By the Committee on Budget

576-03460-12 20121980__

A bill to be entitled

An act relating to the Department of Business and Professional Regulation; amending s. 20.165, F.S.; creating the Division of Drugs, Devices, and Cosmetics within the Department of Business and Professional Regulation; amending s. 455.116, F.S.; deleting the Florida Drug, Device, and Cosmetic Trust Fund from the list of trust funds placed in the department, to conform; amending ss. 499.003, 499.01211, 499.024, 499.065, 499.601, and 499.61, F.S.; conforming provisions to the transfer by s. 27, chapter 2010-161, Laws of Florida, of regulatory authority for ch. 499, F.S., from the Department of Health to the Department of Business and Professional Regulation; repealing s. 499.0031, F.S., relating to the Florida Drug, Device, and Cosmetic Trust Fund; terminating the Florida Drug, Device, and Cosmetic Trust Fund; providing for the disposition of balances in and revenues of such trust fund; prescribing procedures for the termination of such trust fund; amending ss. 499.01, 499.028, 499.04, 499.057, 499.062, 499.066, 499.62, 499.72, and 499.79, F.S.; conforming provisions; requiring the Department of Business and Professional Regulation to submit a report to the Legislature by a specified date; providing for future expiration; providing effective dates.

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

Section 1. Paragraphs (d) through (k) of subsection (2) of section 20.165, Florida Statutes, are redesignated as paragraphs (e) through (l), respectively, and a new paragraph (d) is added to that subsection to read:

20.165 Department of Business and Professional Regulation.—There is created a Department of Business and Professional Regulation.

(2) The following divisions of the Department of Business and Professional Regulation are established:

(d) Division of Drugs, Devices, and Cosmetics.

Section 2. Effective November 1, 2012, subsection (8) of section 455.116, Florida Statutes, is amended to read:

455.116 Regulation trust funds.—The following trust funds shall be placed in the department:

~~(8) Florida Drug, Device, and Cosmetic Trust Fund.~~

Section 3. Subsection (15) and paragraph (a) of subsection (54) of section 499.003, Florida Statutes, are amended to read:

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

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

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

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

1. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing

organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of that organization.

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

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

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

a. The agency or entity must obtain written authorization for the sale, purchase, trade, or other transfer of a prescription drug under this subparagraph from the Secretary of Business and Professional Regulation ~~State Surgeon General~~ 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. A contract provider or subcontractor must maintain separate and apart from other prescription drug inventory any prescription drugs of the agency or entity in its possession.

e. 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.

f. 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 e.

g. 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.

Section 4. Subsection (2) of section 499.01211, Florida Statutes, is amended to read:

499.01211 Drug Wholesale Distributor Advisory Council.—

(2) The Secretary of Business and Professional Regulation ~~State Surgeon General,~~ 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 ~~State Surgeon General~~ shall appoint nine additional members to the council who shall be appointed to a term of 4 years each, as follows:

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

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

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

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

(e) One person who is a physician licensed pursuant to

chapter 458 or chapter 459.

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

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

Section 5. Section 499.024, Florida Statutes, is amended to read:

499.024 Drug product classification.—The department ~~State Surgeon General~~ 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(19) may be classified under the authority of this section. This section does not subject portable emergency oxygen inhalators to classification; however, this section does not exempt any person from ss. 499.01 and 499.015.

(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.

Section 6. Subsection (2) of section 499.065, Florida Statutes, is amended to read:

499.065 Inspections; imminent danger.—

(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 ~~State Surgeon General~~ 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.

Section 7. Subsection (2) of section 499.601, Florida Statutes, is amended to read:

499.601 Legislative intent; construction.—

(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 ~~of Health~~ 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.

Section 8. Subsection (2) of section 499.61, Florida Statutes, is amended to read:

499.61 Definitions.—As used in this part:

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

Section 9. Effective November 1, 2012, section 499.0031, Florida Statutes, is repealed.

Section 10. (1) The Florida Drug, Device, and Cosmetic Trust Fund within the Department of Business and Professional Regulation, FLAIR number 20-2-173005, is terminated.

(2) The current balance remaining in, and all revenues of, the Florida Drug, Device, and Cosmetic Trust Fund shall be transferred to the Professional Regulation Trust Fund.

(3) The Department of Business and Professional Regulation shall pay any outstanding debts or obligations of the Florida Drug, Device, and Cosmetic Trust Fund as soon as practicable, and the Chief Financial Officer shall close out and remove the terminated fund from the various state accounting systems using generally accepted accounting principles concerning warrants outstanding, assets, and liabilities.

(4) This section shall take effect November 1, 2012.

Section 11. Paragraphs (d), (e), and (l) of subsection (2) of section 499.01, Florida Statutes, are amended to read:

499.01 Permits.—

(2) The following permits are established:

(d) *Prescription drug wholesale distributor permit.*—A prescription drug wholesale distributor is a wholesale distributor that may engage in the wholesale distribution of prescription drugs. A prescription drug wholesale distributor

that applies to the department for a new permit or the renewal of a permit must submit a bond of $100,000, 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 ~~Florida Drug, Device, and Cosmetic~~ 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. 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.

(e) *Out-of-state prescription drug wholesale distributor permit.*—An out-of-state prescription drug wholesale distributor is a wholesale distributor located outside this state which engages in the wholesale distribution of prescription drugs into this state and which must be permitted by the department and comply with all the provisions required of a wholesale distributor under this part. An out-of-state prescription drug wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of

$100,000, 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 ~~Florida Drug, Device, and Cosmetic~~ 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.

1. 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.

2. 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 ss. 499.0121(6) and 499.01212 must be followed for this transaction.

(l) *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 ~~Florida Drug, Device, and Cosmetic~~ 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 ss. 499.0121 and 499.01212, except that a limited prescription drug veterinary wholesale distributor is not required to provide a pedigree paper as required by s. 499.01212 upon the wholesale distribution of a prescription drug

to a veterinarian.

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 ss. 499.0121(6) and 499.01212 must be followed for this transaction.

Section 12. Subsection (13) of section 499.028, Florida Statutes, is amended to read:

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

(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 ~~Drug, Device, and Cosmetic~~ 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.

Section 13. Section 499.04, Florida Statutes, is amended to read:

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 ~~Florida Drug, Device, and Cosmetic~~ Trust Fund for the sole purpose of carrying out ~~the provisions of~~ this part.

Section 14. Section 499.057, Florida Statutes, is amended to read:

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. ~~special fund hereby created in the office of the Chief Financial Officer, which fund is to be known as the "Florida Drug, Device, and Cosmetic Trust Fund."~~

Section 15. Paragraph (a) of subsection (2) of section

499.062, Florida Statutes, is amended to read:

499.062 Seizure and condemnation of 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 ~~Florida Drug, Device, and Cosmetic~~ Trust Fund.

Section 16. Subsections (3) and (4) of section 499.066, Florida Statutes, are amended to read:

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

(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 part or rules adopted under this part. Each day a violation continues constitutes a separate violation, and each separate violation is subject to a separate fine. All amounts collected pursuant to this section shall be deposited into the Professional Regulation ~~Florida Drug, Device, and Cosmetic~~ Trust Fund and are appropriated for the use of the department in administering this part. In determining the amount of the fine to be levied for a violation, the department shall consider:

(a) The severity of the violation;

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

(c) Any previous violations.

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

Section 17. Subsection (7) of section 499.62, Florida Statutes, is amended to read:

499.62 License or permit required of manufacturer, distributor, dealer, or purchaser of ether.—

(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 ~~Florida Drug, Device, and Cosmetic~~ Trust Fund.

Section 18. Subsection (2) of section 499.72, Florida Statutes, is amended to read:

499.72 Administrative fines.—

(2) All such fines, monetary penalties, and costs received by the department in connection with this part shall be deposited in the Professional Regulation ~~Florida Drug, Device, and Cosmetic~~ Trust Fund.

Section 19. Section 499.79, Florida Statutes, is amended to read:

499.79 Deposit of fees.—All fees collected for licenses and permits required by this part shall be deposited in the Professional Regulation ~~Florida Drug, Device, and Cosmetic~~ Trust Fund ~~created by s. 499.057~~, and all moneys collected under ~~the provisions of~~ this part and deposited in the ~~such~~ trust fund shall be used by ~~are hereby appropriated for the use of~~ the department in the administration of this part.

Section 20. (1)(a) 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.

(b) The Drugs, Devices, and Cosmetics Program protects the public health, safety, and welfare by preventing fraud, adulteration, misbranding, and false advertising in the manufacture, repackaging, or distribution of drugs, devices, and cosmetics. The program promotes consistency between state and federal laws governing drugs, devices, and cosmetics by licensing manufacturers, repackagers, distributors, and certain retailers as required by federal law, and regulating persons and entities engaged in related activities, including, but not limited to, licensees, practitioners, pharmacies, clinics, and hospitals.

(2) By January 15, 2013, the Department of Business and Professional Regulation shall submit a report to the chairs of the Senate Budget Subcommittee on General Government Appropriations, the Senate Committee on Regulated Industries, the House Government Operations Appropriations Subcommittee, and the House of Representatives Subcommittee on Business and Consumer Affairs regarding the operation of the Drugs, Devices, and Cosmetics Program. The report must provide detailed options and recommendations to the Legislature relating to:

(a) Eliminating the program's operating deficit through operational changes or improved efficiencies;

(b) The cost-efficient alignment of the licensure renewal process under the program with other professions; and

(c) Regulating the program under chapter 455, Florida Statutes.

(d) This subsection expires July 1, 2013.

Section 21. Except as otherwise expressly provided in this act, this act shall take effect July 1, 2012.