s. 10, ch. 2016-6; s. 22, ch. 2016-105; s. 26, ch. 2016-145; s. 9, ch. 2016-212.

Note.—Paragraph (6)(d) former s. 499.013(4).

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 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 additional members to the council who shall be appointed to a term of 4 years each, as follows:

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

(b) One person employed by a prescription drug wholesale distributor permitted under this part as defined in s. 499.003.

(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.

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

History.—s. 17, ch. 2003-155; s. 23, ch. 2007-6; s. 105, ch. 2008-6; s. 14, ch. 2008-207; s. 41, ch. 2010-161; s. 4, ch. 2012-143; s. 5, ch. 2014-89; s. 78, ch. 2018-110.

499.015 Registration of drugs and devices; issuance of certificates of free sale.—

[1](1)(a) Except for those persons exempted from the definition of manufacturer in s. 499.003, any person who manufactures, packages, repackages, labels, or relabels a drug or device in this state must register such drug or device 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 or device at the time of registration.

(b) The department may not register any product that does not comply with the Federal Food, Drug, and Cosmetic Act, as amended, or Title 21 C.F.R. Registration of a product by the department does not mean that the product does in fact comply with all provisions of the Federal Food, Drug, and Cosmetic Act, as amended.

(2) The department may require the submission of a catalog and specimens of labels at the time of application for registration of drugs or devices packaged and prepared in compliance with the federal act, which submission constitutes a satisfactory compliance for registration of the products. With respect to all other drugs and devices, the department may require the submission of a catalog and specimens of labels at the time of application for registration, but the registration will not become effective until the department has examined and approved the label of the drug or device. This approval or denial must include written notification to the manufacturer.

(3) Except for those persons exempted from the definition of manufacturer in s. 499.003, 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 or device to seizure and condemnation as provided in s. 499.062, and subjects such person to the penalties and remedies provided in this part.

(4) Unless a registration is renewed, it expires 2 years after the last day of the month in which it was issued. Any product registration issued or renewed on or after July 1, 2016, shall expire on the same date as the manufacturer or repackager permit of the person seeking to register the product. If the first product registration issued to a person on or after July 1, 2016, expires less than 366 days after issuance, the fee for product registration shall be $15. If the first product registration issued to a person on or after July 1, 2016, expires more than 365 days after issuance, the fee for product registration shall be $30. The department may issue a stop-sale notice or order against a person that is subject to the requirements of this section and that fails to comply with this section within 31 days after the date the registration expires. The notice or order shall prohibit such person from selling or causing to be sold any drugs or devices covered by this part until he or she complies with the requirements of this section.

(5) A product regulated under this section which is not included in the biennial registration may not be sold until it is registered and complies with this section.

(6) The department may issue a certificate of free sale for any product that is required to be registered under this part.

(7) A product registration is valid only for the company named on the registration and located at the address on the registration. A person whose product is registered by the department under this section must notify the department before any change in the name or address of the establishment to which the product is registered. If a person whose product is registered ceases conducting business, the person must notify the department before closing the business.

(8) Notwithstanding any requirements set forth in this part, a manufacturer of medical devices that is registered with the federal Food and Drug Administration is exempt from this section and s. 499.041(6) if:

(a) The manufacturer's medical devices are approved for marketing by, or listed with the federal Food and Drug Administration in accordance with federal law for commercial distribution; or

(b) The manufacturer subcontracts with a manufacturer of medical devices to manufacture components of such devices.

(9) However, the manufacturer must submit evidence of such registration, listing, or approval with its

initial application for a permit to do business in this state, as required in s. 499.01, and any changes to such information previously submitted at the time of renewal of the permit. Evidence of approval, listing, and registration by the federal Food and Drug Administration must include:

(a) For Class II devices, a copy of the premarket notification letter (510K);

(b) For Class III devices, a federal Food and Drug Administration premarket approval number;

(c) For a manufacturer who subcontracts with a manufacturer of medical devices to manufacture components of such devices, a federal Food and Drug Administration registration number; or

(d) For a manufacturer of medical devices whose devices are exempt from premarket approval by the federal Food and Drug Administration, a federal Food and Drug Administration registration number.

History.—s. 34, ch. 82-225; s. 110, ch. 83-218; s. 1, ch. 83-265; s. 3, ch. 84-115; ss. 20, 52, ch. 92-69; s. 587, ch. 97-103; s. 36, ch. 98-151; s. 1, ch. 99-165; s. 41, ch. 2000-242; s. 12, ch. 2000-326; s. 18, ch. 2001-63; s. 33, ch. 2001-89; s. 88, ch. 2004-5; s. 18, ch. 2008-207; s. 63, ch. 2009-21; s. 36, ch. 2014-89; s. 10, ch. 2016-212; s. 33, ch. 2017-3; s. 1, ch. 2017-51; s. 8, ch. 2019-99.

[1]**Note.**—

A. Section 11, ch. 2019-99, provides in part that "[i]mplementation of sections 2 through 10 of this act is contingent upon authorization granted under federal law, rule, or approval." Section 11, ch. 2019-99, was codified as s. 499.02851. Section 12, ch. 2019-99, provides that "[t]his act shall take effect July 1, 2019."

B. Subject to the contingency as to implementation in s. 11, ch. 2019-99, s. 8, ch. 2019-99, amends subsection (1), to read:

(1)(a) Except for those persons exempted from the definition of manufacturer in s. 499.003, any person who manufactures, packages, repackages, labels, or relabels a drug or device in this state must register such drug or device 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 or device at the time of registration.

(b) The department may not register any product that does not comply with the Federal Food, Drug, and Cosmetic Act, as amended, or Title 21 C.F.R. Registration of a product by the department does not mean that the product does in fact comply with all provisions of the Federal Food, Drug, and Cosmetic Act, as amended.

(c) Registration under this section is not required for prescription drugs imported under the International Prescription Drug Importation Program established in s. 499.0285.

499.023 New drugs; sale, manufacture, repackaging, distribution.—A person may not sell, offer for sale, hold for sale, manufacture, repackage, distribute, or give away any new drug unless an approved application has become effective under s. 505 of the federal act or unless otherwise permitted by the Secretary of the United States Department of Health and Human Services for shipment in interstate commerce.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 26, 52, ch. 92-69.

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.

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

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

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

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

(5) The department may by rule reclassify drugs subject to this part when such classification action is necessary to protect the public health.

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

History.—s. 9, ch. 88-159; s. 1, ch. 89-296; ss. 27, 52, ch. 92-69; s. 589, ch. 97-103; s. 42, ch. 2000-242; s. 13, ch. 2000-326; s. 61, ch. 2006-1; s. 106, ch. 2008-6; s. 19, ch. 2008-207; s. 5, ch. 2012-143; s. 37, ch. 2014-89.

499.025 Drug products in finished, solid, oral dosage form; identification requirements.—

(1) A drug product in finished, solid, oral dosage form for which a prescription is required by federal or state law may not be manufactured or distributed within this state unless it is clearly and prominently marked or imprinted with an individual symbol, number, company name, words, letters, marking, or national drug code, or any combination thereof, that identifies the drug product and the manufacturer or distributor of the drug product which has the ability to respond to requests for information regarding the drug product.

(2) A manufacturer or distributor must make available to the department on request descriptive material that identifies each current imprint used by the manufacturer.

(3) The department, upon application by a manufacturer, may exempt a particular drug product from the requirements of subsection (1) on the ground that imprinting is not feasible because of the size, texture, or other unique characteristic of the drug product.

(4) This section does not apply to drug products compounded by a pharmacist licensed under chapter 465 in a pharmacy operating under a permit issued by the Board of Pharmacy.

(5) The department shall adopt rules for implementing this section.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; s. 22, ch. 86-256; ss. 28, 52, ch. 92-69; s. 18, ch. 2000-326.

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

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

(a) "Drug sample," or "complimentary drug," means a human prescription drug that is labeled "sample," "not to be sold," "complimentary," or other words to that effect, that is provided as a courtesy, that is not intended to be sold, and that is intended to promote the sale of the drug.

(b) "Starter packs," also known as "stock samples," "trade packages," "initial dose packs," or "starter stocks," means human prescription drugs that are generally distributed without charge by manufacturers or distributors to pharmacies to be placed in stock and sold at retail. Although starter packs are generally given without charge to the pharmacy, they are not intended to be a free sample to the consumer nor are they labeled as such. Starter packs are subject to regulation as prescription drugs under the Florida Drug and Cosmetic

Act in the same manner as stock shipments of prescription drugs. Starter packs are not drug samples.

(2) A person may not sell, purchase, or trade or offer to sell, purchase, or trade any drug sample. An officer or executive of a drug manufacturer or distributor is not subject to criminal liability solely because of a sale, purchase, trade, or offer to sell, purchase, or trade of a drug sample in violation of this subsection by other employees of the manufacturer or distributor.

(3) Except as provided in this section, a representative of a drug manufacturer or distributor may not distribute any drug sample.

(a) The manufacturer or distributor of a human prescription drug may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed to prescribe such drugs or, at the request of a licensed practitioner, to pharmacies of hospitals or to pharmacies of other health care entities. Such a distribution of drug samples may only be made:

1. In response to a written request for drug samples made on a form that meets the requirements of paragraph (b); and

2. Under a system that requires the recipient of the drug sample to execute a written receipt for the drug sample upon its delivery and to return the receipt to the manufacturer or distributor.

(b) A written request for a drug sample that is required by this section must contain:

1. The name, address, professional designation, and signature of the practitioner who makes the request;

2. The name, strength, and dosage form of the drug sample requested and the quantity requested;

3. The name of the manufacturer of the drug sample requested; and

4. The date of the request.

(c) Each drug manufacturer or distributor that makes distributions by mail or common carrier under this paragraph must maintain, for a period of 3 years, the request forms submitted for such distributions and the receipts submitted for such distributions and must maintain a record of distributions of drug samples which identifies the drugs distributed and the recipients of the distributions. Forms, receipts, and records required to be maintained under this paragraph must be made available by the drug manufacturer or distributor to the department for its review and inspection.

(d) The manufacturer or distributor of a drug subject to paragraph (1)(a) may, by means other than mail or common carrier, distribute drug samples only if the manufacturer or distributor makes the distributions in accordance with paragraph (e) and carries out the activities described in subsections (4)-(9).

(e) Drug samples may only be distributed:

1. To a practitioner authorized by law to prescribe such drugs if the practitioner makes a written request for the drug samples; or

2. At the written request of such a practitioner, to pharmacies of hospitals or to pharmacies of other health care entities. The written request for drug samples must be made on a form that contains the practitioner's name, address, and professional designation, the name, strength, and dosage form of the drug sample requested, the quantity of drug samples requested, the name of the manufacturer or distributor of the drug sample, the date of the request, and the signature of the practitioner that makes the request.

(4) A drug manufacturer or distributor must store drug samples under the conditions described on their labels that will maintain the stability, integrity, and effectiveness of the drug samples and will assure that the drug samples remain free of contamination, deterioration, and adulteration.

(5) A drug manufacturer or distributor must conduct, at least annually, a complete and accurate inventory of all drug samples in the possession of representatives of the manufacturer or distributor. A drug manufacturer or distributor must maintain lists of the names and addresses of each of its representatives who distribute drug samples and of the sites where drug samples are stored. A drug manufacturer or distributor must maintain for at least 3 years records of all drug samples distributed, destroyed, or returned to the manufacturer or distributor, of all inventories maintained under this subsection, of all thefts or significant losses of drug samples, and of all requests made under[1] subparagraph 1. for drug samples. The drug manufacturer or distributor must make available to the department upon request any record or list maintained under this subsection. The department shall provide to the Department of Business and Professional Regulation the names of those practitioners who have received an excessive or inappropriate quantity of such drugs.

(6) A drug manufacturer or distributor must notify the department of any significant loss of drug samples and any known theft of drug samples.

(7) A drug manufacturer or distributor must report to the department any conviction of itself or of its assigns, agents, employees, or representatives for a violation of s. 503(c)(1) of the federal act or of this part because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample.

(8) Drug manufacturers or distributors must provide to the department the name and telephone number of the individual responsible for responding to a request for information regarding drug samples.

(9) All out-of-date drug samples must be returned to the manufacturer or distributor of that drug sample.

(10) A manufacturer or distributor may not directly or through its agents, employees, or independent contractors, hold, distribute, or otherwise dispose of any complimentary drugs or drug samples in this state without first obtaining a complimentary drug distributor permit pursuant to this section.

(11)(a) Application for a permit by a manufacturer or distributor to hold, distribute, or otherwise dispose of drugs pursuant to this section must be made on a form prescribed by the department and must be accompanied by an application fee in an amount not exceeding $250 per year, as is determined by the department.

(b) A permit issued under this section expires 2 years after the date of issuance, unless sooner suspended or revoked.

(c) A permit is renewable biennially upon the filing of an application for renewal and the payment of a renewal

fee of not more than $250 per year, as determined by the department, if the applicant meets the requirements established by this section and the rules adopted under this section.

(12) The department may suspend or revoke a permit issued under this section, after giving notice and an opportunity to be heard pursuant to chapter 120, when:

(a) Such permit was obtained by misrepresentation or fraud or through a mistake of the department.

(b) The holder of the permit has distributed or disposed of any prescription drug, directly or through its agents, employees, or independent contractors, to any person not authorized to possess such drug.

(c) The holder of the permit, or its agents, employees, or independent contractors, has distributed or possessed any prescription drug except in the usual course of its business.

(d) The holder of the permit, or its agents, employees, or independent contractors, has distributed any prescription drug that is misbranded or adulterated under this part.

(e) The holder of the permit, or its agents, employees, or independent contractors, has distributed any prescription drug without written request, when a written request is required by this section.

(f) The holder of the permit has in its employ, or uses as agent or independent contractor for the purpose of distributing or disposing of drugs, any person who has:

1. Violated the requirements of this section or any rule adopted under this section.

2. Been convicted in any of the courts of this state, the United States, or any other state of a felony or any other crime involving moral turpitude or involving those drugs named or described in chapter 893.

(13) The department may, pursuant to chapter 120, impose an administrative fine, not to exceed $5,000 per violation per day, for the violation of this section or rules adopted under this section. Each day such violation continues constitutes a separate violation, and each such separate violation is subject to a separate fine. All amounts collected under this section shall be deposited into the Professional Regulation Trust Fund. In determining the amount of fine to be levied for a violation, the following factors must be considered:

(a) The severity of the violation.

(b) Any actions taken by the permittee to correct the violation or to remedy complaints.

(c) Any previous violations.

(14) Chapter 893 applies to all drug samples that are controlled substances.

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

(a) The drug sample was prescribed to her or him as evidenced by the label required in s. 465.0276(4).

(b) She or he is the employee of a complimentary drug distributor that holds a permit issued under this part.

(c) She or he is a person to whom prescription drug samples may be distributed pursuant to this section.

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

History.—s. 34, ch. 82-225; s. 114, ch. 83-218; s. 1, ch. 83-265; s. 8, ch. 84-115; s. 23, ch. 86-256; ss. 29, 52, ch. 92-69; s. 198, ch. 94-218; s. 23, ch. 97-98; s. 590, ch. 97-103; s. 39, ch. 99-397; s. 20, ch. 2008-207; s. 12, ch. 2012-143; s. 34, ch. 2016-230.

[1]**Note.**—Subsection (5) does not contain subparagraphs.

[1]499.0285 International Prescription Drug Importation Program.—

(1) PROGRAM ESTABLISHED.—The department shall establish a program for the importation of safe and effective prescription drugs from foreign nations with which the United States has current mutual recognition agreements, cooperation agreements, memoranda of understanding, or other federal mechanisms recognizing their adherence to current good manufacturing practices for pharmaceutical products.

(2) DEFINITIONS.—As used in this section, the term:

(a) "Exporter" means an international prescription drug wholesale distributor, a nonresident prescription drug manufacturer registered to participate in the program, or an international export pharmacy that exports prescription drugs into this state under the program.

(b) "Federal act" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq. as amended by the Drug Quality and Security Act, 21 U.S.C. s. 351 et seq.

(c) "Foreign recipient" means an entity other than the original prescription drug manufacturer which receives the prescription drug before its importation into this state under the program.

(d) "Good manufacturing practice" refers to the good manufacturing practice regulations in 21 C.F.R. parts 210 and 211.

(e) "Importer" means a wholesale distributor, pharmacy, or pharmacist importing prescription drugs into this state under the program.

(f) "International export pharmacy" means a pharmacy located outside of the United States which holds an active and unencumbered permit under chapter 465 to export prescription drugs into this state under the program.

(g) "International prescription drug wholesale distributor" means a prescription drug wholesale distributor located outside of the United States which holds an active and unencumbered permit under this part to export and distribute prescription drugs into this state under the program.

(h) "Nonresident prescription drug manufacturer" means an entity located outside of the United States which holds an active and unencumbered permit under this part to manufacture prescription drugs and has registered with the department to export and distribute such prescription drugs into this state under the program.

(i) "Pharmacist" means a person who holds an active and unencumbered license to practice pharmacy under chapter 465.

(j) "Pharmacy" means an entity that holds an active and unencumbered permit under chapter 465.

(k) "Prescription drug" has the same meaning as defined in this part, but is limited to drugs intended for human use.

(l) "Program" means the International Prescription Drug Importation Program established under this section.

(m) "Qualified laboratory" means a laboratory that has been approved by the department for the purposes of this section.

(3) ELIGIBLE PRESCRIPTION DRUGS.—An eligible importer may import a prescription drug from an eligible exporter if:

(a) The drug meets the United States Food and Drug Administration's standards related to safety, effectiveness, misbranding, and adulteration;

(b) Importing the drug would not violate the patent laws of the United States; and

(c) The drug is not:

1. A controlled substance as defined in 21 U.S.C. s. 802;

2. A biological product as defined in 42 U.S.C. s. 262;

3. An infused drug;

4. An intravenously injected drug;

5. A drug that is inhaled during surgery; or

6. A drug that is a parenteral drug, the importation of which is determined by the United States Secretary of Health and Human Services to pose a threat to the public health.

(4) EXPORTERS.—

(a) The following entities may export prescription drugs into this state under the program:

1. An international prescription drug wholesale distributor.

2. A nonresident prescription drug manufacturer.

3. An international export pharmacy.

(b) An eligible exporter must register with the department before exporting prescription drugs into this state under the program.

(c) An exporter may not distribute, sell, or dispense prescription drugs imported under the program to any person residing outside of the state.

(5) IMPORTERS.—

(a) The following entities may import prescription drugs under the program:

1. A wholesale distributor.

2. A pharmacy.

3. A pharmacist.

(b) An eligible importer must register with the department before importing prescription drugs into this state under the program.

(c) An importer may not distribute, sell, or dispense prescription drugs imported under the program to any person residing outside of the state.

(6) PRESCRIPTION DRUG SUPPLY CHAIN DOCUMENTATION.—

(a) A participating importer must submit the following information and documentation to the department:

1. The name and quantity of the active ingredient of the prescription drug.

2. A description of the dosage form of the prescription drug.

3. The date on which the prescription drug is shipped.

4. The quantity of the prescription drug that is shipped.

5. The point of origin and destination of the prescription drug.

6. The price paid by the importer for the prescription drug.

7. Documentation from the exporter specifying:

a. The original source of the prescription drug; and

b. The quantity of each lot of the prescription drug originally received by the seller from that source.

8. The lot or control number assigned to the prescription drug by the manufacturer.

9. The name, address, telephone number, and professional license or permit number of the importer.

10. In the case of a prescription drug that is shipped directly by the first foreign recipient from the manufacturer:

a. Documentation demonstrating that the prescription drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer.

b. Documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating that the quantity being imported into this state is not more than the quantity that was received by the first foreign recipient.

c. For an initial imported shipment, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation.

11. In the case of a prescription drug that is not shipped directly from the first foreign recipient, documentation demonstrating that each batch in each shipment offered for importation into this state was statistically sampled and tested for authenticity and degradation.

12. For an initial imported shipment of a specific drug by an importer, the department shall ensure that each batch of the drug in the shipment is statistically sampled and tested for authenticity and degradation in a manner consistent with the federal act. The agency may contract with a vendor for these functions.

13. For every subsequent imported shipment of that drug by that importer, the department shall ensure that a statistically valid sample of the shipment was tested for authenticity and degradation in a manner consistent with the federal act.

14. Certify that the drug:

a. Is approved for marketing in the United States and is not adulterated or misbranded; and

b. Meets all of the labeling requirements under 21 U.S.C. s. 352.

15. Maintain qualified laboratory records, including complete data derived from all tests necessary to ensure that the drug is in compliance with the requirements of this section.

16. Maintain documentation demonstrating that the testing required by this section was conducted at a qualified laboratory in accordance with the federal act and any other applicable federal and state laws and regulations governing laboratory qualifications.

(b) All testing required by this section must be conducted in a qualified laboratory that meets the standards under the federal act and any other applicable federal and state laws and regulations governing laboratory qualifications for drug testing.

(c) The vendor shall maintain information and documentation submitted under this section for a period of at least 7 years.

(d) A participating importer must submit all of the following information to the department:

1. The name and quantity of the active ingredient of the drug.
2. A description of the dosage form of the drug.
3. The date on which the drug is received.
4. The quantity of the drug that is received.
5. The point of origin and destination of the drug.
6. The price paid by the importer for the drug.

(e) A participating International Importation Drug supplier must submit the following information and documentation to the agency or the agency's designated vendor specifying all of the following:

1. The original source of the drug, including:
a. The name of the manufacturer of the drug.
b. The date on which the drug was manufactured.
c. The location (country, state or province, and city) where the drug was manufactured.
2. The date on which the drug is shipped.
3. The quantity of the drug that is shipped.
4. The quantity of each lot of the drug originally received and from which source.
5. The lot or control number and the batch number assigned to the drug by the manufacturer.
6. The name, address, and telephone number, and professional license or permit number of the importer.

(f) The department may require any other information necessary to ensure the protection of the public health.

(7) IMMEDIATE SUSPENSION.—The department shall immediately suspend the importation of a specific prescription drug or the importation of prescription drugs by a specific importer if it discovers that any prescription drug or activity is in violation of this section. The department may revoke the suspension if, after conducting an investigation, it determines that the public is adequately protected from counterfeit or unsafe prescription drugs being imported into this state.

(8) RULEMAKING AUTHORITY.—The department shall adopt rules necessary to implement this section.

History.—s. 10, ch. 2019-99.

[1]**Note.**—Section 11, ch. 2019-99, provides in part that "[i]mplementation of sections 2 through 10 of this act is contingent upon authorization granted under federal law, rule, or approval." Section 11, ch. 2019-99, was codified as s. 499.02851. Section 12, ch. 2019-99, provides that "[t]his act shall take effect July 1, 2019."

499.02851 Federal arrangement to operate a pilot program for importing prescription drugs.— Notwithstanding the Federal Food, Drug, and Cosmetic Act, the Department of Business and Professional Regulation, in collaboration with the Department of Health, shall negotiate a federal arrangement to operate a pilot program for importing prescription drugs into this state. The proposal to operate such a pilot program shall demonstrate that the program sets safety standards consistent with the current federal requirements for the manufacturing and distribution of prescription drugs; limits the importation of prescription drugs under the program to entities licensed or permitted by the state to manufacture, distribute, or dispense prescription drugs; and includes inspection and enforcement authority. Implementation of sections 2 through 10 of this act is contingent upon authorization granted under federal law, rule, or approval. The department shall notify the President of the Senate, the Speaker of the House of Representatives, and the relevant committees of the Senate and the House of Representatives before implementation of the pilot program. The department shall submit to all parties a proposal for program implementation and program funding.

History.—s. 11, ch. 2019-99.

499.029 Cancer Drug Donation Program.—

(1) This section may be cited as the "Cancer Drug Donation Program Act."

(2) There is created a Cancer Drug Donation Program within the department for the purpose of authorizing and facilitating the donation of cancer drugs and supplies to eligible patients.

(3) As used in this section:

(a) "Cancer drug" means a prescription drug that has been approved under s. 505 of the Federal Food, Drug, and Cosmetic Act and is used to treat cancer or its side effects or is used to treat the side effects of a prescription drug used to treat cancer or its side effects. "Cancer drug" does not include a substance listed in Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03.

(b) "Closed drug delivery system" means a system in which the actual control of the unit-dose medication package is maintained by the facility rather than by the individual patient.

(c) "Donor" means a patient or patient representative who donates cancer drugs or supplies needed to administer cancer drugs that have been maintained within a closed drug delivery system; health care facilities, nursing homes, hospices, or hospitals with closed drug delivery systems; or pharmacies, drug manufacturers, medical device manufacturers or suppliers, or wholesalers of drugs or supplies, in accordance with this section. "Donor" includes a physician licensed under chapter 458 or chapter 459 who receives cancer drugs or supplies directly from a drug manufacturer, wholesale distributor, or pharmacy.

(d) "Eligible patient" means a person who the department determines is eligible to receive cancer drugs from the program.

(e) "Participant facility" means a class II hospital pharmacy that has elected to participate in the program and that accepts donated cancer drugs and supplies under the rules adopted by the department for the program.

(f) "Prescribing practitioner" means a physician licensed under chapter 458 or chapter 459 or any other medical professional with authority under state law to prescribe cancer medication.

(g) "Program" means the Cancer Drug Donation Program created by this section.

(h) "Supplies" means any supplies used in the administration of a cancer drug.

(4) Any donor may donate cancer drugs or supplies to a participant facility that elects to participate in the program and meets criteria established by the department for such participation. Cancer drugs or supplies may not be donated to a specific cancer patient, and donated drugs or supplies may not be resold by the program. Cancer drugs billed to and paid for by Medicaid in long-term care facilities that are eligible for return to stock under federal Medicaid regulations shall be credited to Medicaid and are not eligible for donation under the program. A participant facility may provide dispensing and consulting services to individuals who are not patients of the hospital.

(5) The cancer drugs or supplies donated to the program may be prescribed only by a prescribing practitioner for use by an eligible patient and may be dispensed only by a pharmacist.

(6)(a) A cancer drug may only be accepted or dispensed under the program if the drug is in its original, unopened, sealed container, or in a tamper-evident unit-dose packaging, except that a cancer drug packaged in single-unit doses may be accepted and dispensed if the outside packaging is opened but the single-unit-dose packaging is unopened with tamper-resistant packaging intact.

(b) A cancer drug may not be accepted or dispensed under the program if the drug bears an expiration date that is less than 6 months after the date the drug was donated or if the drug appears to have been tampered with or mislabeled as determined in paragraph (c).

(c) Prior to being dispensed to an eligible patient, the cancer drug or supplies donated under the program shall be inspected by a pharmacist to determine that the drug and supplies do not appear to have been tampered with or mislabeled.

(d) A dispenser of donated cancer drugs or supplies may not submit a claim or otherwise seek reimbursement from any public or private third-party payor for donated cancer drugs or supplies dispensed to any patient under the program, and a public or private third-party payor is not required to provide reimbursement to a dispenser for donated cancer drugs or supplies dispensed to any patient under the program.

(7)(a) A donation of cancer drugs or supplies shall be made only at a participant facility. A participant facility may decline to accept a donation. A participant facility that accepts donated cancer drugs or supplies under the program shall comply with all applicable provisions of state and federal law relating to the storage and dispensing of the donated cancer drugs or supplies.

(b) A participant facility that voluntarily takes part in the program may charge a handling fee sufficient to cover the cost of preparation and dispensing of cancer drugs or supplies under the program. The fee shall be established in rules adopted by the department.

(8) The department, upon the recommendation of the Board of Pharmacy, shall adopt rules to carry out the provisions of this section. Initial rules under this section shall be adopted no later than 90 days after the effective date of this act. The rules shall include, but not be limited to:

(a) Eligibility criteria, including a method to determine priority of eligible patients under the program.

(b) Standards and procedures for participant facilities that accept, store, distribute, or dispense donated cancer drugs or supplies.

(c) Necessary forms for administration of the program, including, but not limited to, forms for use by entities that donate, accept, distribute, or dispense cancer drugs or supplies under the program.

(d) The maximum handling fee that may be charged by a participant facility that accepts and distributes or dispenses donated cancer drugs or supplies.

(e) Categories of cancer drugs and supplies that the program will accept for dispensing; however, the department may exclude any drug based on its therapeutic effectiveness or high potential for abuse or diversion.

(f) Maintenance and distribution of the participant facility registry established in subsection (10).

(9) A person who is eligible to receive cancer drugs or supplies under the state Medicaid program or under any other prescription drug program funded in whole or in part by the state, by any other prescription drug program funded in whole or in part by the Federal Government, or by any other prescription drug program offered by a third-party insurer, unless benefits have been exhausted, or a certain cancer drug or supply is not covered by the prescription drug program, is ineligible to participate in the program created under this section.

(10) The department shall establish and maintain a participant facility registry for the program. The participant facility registry shall include the participant facility's name, address, and telephone number. The department shall make the participant facility registry available on the department's website to any donor wishing to donate cancer drugs or supplies to the program. The department's website shall also contain links to cancer drug manufacturers that offer drug assistance programs or free medication.

(11) Any donor of cancer drugs or supplies, or any participant in the program, who exercises reasonable care in donating, accepting, distributing, or dispensing cancer drugs or supplies under the program and the rules adopted under this section shall be immune from civil or criminal liability and from professional disciplinary action of any kind for any injury, death, or loss to person or property relating to such activities.

(12) A pharmaceutical manufacturer is not liable for any claim or injury arising from the transfer of any cancer drug under this section, including, but not limited to, liability for failure to transfer or communicate product or consumer information regarding the transferred drug, as well as the expiration date of the transferred drug.

(13) If any conflict exists between the provisions in this section and the provisions in this chapter or chapter 465, the provisions in this section shall control the operation of the Cancer Drug Donation Program.

History.—s. 1, ch. 2006-310; s. 122, ch. 2007-5; ss. 2, 21, ch. 2008-207; s. 23, ch. 2016-105.

499.0295 Experimental treatments for terminal conditions.—

(1) This section may be cited as the "Right to Try Act."

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

(a) "Eligible patient" means a person who:

1. Has a terminal condition that is attested to by the patient's physician and confirmed by a second independent evaluation by a board-certified physician in an appropriate specialty for that condition;

2. Has considered all other treatment options for the terminal condition currently approved by the United States Food and Drug Administration;

3. Has given written informed consent for the use of an investigational drug, biological product, or device; and

4. Has documentation from his or her treating physician that the patient meets the requirements of this paragraph.

[1](b) "Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed phase 1 of a clinical trial but has not been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial approved by the United States Food and Drug Administration.

(c) "Terminal condition" means a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by a treating physician to be reversible even with the administration of available treatment options currently approved by the United States Food and Drug Administration, and, without the administration of life-sustaining procedures, will result in death within 1 year after diagnosis if the condition runs its normal course.

(d) "Written informed consent" means a document that is signed by a patient, a parent of a minor patient, a court-appointed guardian for a patient, or a health care surrogate designated by a patient and includes:

1. An explanation of the currently approved products and treatments for the patient's terminal condition.

2. An attestation that the patient concurs with his or her physician in believing that all currently approved products and treatments are unlikely to prolong the patient's life.

3. Identification of the specific investigational drug, biological product, or device that the patient is seeking to use.

4. A realistic description of the most likely outcomes of using the investigational drug, biological product, or device. The description shall include the possibility that new, unanticipated, different, or worse symptoms might result and death could be hastened by the proposed treatment. The description shall be based on the physician's knowledge of the proposed treatment for the patient's terminal condition.

5. A statement that the patient's health plan or third-party administrator and physician are not obligated to pay for care or treatment consequent to the use of the investigational drug, biological product, or device unless required to do so by law or contract.

6. A statement that the patient's eligibility for hospice care may be withdrawn if the patient begins treatment with the investigational drug, biological product, or device and that hospice care may be reinstated if the treatment ends and the patient meets hospice eligibility requirements.

7. A statement that the patient understands he or she is liable for all expenses consequent to the use of the investigational drug, biological product, or device and that liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the investigational drug, biological product, or device states otherwise.

[1](3) Upon the request of an eligible patient, a manufacturer may:

(a) Make its investigational drug, biological product, or device available under this section.

(b) Provide an investigational drug, biological product, or device to an eligible patient without receiving compensation.

(c) Require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, or device.

(4) A health plan, third-party administrator, or governmental agency may provide coverage for the cost of, or the cost of services related to the use of, an investigational drug, biological product, or device.

(5) A hospital or health care facility licensed under chapter 395 is not required to provide new or additional services unless those services are approved by the hospital or health care facility.

(6) If an eligible patient dies while using an investigational drug, biological product, or device pursuant to this section, the patient's heirs are not liable for any outstanding debt related to the patient's use of the investigational drug, biological product, or device.

(7) A licensing board may not revoke, fail to renew, suspend, or take any action against a physician's license issued under chapter 458 or chapter 459 based solely on the physician's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device. A state entity responsible for Medicare certification may not take action against a physician's Medicare certification based solely on the physician's recommendation that an eligible patient have access to an investigational drug, biological product, or device.

(8) This section does not create a private cause of action against the manufacturer of an investigational drug, biological product, or device; against a person or entity involved in the care of an eligible patient who is using the investigational drug, biological product, or device; or for any harm to the eligible patient that is a result of the use of the investigational drug, biological product, or device if the manufacturer or other person or entity complies in good faith with the terms of this section and exercises reasonable care.

(9) This section does not expand the coverage an insurer must provide under the Florida Insurance Code and does not affect mandatory health coverage for participation in clinical trials.

History.—s. 1, ch. 2015-107; s. 2, ch. 2016-123; ss. 1, 9, ch. 2017-232.

[1]**Note.**—Section 1, ch. 2017-232, provides that "[i]t is the intent of the Legislature to implement s. 29, Article X of the State Constitution by creating a unified regulatory structure. If s. 29, Article X of the State Constitution is amended or a constitutional amendment related to cannabis or marijuana is adopted, this act shall expire 6 months after the effective date of such amendment." Section 9, ch. 2017-232,

deleted paragraph (2)(a); redesignated paragraphs (2)(b)-(e) as paragraphs (2)(a)-(d); and amended former paragraph (2)(c), now paragraph (2)(b), and subsection (3). If such amendment or adoption takes place, paragraph (2)(a), paragraph (2)(b), renumbered as paragraph (2)(c), and subsection (3), as amended by s. 1, ch. 2017-232, will read:

(a) "Dispensing organization" means an organization approved by the Department of Health under s. 381.986(5) to cultivate, process, transport, and dispense low-THC cannabis, medical cannabis, and cannabis delivery devices.

* * * * *

(c) "Investigational drug, biological product, or device" means:

1. A drug, biological product, or device that has successfully completed phase 1 of a clinical trial but has not been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial approved by the United States Food and Drug Administration; or

2. Medical cannabis that is manufactured and sold by a dispensing organization.

* * * * *

(3) Upon the request of an eligible patient, a manufacturer may, or upon a physician's order pursuant to s. 381.986, a dispensing organization may:

(a) Make its investigational drug, biological product, or device available under this section.

(b) Provide an investigational drug, biological product, device, or cannabis delivery device as defined in s. 381.986 to an eligible patient without receiving compensation.

(c) Require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, device, or cannabis delivery device as defined in s. 381.986.

499.03 Possession of certain drugs without prescriptions unlawful; exemptions and exceptions.—

(1) A person may not possess, or possess with intent to sell, dispense, or deliver, any habit-forming, toxic, harmful, or new drug subject to s. 499.003(32), or prescription drug as defined in s. 499.003(40), unless the possession of the drug has been obtained by a valid prescription of a practitioner licensed by law to prescribe the drug. However, this section does not apply to the delivery of such drugs to persons included in any of the classes named in this subsection, or to the agents or employees of such persons, for use in the usual course of their businesses or practices or in the performance of their official duties, as the case may be; nor does this section apply to the possession of such drugs by those persons or their agents or employees for such use:

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

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

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

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

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

(f) A person that holds a valid permit issued by the department pursuant to this part which authorizes that person to possess prescription drugs.

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

(3) Violation of subsection (1) is a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083, except that possession with the intent to sell, dispense, or deliver is a third degree felony, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(4) The department may adopt rules regarding persons engaged in lawful teaching, research, or testing who possess prescription drugs and may issue letters of exemption to facilitate the lawful possession of prescription drugs under this section.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; s. 5, ch. 84-115; s. 75, ch. 87-243; ss. 30, 52, ch. 92-69; s. 37, ch. 98-151; s. 43, ch. 2000-242; s. 14, ch. 2000-326; s. 19, ch. 2001-63; s. 89, ch. 2004-5; s. 22, ch. 2008-207; s. 42, ch. 2010-161; s. 11, ch. 2016-212.

499.032 Phenylalanine; prescription required. Phenylalanine restricted formula is declared to be a prescription drug and may be dispensed only upon the prescription of a practitioner authorized by law to prescribe prescription drugs.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 31, 52, ch. 92-69; s. 23, ch. 2008-207.

499.033 Ephedrine; prescription required.— Ephedrine is declared to be a prescription drug.

(1) Except as provided in subsection (2), any product that contains any quantity of ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine may be dispensed only upon the prescription of a duly licensed practitioner authorized by the laws of the state to prescribe prescription drugs.

(2) A product containing ephedrine described in paragraphs (a)-(e) is exempt from subsection (1) if it may lawfully be sold over the counter without a prescription under the federal act; is labeled and marketed in a manner consistent with the pertinent United States Food and Drug Administration Over-the-Counter Tentative Final or Final Monograph; and is manufactured and distributed for legitimate medicinal use in a manner that reduces or eliminates the likelihood of abuse, when considered in the context with: the package sizes and the manner of packaging of the drug product; the name and labeling of the product; the manner of distribution, advertising, and promotion of the product; the duration, scope, health significance, and societal cost of abuse of the particular product; the need to provide medically important ephedrine-containing therapies to the public for United States Food and Drug Administration approved indications on an unrestricted, over-the-counter basis; and other facts as may be relevant to and consistent with public health and safety.

(a) Solid oral dosage forms that combine active ingredients in the following ranges for each dosage unit:

1. Theophylline (100-130mg), ephedrine (12.5-24mg).

2. Theophylline (60-100mg), ephedrine (12.5-24mg), guaifenesin (200-400mg).

3. Ephedrine (12.5-25mg), guaifenesin (200-400mg).

4. Phenobarbital (not greater than 8mg) in combination with the ingredients of subparagraph 1. or subparagraph 2.

(b) Liquid oral dosage forms that combine active ingredients in the following ranges for each (5ml) dose:

1. Theophylline (not greater than 45mg), ephedrine (not greater than 36mg), guaifenesin (not greater than 100mg), phenobarbital (not greater than 12mg).

2. Phenylephrine (not greater than 5mg), ephedrine (not greater than 5mg), chlorpheniramine (not greater than 2mg), dextromethorphan (not greater than 10mg), ammonium chloride (not greater than 40mg), ipecac fluid extract (not greater than 0.005ml).

(c) Anorectal preparations containing less than 5 percent ephedrine.

(d) Nasal decongestant compounds, mixtures, or preparations containing 0.5 percent or less ephedrine.

(e) Any drug product containing ephedrine that is marketed pursuant to an approved new drug application or legal equivalent under the federal act.

(3) The department may implement this section by rule.

History.—s. 7, ch. 94-309; s. 1, ch. 95-415; s. 61, ch. 2003-1; s. 24, ch. 2008-207.

499.035 Dimethyl sulfoxide (DMSO); labeling and advertising.—

(1) Dimethyl sulfoxide (DMSO) not approved for drug use must be clearly marked in at least 12-point boldfaced type: "May be unsafe. Not approved for human use."

(2) All advertisements for the sale of dimethyl sulfoxide (DMSO) not approved for drug use must contain, within the advertisement and in bold lettering, the following statement: "Warning. May be unsafe. Not approved for human use."

History.—s. 34, ch. 82-225; s. 26, ch. 82-402; s. 1, ch. 83-265; ss. 32, 52, ch. 92-69; ss. 1, 5, 8, ch. 94-309.

499.036 Restrictions on sale of dextromethorphan.—

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

(a) "Finished drug product" means a drug legally marketed under the Federal Food, Drug, and Cosmetic Act that is in finished dosage form. For purposes of this paragraph, the term "drug" has the same meaning as provided in s. 499.003(17).

(b) "Proof of age" means any document issued by a governmental agency that contains the date of birth and a description or photograph of the person purchasing the finished drug product. The term includes, but is not limited to, a passport, a driver license, or an identification card issued by this state, another state, or any branch of the United States Armed Forces.

(2)(a) A manufacturer, distributor, or retailer, or its employees and representatives, may not knowingly or willfully sell a finished drug product containing any quantity of dextromethorphan to a person younger than 18 years of age.

(b) A person younger than 18 years of age may not purchase a finished drug product containing any quantity of dextromethorphan.

(3) An employee or representative of a retailer making a retail sale of a finished drug product containing any quantity of dextromethorphan must require and obtain proof of age from the purchaser before completing the sale, unless from the purchaser's outward appearance the person making the sale would reasonably presume the purchaser to be 25 years of age or older.

(4)(a) Each sales location of a manufacturer, distributor, or retailer whose employee or representative, during the course of the employee's or representative's employment or association with the manufacturer, distributor, or retailer, sells a finished drug product containing any quantity of dextromethorphan in violation of this section is subject to a written warning for an initial violation and, for each subsequent violation, a civil citation imposing a fine of not more than $100, which shall accrue and may be recovered in a civil action brought by the local jurisdiction. A manufacturer, distributor, or retailer who demonstrates a good faith effort to comply with this section is not subject to citation.

(b) An employee or representative of a manufacturer, distributor, or retailer who, during the course of the employee's or representative's employment or association with the manufacturer, distributor, or retailer, sells a finished drug product containing any quantity of dextromethorphan in violation of this section is subject to a written warning.

(c) A person who possesses or receives a finished drug product containing any quantity of dextromethorphan in violation of this section with the intent to distribute is subject to a civil citation imposing a fine of not more than $100 for each violation, which shall accrue and may be recovered in a civil action brought by the local jurisdiction. A civil citation issued to a person pursuant to this paragraph shall include information regarding how to dispute the citation and shall clearly state that the violation is a noncriminal violation.

(5) A civil citation issued to a manufacturer, distributor, or retailer pursuant to this section shall be provided to the manager on duty at the time the citation is issued. If a manager is not available, a local law enforcement officer shall attempt to contact the manager to issue the citation. If the local law enforcement officer is unsuccessful in contacting the manager, he or she may leave a copy of the citation with an employee 18 years of age or older and mail a copy of the citation by certified mail to the owner's business address, as filed with the Department of State, or he or she may return to issue the citation at a later time. The civil citation shall provide:

(a) The date and approximate time of the sale in violation of this section.

(b) The location of the sale, including the address.

(c) The name of the employee or representative who completed the sale.

(d) Information regarding how to dispute the citation.

(e) Notice that the violation is a noncriminal violation.

(6) To dispute the citation, the recipient of the citation must provide notice of the dispute to the clerk of the county court in the jurisdiction in which the violation occurred within 15 days after receipt of the citation. The local jurisdiction, through its duly

authorized officers, shall hold a hearing in the court of competent jurisdiction when a citation for a violation of this section is issued, when the violation is disputed, and when the recipient is issued the citation by a local law enforcement officer employed by or acting on behalf of the jurisdiction. If the court finds in favor of the jurisdiction, the court shall require payment of the fine as provided in this section.

(7) This section shall be applied uniformly throughout the state. Enforcement of this section shall remain with local law enforcement departments and officials charged with the enforcement of the laws of the state.

(8) This section does not:

(a) Impose any restriction on the placement of products in a retail store, direct access of customers to finished drug products, or the maintenance of transaction records.

(b) Apply to a medication containing dextromethorphan that is sold by a retailer pursuant to a valid prescription.

(c) Create a criminal violation. A person who violates this section commits a noncriminal violation as defined in s. 775.08(3).

(9) This section preempts any ordinance regulating the sale, distribution, receipt, or possession of dextromethorphan enacted by a county, municipality, or other political subdivision of the state, and dextromethorphan is not subject to further regulation by such political subdivisions.

History.—s. 1, ch. 2016-176; s. 34, ch. 2017-3.

499.039 Sale, distribution, or transfer of harmful chemical substances; penalties; authority for enforcement.—It is unlawful for a person to sell, deliver, or give to a person under the age of 18 years any compound, liquid, or chemical containing toluol, hexane, trichloroethylene, acetone, toluene, ethyl acetate, methyl ethyl ketone, trichloroethane, isopropanol, methyl isobutyl ketone, ethylene glycol monomethyl ether acetate, cyclohexanone, nitrous oxide, diethyl ether, alkyl nitrites (butyl nitrite), or any similar substance for the purpose of inducing by breathing, inhaling, or ingesting a condition of intoxication or which is intended to distort or disturb the auditory, visual, or other physical or mental processes.

(1) On the first violation of this section, the department may issue a warning according to s. 499.002(5), if the violation has not caused temporary or permanent physical or mental injury to the user.

(2) If any violation of this section has caused temporary or permanent physical or mental injury to the user, the department may, pursuant to chapter 120, impose fines according to s. 499.066 and may report any violation to the appropriate state attorney for prosecution.

(3) The department shall adopt rules to implement this section.

History.—s. 12, ch. 86-133; s. 1, ch. 89-296; ss. 33, 52, ch. 92-69; s. 239, ch. 99-8; s. 25, ch. 2008-207.

499.04 Fee authority.—The department may collect fees for all drug, device, and cosmetic applications, permits, product registrations, and free-sale certificates. The total amount of fees collected from all permits, applications, product registrations, and free-sale certificates must be adequate to fund the expenses incurred by the department in carrying out this part. The department shall, by rule, establish a schedule of fees that are within the ranges provided in this section and shall adjust those fees from time to time based on the costs associated with administering this part. The fees are payable to the department to be deposited into the Professional Regulation Trust Fund for the sole purpose of carrying out this part.

History.—s. 34, ch. 82-225; s. 115, ch. 83-218; s. 1, ch. 83-265; ss. 34, 52, ch. 92-69; s. 15, ch. 2000-326; s. 26, ch. 2008-207; s. 13, ch. 2012-143.

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.

(a) The fee for a prescription drug manufacturer permit may not be less than $500 or more than $750 annually.

(b) The fee for a device manufacturer permit may not be less than $500 or more than $600 annually.

(c) The fee for a cosmetic manufacturer permit shall be sufficient to cover the costs of administering the cosmetic manufacturer permit program.

(d) The fee for an over-the-counter drug manufacturer permit may not be less than $300 or more than $400 annually.

(e) The fee for a prescription drug repackager permit may not be less than $500 or more than $750 annually.

(f) A manufacturer may not be required to pay more than one fee per establishment to obtain an additional manufacturing permit, but each manufacturer must pay the highest fee applicable to his or her operation in each establishment.

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

(a) The fee for a prescription drug wholesale distributor permit may not be less than $300 or more than $800 annually.

(b) The fee for an out-of-state prescription drug wholesale distributor permit may not be less than $300 or more than $800 annually.

(c) The fee for a nonresident prescription drug manufacturer permit may not be less than $300 or more than $500 annually.

(d) The fee for a retail pharmacy drug wholesale distributor permit may not be less than $35 or more than $50 annually.

(e) The fee for a freight forwarder permit may not be less than $200 or more than $300 annually.

(f) The fee for a veterinary prescription drug wholesale distributor permit may not be less than $300 or more than $500 annually.

(g) The fee for a limited prescription drug veterinary wholesale distributor permit may not be less than $300 or more than $500 annually.

(h) The fee for a third party logistics provider 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.

(a) The fee for a veterinary prescription drug retail establishment permit may not be less than $200 or more than $300 annually.

(b) The fee for a health care clinic establishment permit may not be less than $125 or more than $250 annually.

(4) The department shall assess an applicant that is required to have a restricted prescription drug distributor permit an annual fee of not less than $200 or more than $300.

(5) In addition to the fee charged for a permit required by this part, the department shall assess applicants an initial application fee of $150 for each new permit issued by the department which requires an onsite inspection.

(6) A person that is required to register drugs or devices under s. 499.015 shall pay an annual product registration fee of not less than $5 or more than $15 for each separate and distinct product in package form. The registration fee is in addition to the fee charged for a free-sale certificate.

(7) The department shall assess an applicant that requests a free-sale certificate a fee of $25. A fee of $2 will be charged for each signature copy of a free-sale certificate that is obtained at the same time the free-sale certificate is issued.

(8) The department shall assess an out-of-state prescription drug wholesale distributor applicant or permittee an onsite inspection fee of not less than $1,000 or more than $3,000 annually, to be based on the actual cost of the inspection if an onsite inspection is performed by agents of the department.

(9) The department shall assess each person applying for certification as a designated representative a fee of $150, plus the cost of processing the criminal history record check.

(10) The department shall assess other fees as provided in this part.

History.—s. 34, ch. 82-225; s. 116, ch. 83-218; s. 1, ch. 83-265; ss. 10, 14, ch. 88-159; s. 4, ch. 89-296; ss. 35, 52, ch. 92-69; s. 591, ch. 97-103; s. 16, ch. 2000-326; s. 20, ch. 2003-155; s. 5, ch. 2004-328; s. 5, ch. 2006-92; s. 27, ch. 2008-207; s. 6, ch. 2014-89; s. 3, ch. 2017-51.

499.05 Rules.—

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

(a) The definition of terms used in this chapter, and used in the rules adopted under this chapter, 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.

(d) The identification of permits that require an initial 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.

(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, 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; and a process for the uncontested settlement of alleged violations.

(i) Additional conditions that qualify as an emergency medical reason under s. 499.003(48)(b)2. or s. 499.82.

(j) 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.

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

(l) The recordkeeping, storage, and handling with respect to each of the distributions of prescription drugs specified in s. 499.003(48)(a)-(v) or s. 499.82(14).

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

(n) 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.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; s. 6, ch. 84-115; s. 88, ch. 85-81; s. 4, ch. 86-133; ss. 17, 18, 36, ch. 92-69; ss. 2, 5, 8, ch. 94-309; ss. 31, 34, 38, ch. 98-151; s. 172, ch. 99-397; ss. 39, 44, ch. 2000-242; s. 20, ch. 2001-63; s. 32, ch. 2001-89; ss. 13, 14, 18, ch. 2003-155; ss. 87, 90, ch. 2004-5; s. 28, ch. 2008-207; s. 43, ch. 2010-161; s. 19, ch. 2011-141; s. 7, ch. 2014-89; s. 12, ch. 2016-212.

Note.—Paragraph (1)(k) former s. 499.013(3); paragraph (1)(l) former s. 499.0122(2)(b); paragraph (1)(m) former s. 499.012(12).

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 during business hours for the purpose of enforcing this chapter, 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 and rules adopted under this chapter regarding any drug, device, or cosmetic.

(3) Any application for a permit or product registration or for renewal of such permit or registration made pursuant to this chapter and rules adopted under this chapter constitutes permission for any entry or

inspection of the premises in order to verify compliance with this chapter 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 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 and the rules adopted by the department to administer this chapter, in order to discover, investigate, and determine the existence of compliance, or to elicit, receive, respond to, and resolve complaints and violations.

(5) The authority to inspect under this section includes the authority to access, review, and copy any and all financial documents related to the activity of manufacturing, repackaging, or distributing prescription drugs.

(6) The authority to inspect under this section includes the authority to secure:

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

(b) Such other evidence as is needed for any action to enforce this part and the rules adopted under this part.

(7)(a) The complaint and all information obtained pursuant to the investigation by the department are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution until the investigation and the enforcement action are completed.

(b) Information that constitutes a trade secret, as defined in s. 812.081, contained in the complaint or obtained by the department pursuant to the investigation must remain confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution as long as the information is held by the department. This paragraph is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2021, unless reviewed and saved from repeal through reenactment by the Legislature.

(c) This subsection does not prohibit the department from using such information for regulatory or enforcement proceedings under this chapter or from providing such information to any law enforcement agency or any other regulatory agency. However, the receiving agency shall keep such records confidential and exempt as provided in this subsection.

History.—s. 34, ch. 82-225; s. 26, ch. 82-402; s. 1, ch. 83-265; s. 5, ch. 86-133; s. 11, ch. 88-159; ss. 37, 52, ch. 92-69; s. 199, ch. 94-218; ss. 3, 5, 8, ch. 94-309; s. 7, ch. 95-366; s. 332, ch. 96-406; s. 240, ch. 99-8; s. 62, ch. 2003-1; s. 21, ch. 2003-155; s. 26, ch. 2007-6; s. 29, ch. 2008-207; s. 8, ch. 2014-89; s. 11, ch. 2016-6; s. 13, ch. 2016-212; s. 4, ch. 2017-51.

499.052 Records of interstate shipment.—For the purpose of enforcing this part, carriers engaged in interstate commerce and persons receiving drugs, devices, or cosmetics in interstate commerce must, upon the request, in the manner set out below, by an officer or employee duly designated by the department, permit the officer or employee to have access to and to copy all records showing the movement in interstate commerce of any drug, device, or cosmetic, and the quantity, shipper, and consignee thereof.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 38, 52, ch. 92-69; s. 30, ch. 2008-207.

499.055 Reports and dissemination of information by department.—

(1) The department may cause to be published from time to time reports summarizing all judgments, decrees, and court orders that have been rendered under ss. 499.001-499.79, including the nature of any charges and the dispositions of the charges.

(2) The department may also cause to be disseminated such information regarding drugs, devices, and cosmetics as considered necessary in the interest of public health and the protection of consumers against fraud.

(3) This section does not prohibit the department from collecting, reporting, and illustrating the results of its investigations.

(4) The department shall publish on the department's website and update at least monthly:

(a) A list of the prescription drug wholesale distributors, out-of-state prescription drug wholesale distributors, and retail pharmacy drug wholesale distributors against whom the department has initiated enforcement action pursuant to this part to suspend or revoke a permit, seek an injunction, or otherwise file an administrative complaint and the permit number of each such wholesale distributor.

(b) A list of the prescription drug wholesale distributors, out-of-state prescription drug wholesale distributors, and retail pharmacy drug wholesale distributors to which the department has issued a permit, including the date on which each permit will expire.

(c) A list of the prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, and retail pharmacy drug wholesale distributor permits that have been returned to the department, were suspended, were revoked, have expired, or were not renewed in the previous year.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; s. 6, ch. 86-133; ss. 39, 52, ch. 92-69; s. 22, ch. 2003-155; s. 31, ch. 2008-207.

499.057 Expenses and salaries.—Except as otherwise provided in the General Appropriations Act, all expenses and salaries shall be paid out of the Professional Regulation Trust Fund.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 40, 52, ch. 92-69; s. 564, ch. 2003-261; s. 14, ch. 2012-143.

499.06 Embargoing, detaining, or destroying article or processing equipment which is in violation of law or rule.—

(1) When a duly authorized agent of the department finds, or has probable cause to believe, that any drug, device, or cosmetic is in violation of any provision of this part or any rule adopted under this part so as to be dangerous, unwholesome, or fraudulent within the meaning of this part, she or he may issue and enforce a stop-sale, stop-use, removal, or hold order, which order gives notice that such article or processing equipment is, or is suspected of being, in violation and has been detained or embargoed, and which order

warns all persons not to remove, use, or dispose of such article or processing equipment by sale or otherwise until permission for removal, use, or disposal is given by such agent or the court. It is unlawful for any person to remove, use, or dispose of such detained or embargoed article or processing equipment by sale or otherwise without such permission; and such act is a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(2) When an article or processing equipment detained or embargoed under subsection (1) has been found by such agent to be in violation of law or rule, she or he shall, within 90 days after the issuance of such notice, petition the circuit court, in the jurisdiction of which the article or processing equipment is detained or embargoed, for an order for condemnation of such article or processing equipment. When such agent has found that an article or processing equipment so detained or embargoed is not in violation, she or he shall rescind the stop-sale, stop-use, removal, or hold order.

(3) If the court finds that the detained or embargoed article or processing equipment is in violation, such article or processing equipment shall, after entry of the court order, be destroyed or made sanitary at the expense of the claimant thereof, under the supervision of such agent; and all court costs, fees, and storage and other proper expenses shall be taxed against the claimant of such article or processing equipment or her or his agent. However, when the violation can be corrected by proper labeling of the article or sanitizing of the processing equipment, and after such costs, fees, and expenses have been paid and a good and sufficient bond, conditioned that such article be so labeled or processed or such processing equipment be so sanitized, has been executed, the court may by order direct that such article or processing equipment be delivered to the claimant thereof for such labeling, processing, or sanitizing, under the supervision of an agent of the department. The expense of such supervision shall be paid by the claimant. Such bond shall be returned to the claimant of the article or processing equipment upon representation to the court by the department that the article or processing equipment is no longer in violation of this part and that the expenses of such supervision have been paid.

(4) When the department or any of its authorized agents finds in any room, building, vehicle of transportation, or other structure any perishable articles that are unsound or contain any filthy, decomposed, or putrid substances, or which may be poisonous or deleterious to health or otherwise unsafe, the same being hereby declared to be a nuisance, the department, or its authorized agent, shall forthwith condemn or destroy such articles or in any other manner render such articles unsalable.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 41, 52, ch. 92-69; s. 592, ch. 97-103; s. 32, ch. 2008-207.

499.062 Seizure and condemnation of drugs, devices, or cosmetics.—

(1) Any article of any drug, device, or cosmetic that is adulterated or misbranded under this part is subject to seizure and condemnation by the department or by its duly authorized agents designated for that purpose in regard to drugs, devices, or cosmetics.

(2) Whenever a duly authorized officer or employee of the department finds cause, or has probable cause to believe that cause exists, for the seizure of any drug, device, or cosmetic, as set out in this part, he or she shall affix to the article a tag, stamp, or other appropriate marking, giving notice that the article is, or is suspected of being, subject to seizure under this part and that the article has been detained and seized by the department. Such officer or employee shall also warn all persons not to remove or dispose of the article, by sale or otherwise, until permission is given by the department or the court. Any person who violates this subsection is guilty of a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(a) When any article detained or seized under this subsection has been found by the department to be subject to seizure and condemnation, the department shall petition the court for an order of condemnation or sale, as the court directs. The proceeds of the sale of drugs, devices, and cosmetics, less the legal costs and charges, shall be deposited into the Professional Regulation Trust Fund.

(b) If the department finds that any article seized under this subsection was not subject to seizure, the department or the designated officer or employee shall remove the tag or marking.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 42, 43, 44, 52, ch. 92-69; s. 593, ch. 97-103; s. 33, ch. 2008-207; s. 15, ch. 2012-143.

Note.—Subsection (2) intro. former s. 499.063; paragraphs (2)(a), (b) former s. 499.064.

499.065 Inspections; imminent danger.—

[1](1) Notwithstanding s. 499.051, the department shall inspect each prescription drug wholesale distributor establishment, prescription drug repackager establishment, veterinary prescription drug wholesale distributor establishment, limited prescription drug veterinary wholesale distributor establishment, and retail pharmacy drug wholesale distributor establishment that is required to be permitted under this part as often as necessary to ensure compliance with applicable laws and rules. The department shall have the right of entry and access to these facilities at any reasonable time.

(2) To protect the public from prescription drugs that are adulterated or otherwise unfit for human or animal consumption, the department may examine, sample, seize, and stop the sale or use of prescription drugs to determine the condition of those drugs. The department may immediately seize and remove any prescription drugs if the Secretary of Business and Professional Regulation or his or her designee determines that the prescription drugs represent a threat to the public health. The owner of any property seized under this section may, within 10 days after the seizure, apply to a court of competent jurisdiction for whatever relief is appropriate. At any time after 10 days, the department may destroy the drugs as contraband.

[1](3) The department may determine that a prescription drug wholesale distributor establishment, prescription drug repackager establishment, veterinary prescription drug wholesale distributor establishment,

limited prescription drug veterinary wholesale distributor establishment, or retail pharmacy drug wholesale distributor establishment that is required to be permitted under this part is an imminent danger to the public health and shall require its immediate closure if the establishment fails to comply with applicable laws and rules and, because of the failure, presents an imminent threat to the public's health, safety, or welfare. Any establishment so deemed and closed shall remain closed until allowed by the department or by judicial order to reopen.

(4) For purposes of this section, a refusal to allow entry to the department for inspection at reasonable times, or a failure or refusal to provide the department with required documentation for purposes of inspection, constitutes an imminent danger to the public health.

History.—s. 23, ch. 2003-155; s. 6, ch. 2004-328; s. 6, ch. 2006-92; s. 107, ch. 2008-6; s. 34, ch. 2008-207; s. 6, ch. 2012-143; s. 9, ch. 2019-99.

[1]**Note.**—

A. Section 11, ch. 2019-99, provides in part that "[i]mplementation of sections 2 through 10 of this act is contingent upon authorization granted under federal law, rule, or approval." Section 11, ch. 2019-99, was codified as s. 499.02851. Section 12, ch. 2019-99, provides that "[t]his act shall take effect July 1, 2019."

B. Subject to the contingency as to implementation in s. 11, ch. 2019-99, s. 9, ch. 2019-99, amends subsections (1) and (3), to read:

(1) Notwithstanding s. 499.051, the department shall inspect each prescription drug wholesale distributor establishment, international prescription drug wholesale distributor establishment, prescription drug repackager establishment, veterinary prescription drug wholesale distributor establishment, limited prescription drug veterinary wholesale distributor establishment, and retail pharmacy drug wholesale distributor establishment that is required to be permitted under this part as often as necessary to ensure compliance with applicable laws and rules. The department shall have the right of entry and access to these facilities at any reasonable time.

* * * * *

(3) The department may determine that a prescription drug wholesale distributor establishment, international prescription drug wholesale distributor establishment, prescription drug repackager establishment, veterinary prescription drug wholesale distributor establishment, limited prescription drug veterinary wholesale distributor establishment, or retail pharmacy drug wholesale distributor establishment that is required to be permitted under this part is an imminent danger to the public health and shall require its immediate closure if the establishment fails to comply with applicable laws and rules and, because of the failure, presents an imminent threat to the public's health, safety, or welfare. Any establishment so deemed and closed shall remain closed until allowed by the department or by judicial order to reopen.

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. If it appears that a person has violated any provision of this chapter 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 violates any provision of this chapter, any rule adopted under this chapter, or a cease and desist order as provided by this chapter, 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, the rules adopted under this chapter, and the orders of the department authorized by this chapter or to mandate compliance with this chapter, the rules adopted under this chapter, and any order or permit issued by the department under this chapter.

(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 or rules adopted under this chapter. 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. 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, 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.

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

(6) The department may issue an emergency order to immediately remove from commerce and public access any drug, device, or cosmetic, if the department determines that the drug, device, or cosmetic presents a clear and present danger to the public health, safety, and welfare.

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

History.—s. 34, ch. 82-225; s. 26, ch. 82-402; s. 117, ch. 83-218; s. 1, ch. 83-265; s. 7, ch. 86-133; s. 3, ch. 86-271; ss. 45, 52, ch. 92-69; ss. 4, 5, 8, ch. 94-309; s. 24, ch. 2003-155; s. 35, ch. 2008-207; s. 16, ch. 2012-143; s. 9, ch. 2014-89.

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 permittee or upon an 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, is hazardous to the public health, or constitutes business operations that are a detriment to the public health;
2. A violation of a provision of this chapter;
3. A violation of a rule of the department;
4. A violation of an order of the department; or

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

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

(c) If a hearing is not requested within the time allowed by ss. 120.569 and 120.57, or if a hearing is held and the department finds that any of the charges are proven, the department may enter an order directing the permittee or the affiliated party named in the complaint to cease and desist from engaging in the conduct complained of and take corrective action to remedy the effects of past improper conduct and assure future compliance.

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

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

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

(a) The department may issue and serve a complaint stating charges upon an 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, 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; 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 law involving fraud or moral turpitude which constitutes a felony;

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

5. A willful violation of an 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.

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

(c) If a hearing is not requested within the time allotted by ss. 120.569 and 120.57, or if a hearing is held and the department finds that any of the charges in the complaint are proven true, the department may enter an order removing the affiliated party or restricting or prohibiting participation by the person in the affairs of that permittee or of any other permittee.

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

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

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

(f) Any affiliated party removed pursuant to this section is not eligible for reemployment by the permittee or to be an affiliated party of any permittee except upon the written consent of the department. Any affiliated party who is removed, restricted, or prohibited from participating in the affairs of a permittee pursuant to this section may petition the department for modification or termination of the removal, restriction, or prohibition.

History.—s. 25, ch. 2003-155; ss. 2, 36, ch. 2008-207; s. 10, ch. 2014-89.

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 or chapter 465, chapter 501, or chapter 893, the rules adopted under 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(15) demonstrates any of the conditions enumerated in s. 499.012.

5. The applicant, permittee, or person certified under s. 499.012(15) has committed any violation of this chapter.

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

(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 this chapter or rules adopted under this chapter.

(4) If a permit issued under this chapter 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 permit under this chapter for a period of 1 year after the date of the revocation. A revocation of a permit may be permanent if the department considers that to be in the best interest of the public health.

(5) The department may deny, suspend, or revoke a permit issued under this chapter which authorizes the permittee to purchase prescription drugs if an owner, officer, employee, or other person who participates in administering or operating the establishment has been found guilty of a violation of this chapter or chapter 465, chapter 501, or chapter 893, any rules adopted under 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 person or establishment if the assignment, sale, transfer, or lease of an establishment permitted under this chapter 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 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).

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; s. 8, ch. 86-133; ss. 12, 14, ch. 88-159; s. 4, ch. 89-296; ss. 46, 52, ch. 92-69; s. 44, ch. 95-144; s. 594, ch. 97-103; s. 17, ch. 2000-326; s. 26, ch. 2003-155; s. 37, ch. 2008-207; s. 20, ch. 2011-141; s. 11, ch. 2014-89; s. 19, ch. 2016-212.

PART II

ETHER

499.601 Legislative intent; construction.—

(1) The Legislature finds that the unregulated possession of bulk quantities of ether poses a substantial risk to the health, safety, and welfare of the citizens of this state, and it is the intent of the Legislature that this part be liberally construed to provide all protection necessary for the citizens of this state.

(2) The provisions of this part are cumulative and shall not be construed as repealing or affecting any powers, duties, or authority of the department under any other law of this state; except that, with respect to the regulation of ether as herein provided, in instances in which the provisions of this part may conflict with any other such law, the provisions of this part shall control.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 241, ch. 99-8; s. 7, ch. 2012-143; s. 123, ch. 2012-184.

499.61 Definitions.—As used in this part:

(1) "Dealer" means any person, firm, corporation, or other entity selling, brokering, or transferring ether to anyone other than a licensed ether manufacturer, distributor, or dealer.

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

(3) "Distributor" means any person, firm, corporation, or other entity distributing, selling, marketing, transferring, or otherwise supplying ether to retailers, dealers, or any other entity in the primary channel of trade, but does not include retailers.

(4) "Ether" means diethyl ether in any form.

(5) "Manufacturer" means any person, firm, corporation, or other entity preparing, deriving, producing, synthesizing, or otherwise making ether in any form or repacking, relabeling, or manipulating ether.

(6) "Purchaser" means any person, firm, corporation, or other entity who purchases ether in quantities of 2.5 gallons, or equivalent by weight, or more for any purpose whatsoever, but does not include a dealer, distributor, or manufacturer.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 242, ch. 99-8; s. 8, ch. 2012-143; s. 124, ch. 2012-184.

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

(1) It shall be unlawful for any person to engage in the business of manufacturing, distributing, or dealing in ether in this state, except when done in conformity with the provisions of this part. No person shall be required to obtain more than one license under this part to handle ether, but each person shall pay the highest fee applicable to her or his operation in each location.

(2) Any person who manufactures, distributes, or deals in ether in this state must possess a current valid license issued by the department, except that a manufacturer, distributor, or dealer who also purchases ether in this state shall not be required to obtain an additional permit as a purchaser of ether.

(3) Any person who manufactures, distributes, or deals in ether at or from more than one location must possess a current valid license for each location.

(4) Any person who purchases ether in this state must possess a current valid permit issued by the department, except that no permit shall be required of any person who purchases ether in quantities of less than 2.5 gallons, or equivalent by weight.

(5) Annual fees for licenses and permits shall be specified by rule of the department, but shall not exceed the following amounts:

(a) Manufacturer's license.....$700
(b) Distributor's license.....$700
(c) Dealer's license..... $350
(d) Purchaser's permit.....$150

(6) Licenses and permits issued by the department shall be valid beginning on October 1 of the year for which they are issued and shall expire on the following September 30.

(7) A licensed or permitted facility shall renew its license or permit prior to its expiration date. If a renewal application and fee are not filed by the expiration date of any year, the permit may be reinstated only upon payment of a delinquent fee of $50, plus the required renewal fee, within 30 days after the date of expiration. If any person who is subject to the requirements of this part fails to comply with the renewal, the department shall have the authority to seize all ether products and dispose of them as of November 1 of the year the license or permit expires. Any funds collected from the disposal shall be placed in the Professional Regulation Trust Fund.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 596, ch. 97-103; s. 17, ch. 2012-143.

499.63 Forms for applications for licenses and permits.—

(1) The forms for applications for ether licenses and permits shall be prescribed by the department.

(2) Each application for a license or permit required by the provisions of this part shall be filed in writing with the department. Each application shall require, as a minimum, the full name, date of birth, place of birth, social security number, physical description of the applicant, residence address and telephone number, and business address and telephone number of the applicant. Each application must be accompanied by an accurate and current photograph of the applicant and a complete set of fingerprints of the applicant taken by an authorized law enforcement officer; however, a set of fingerprints shall not be required if the applicant has possessed a valid Florida license or permit under this part during the prior license or permit year and such Florida license or permit has not lapsed or been suspended or revoked. If fingerprints are required, the set of fingerprints shall be submitted by the department to the Department of Law Enforcement for state processing and to the Federal Bureau of Investigation for federal processing. If the application does not require a set of fingerprints, the department shall submit the name and other identifying data to the Department of

Law Enforcement for processing. Each application shall be in such form as to provide that the data and other information set forth therein shall be sworn to by the applicant or, if the applicant is a corporation, by all officers of the corporation. The officers applying on behalf of a corporation shall provide all the data and other information required by this subsection and subsection (3), and shall meet all other requirements, which are required of a natural person.

(3) The department may require an applicant to furnish such other information or data not required by this section if the information or data is deemed necessary by the department.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429.

499.64 Issuance of licenses and permits; prohibitions.—

(1) Each license and permit issued by the department shall set forth, as a minimum, the full name, date of birth, and physical description of the licensee or permittee and shall have permanently affixed an accurate and current photograph of the licensee or permittee. A license or permit issued to a corporation shall set forth the full name, date of birth, and physical description of the chief executive officer and/or resident agent residing in this state and shall have permanently affixed an accurate and current photograph of the chief executive officer and/or resident agent residing in this state. Each license and permit shall also contain a license or permit number.

(2) The department may, in its discretion, include other data or information in the license or permit when deemed appropriate.

(3) No license or permit shall be issued, renewed, or allowed to remain in effect for any natural person, or for any corporation which has any corporate officer:

(a) Under 18 years of age.

(b) Who has been convicted of a felony under the prescription drug or controlled substance laws of this state or any other state or federal jurisdiction, regardless of whether he or she has been pardoned or had his or her civil rights restored.

(c) Who has been convicted of any felony other than a felony under the prescription drug or controlled substance laws of this state or any other state or federal jurisdiction and has not been pardoned or had his or her civil rights restored.

(d) Who has been adjudicated mentally incompetent and has not had his or her civil rights restored.

(4) It is unlawful for any person to knowingly withhold information or present to the department any false, fictitious, or misrepresented application, identification, document, information, or data intended or likely to deceive the department for the purpose of obtaining a license or permit.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 597, ch. 97-103.

499.65 Possession of ether without license or permit prohibited; confiscation and disposal; exceptions.—

(1) It is unlawful for any person to possess 2.5 gallons, or equivalent by weight, or more of ether unless she or he is the holder of a current valid license or permit as provided by this part.

(2) Whenever the department has reason to believe that any person is or has been violating the provisions of this part or any rules adopted pursuant thereto, the department may, without further process of law, confiscate and dispose of the ether in question. The department is authorized to seize and dispose of any abandoned ether.

(3) The department is authorized to enter into contracts with private business entities for the purpose of confiscation and disposal of ether as authorized in subsection (2).

(4) The provisions of subsection (1) shall not apply to:

(a) Any common carrier transporting ether into this state or within the boundaries of this state by air, highway, railroad, or water;

(b) Any contract or private carrier transporting ether on highways into this state or within the boundaries of this state by motor vehicle when such contract or private carrier is engaged in such transport pursuant to certificate or permit, by whatever name, issued to them by any federal or state officer, agency, bureau, commission, or department;

(c) Pharmacists, for use in the usual course of their professional practice or in the performance of their official duties;

(d) Medical practitioners, for use in the usual course of their professional practice or in the performance of their official duties;

(e) Persons who procure ether for disposition by or under the supervision of pharmacists or medical practitioners employed by them or for the purpose of lawful research, teaching, or testing, and not for resale;

(f) Hospitals and other institutions which procure ether for lawful administration by practitioners;

(g) Officers or employees of federal, state, or local governments carrying out their official duties; and

(h) Law enforcement agencies of this state or any of its political subdivisions, and the employees thereof, so long as said agencies and employees are acting within the scope of their respective official capacities and in the performance of their duties.

(5) The department may adopt rules regarding persons engaged in lawful teaching, research, or testing who possess ether and may issue letters of exemption to facilitate the lawful possession of ether under this section.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 598, ch. 97-103; s. 39, ch. 98-151.

499.66 Maintenance of records and sales of ether by manufacturers, distributors, and dealers; inspections.—

(1) It is unlawful for any manufacturer, distributor, or dealer to sell, distribute, or otherwise transfer ether to any person except a person presenting a current valid license or permit as provided by this part.

(2) Each sale or transfer of ether shall be evidenced by an invoice, receipt, sales ticket, or sales slip which shall bear the name, address, and license or permit number of the manufacturer, distributor, or dealer and the purchaser or transferee, the date of sale or transfer,

and the quantity sold or transferred. All original invoices, receipts, sales tickets, and sales slips shall be retained by the manufacturer, distributor, or dealer, and a copy thereof provided to the purchaser or transferee.

(3) Each manufacturer, distributor, and dealer shall keep an accurate and current written account of all inventories, sales, and transfers of ether. Such records shall be maintained by the manufacturer, distributor, or dealer for a period of 5 years.

(4) Records and inventories as required by subsections (2) and (3) shall be made immediately accessible to, and subject to examination and copying by, the department and any law enforcement officer of this state without any requirement of probable cause or search warrant.

(5) It is unlawful for any person to knowingly withhold information or to make any false or fictitious entry or misrepresentation upon any invoice, receipt, sales ticket, or sales slip for the sale, distribution, or transfer of ether or upon any account of inventories of ether.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 40, ch. 98-151.

499.67 Maintenance of records by purchasers; inspections.—

(1) It is unlawful for any person to purchase, receive, store, or use ether without maintaining an accurate and current written inventory of all ether purchased, received, stored, and used.

(2) Such records shall include, but not be limited to, invoices, receipts, sales tickets, and sales slips; locations, quantities, and dates of use; the names of any persons using the ether; and the names and license or permit numbers of all persons making such records. Such records shall be maintained by permittees for a period of 5 years.

(3) Such records shall be made accessible to, and subject to examination and copying by, the department and any law enforcement officer of this state without any requirement of probable cause or search warrant.

(4) It is unlawful for any person to knowingly withhold information or make any false or fictitious entry or misrepresentation upon any such records for the purchase, receipt, storage, or use of ether.

(5) It is unlawful for any person to refuse entry or inspection by the department of factories, warehouses, or establishments in which ether is manufactured, processed, repackaged, or held; to refuse entry by the department into any vehicle being used to transport ether; or to refuse the taking of samples by the department.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 41, ch. 98-151.

499.68 Reports of thefts, illegal use, or illegal possession.—

(1) Any sheriff, police department, or law enforcement officer of this state shall give immediate notice to the department of any theft, illegal use, or illegal possession of ether involving any person and shall forward a copy of his or her final written report to the department.

(2) Any licensee or permittee who incurs a loss, an unexplained shortage, or a theft of ether, or who has knowledge of a loss, an unexplained shortage, or a theft of ether, shall, within 12 hours after the discovery thereof, report such loss, theft, or unexplained shortage to the county sheriff or police chief of the jurisdiction in which the loss, theft, or unexplained shortage occurred. Such loss, theft, or unexplained shortage must also be reported to the department by the close of the next business day following the discovery thereof.

(3) Any law enforcement agency which investigates the causes and circumstances of any loss, theft, or unexplained shortage of ether shall forward a copy of its final written report to the department. The department shall retain all such reports in the respective files of the affected licensees and permittees.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 599, ch. 97-103.

499.69 Possession in or near residential housing prohibited; legal entitlement to possession of premises not a defense.—

(1) Notwithstanding the possession of a current valid license or permit as provided in this part, it is unlawful for any person to possess 2.5 gallons, or equivalent by weight, or more of ether in, or within 500 feet of, any residential housing structure.

(2) A defendant's legal entitlement to possession of the property where the violation occurred shall not be a defense to a prosecution for a violation of subsection (1).

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429.

499.701 Adoption of rules by the department.

(1) The department shall adopt and enforce rules necessary to the administration of its authority under this part. The rules must be such as are reasonably necessary for the protection of the health, welfare, and safety of the public and persons manufacturing, distributing, dealing, and possessing ether, and must provide for application forms and procedures, recordkeeping requirements, and security. The rules must be in substantial conformity with generally accepted standards of safety concerning such subject matter.

(2) The department may adopt rules regarding recordkeeping and security for methyl ethyl ketone (MEK) or butyl acetate as needed. These products and records are open to inspection in the same manner as are ether products and records.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 45, ch. 2000-242.

499.71 Procedure for cease and desist orders.

(1) Whenever the department has reason to believe that any person is or has been violating any provision of this part or any rules adopted pursuant thereto, it shall proceed to determine the matter.

(2) If the department determines that any provision of this part or any rules adopted pursuant thereto have been violated, it shall issue to the person charged with such violation an order requiring such person to cease and desist from such violation or imposing an administrative fine, or both.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429.

499.72 Administrative fines.—

(1) If any person violates any provision of this part or any rule adopted pursuant thereto, or violates a cease and desist order issued by the department, the

department may impose an administrative fine, not to exceed $5,000 for each violation per day, or may suspend or revoke the license or permit issued to such person, or both. Each day such violation continues constitutes a separate violation, and each such separate violation is subject to a separate fine. The department shall allow the licensee or permittee a reasonable period, not to exceed 30 days, within which to pay to the department the amount of the fine so imposed. If the licensee or permittee fails to pay the fine in its entirety to the department at its office in Tallahassee within the period so allowed, the licenses or permits of such person shall stand revoked upon expiration of such period.

(2) All such fines, monetary penalties, and costs received by the department in connection with this part shall be deposited in the Professional Regulation Trust Fund.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 18, ch. 2012-143.

499.73 Suspension or revocation of license or permit.—

(1) The violation of any provision of this part, any rule adopted pursuant thereto, or any cease and desist order issued by the department by a licensee or permittee as provided in this part shall be cause for revocation or suspension of all licenses or permits held by such licensee or permittee after the department has determined the licensee or permittee to be guilty of such violation.

(2) If the department finds the licensee or permittee to be guilty of such violation, it shall enter its order suspending or revoking the license or permit of the person charged. An order of suspension shall state the period of time of such suspension, which period shall not be in excess of 1 year from the date of such order. An order of revocation may be entered for a period not exceeding 5 years; such order shall effect the revocation of all licenses or permits then held by the person charged, and during such period no license or permit shall be issued to said person. If, during the period between the beginning of proceedings and the entry of an order of suspension or revocation by the department, a new license or permit has been issued to the person charged, any order of suspension or revocation shall operate effectively with respect to the new license or permit held by such person.

(3) Any person or office of a corporation whose permit or license has been suspended or revoked shall not be issued a new permit or license under any other name or company name until the expiration of the suspension or revocation in which she or he has been involved.

(4) The provisions of this section are cumulative and shall not affect the administrative fine and injunction provisions of ss. 499.72 and 499.76.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 600, ch. 97-103.

499.74 Conduct of hearings; review of orders of the department.—

(1) All hearings shall be conducted in accordance with the provisions of chapter 120.

(2) All review of orders of the department shall be in accordance with the provisions of chapter 120.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429.

499.75 Penalties.—

(1) Any person who knowingly manufactures, distributes, or deals in ether without possessing a valid current license as required by s. 499.62(2) is guilty of a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(2) Any person who knowingly purchases 2.5 gallons, or equivalent by weight, or more of ether without possessing a valid current permit as required by s. 499.62(4) is guilty of a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(3) Any person who knowingly withholds information or presents to the department any false, fictitious, or misrepresented application, identification, document, information, statement, or data intended or likely to deceive the department for the purpose of obtaining a license or permit as prohibited by s. 499.64(4) is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(4) Any person who knowingly possesses 2.5 gallons, or equivalent by weight, or more of ether and is not the holder of a valid current license or permit as prohibited by s. 499.65(1) is guilty of a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(5) Any person who knowingly sells or otherwise transfers 2.5 gallons, or equivalent by weight, or more of ether to any person who is not the holder of a valid current license or permit as prohibited by s. 499.66(1) is guilty of a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(6) Any person who knowingly withholds information or makes any false or fictitious entry or misrepresentation upon any invoice, receipt, sales ticket, sales slip, or account of inventories as prohibited by s. 499.66(5) is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(7) Any licensee who knowingly fails to maintain written accounts of inventories or records of sales or transfers as required by s. 499.66(3) is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(8) Any permittee who knowingly fails to maintain written inventories and records as required by s. 499.67 is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(9) Any licensee or permittee who fails to report the loss, unexplained shortage, or theft of ether as required by s. 499.68(2) is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(10) Any person who knowingly possesses 2.5 gallons, or equivalent by weight, or more of ether in, or within 500 feet of, any residential housing structure as prohibited by s. 499.69(1) is guilty of a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

History.—ss. 10, 11, ch. 86-133; s. 121, ch. 91-224; s. 4, ch. 91-429.

499.76 Injunctive relief.—In addition to the penalties and other enforcement provisions of this part, in the event any person engaged in any of the activities covered by this part violates any provision of this part, any rule adopted pursuant thereto, or any cease and desist order as provided by this part, the department is authorized to resort to proceedings for injunction in the circuit court of the county in which the violation occurred or in which the person resides or has his or her principal place of business and may therein apply for such temporary and permanent orders as the department may deem necessary to restrain such person from engaging in any such activities until such person complies with the provisions of this part, the rules adopted pursuant thereto, and the orders of the department as authorized by this part.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 601, ch. 97-103.

499.77 Exceptions.—Nothing contained in this part shall apply to the regular military and naval forces of the United States, or to the duly organized military forces of any state or territory thereof, provided that they are acting within their respective official capacities and in the performance of their duties.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429.

499.78 County and municipal ordinances.—Nothing contained in this part shall affect any existing ordinance, rule, or regulation pertaining to ether in any county or municipality in this state, which ordinance, rule, or regulation is more restrictive than the provisions of this part and the rules adopted pursuant thereto; nor shall the provisions of this part limit the power of any county or municipality to make ordinances, rules, or regulations pertaining to ether which may be more restrictive than the provisions of this part and the rules adopted pursuant thereto.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429.

499.79 Deposit of fees.—All fees collected for licenses and permits required by this part shall be deposited in the Professional Regulation Trust Fund, and all moneys collected under this part and deposited in the trust fund 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.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 45, ch. 95-144; s. 19, ch. 2012-143.

PART III

MEDICAL GAS

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 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.

History.—s. 13, ch. 2014-89.

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 the 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 distribution schedules.

(b) Sales, purchases, trades, transfers, or use of a medical gas acquired by a medical director or licensed emergency medical services provider for use by the emergency medical services provider and its permitted transport and nontransport vehicles in accordance with the provider's license under part III of chapter 401.

(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, 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) "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 the United States Pharmacopeia.

(13) "USP-NF" means the 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) The sale, purchase, or trade of a medical gas or an offer to sell, purchase, or trade a medical gas for emergency medical reasons.

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

History.—s. 14, ch. 2014-89; s. 14, ch. 2016-212.

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 under this chapter.

(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-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 under this chapter.

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 sells or delivers medical oxygen directly to patients in this state. The sale and delivery must be based on a prescription or 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 under this chapter.

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 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 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.

(6) A hospice licensed by the Agency for Health Care Administration pursuant to part IV of chapter 400 is not required to obtain a medical oxygen retail establishment permit to purchase on behalf of and sell medical oxygen to its hospice patients if the hospice contracts for the purchase and delivery of medical oxygen from an establishment permitted pursuant to this part. Sale and delivery to patients by hospices pursuant to this subsection must be based upon a prescription or an order from a practitioner authorized by law to prescribe medical oxygen. For sales to hospices pursuant to this subsection, the medical gas wholesale distributor or the medical gas manufacturer selling medical oxygen to a hospice shall reflect on its invoice the hospice license number provided by the Agency for Health Care Administration and shall maintain such record pursuant to s. 499.89. Both the hospice and the medical oxygen retailer delivering medical oxygen to the patient must maintain a copy of a valid order or prescription for medical oxygen in accordance with s. 499.89 and department rule, which copy must be readily available for inspection.

History.—s. 15, ch. 2014-89; s. 15, ch. 2016-212; s. 35, ch. 2017-3.

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.

(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 current and former fictitious names, 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.

History.—s. 16, ch. 2014-89.

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 such activities, 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.

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

History.—s. 17, ch. 2014-89.

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 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.

(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.

History.—s. 18, ch. 2014-89.

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.

(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 has established in rule that are relevant to and consistent with the public health and safety.

History.—s. 19, ch. 2014-89.

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 for a personal dwelling location used for on-call delivery of oxygen USP for home care 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.

History.—s. 20, ch. 2014-89; s. 63, ch. 2015-2.

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. Such rules may not be inconsistent with part III of chapter 401 or rules adopted thereunder.

History.—s. 21, ch. 2014-89.

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.

History.—s. 22, ch. 2014-89.

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 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.

History.—s. 23, ch. 2014-89.

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.

History.—s. 24, ch. 2014-89.

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. ss. 211.196 and 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, and 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, and 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 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.

History.—s. 25, ch. 2014-89; s. 16, ch. 2016-212.

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 all of 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.

History.—s. 26, ch. 2014-89.

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

(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, and the delivery or proffered delivery of such medical gas for pay or otherwise.

(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 its 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. 499.833(3)(a), 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 of 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.

History.—s. 27, ch. 2014-89; s. 64, ch. 2015-2.

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 provides oxygen to a permitted medical oxygen retail establishment that is out of compliance with only the change of location notice requirement under s. 499.833(3)(a) does not commit a violation of this paragraph 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 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. Moneys 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.

History.—s. 28, ch. 2014-89; s. 65, ch. 2015-2.

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 routine 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; 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.

History.—s. 29, ch. 2014-89.

499.931 Trade secret information.—Information required to be submitted under this part which is a trade secret as defined in s. 812.081 and designated as a trade secret by an applicant or permitholder must be maintained as required under s. 499.051. This section is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2021, unless reviewed and saved from repeal through reenactment by the Legislature.

History.—s. 30, ch. 2014-89; s. 12, ch. 2016-6.

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.

History.—s. 31, ch. 2014-89.