By Senator McKay

26-1038A-00 See HB

A bill to be entitled

An act relating to obsolete, expired, or repealed provisions of law; repealing various provisions of law that have become obsolete, have had their effect, have served their purpose, or have been impliedly repealed or superseded; repealing s. 404.22(5)(c), F.S., relating to adoption of a fee schedule for fiscal year 1981-1982 for registration and inspection of radiation machines; repealing s. 458.349, F.S., relating to savings clauses applicable to repeal and reenactment in 1979 of ch. 458, F.S., relating to medical practice; repealing s. 459.024, F.S., relating to savings clauses applicable to repeal and reenactment in 1979 of ch. 459, F.S., relating to osteopathic medicine; repealing s. 461.015, F.S., relating to savings clauses applicable to repeal and reenactment in 1979 of ch. 461, F.S., relating to podiatric medicine; repealing s. 463.019, F.S., relating to savings clauses applicable to repeal and reenactment in 1986 of ch. 463, F.S., relating to optometry; repealing s. 464.0035, F.S., relating to staggering of initial terms on the joint committee appointed to approve acts of medical diagnosis and treatment, prescription, and operation that are authorized as advanced or specialized nursing practice; repealing s. 464.023, F.S., relating to savings clauses applicable to repeal and reenactment in 1979 of ch. 464, F.S., relating

to nursing; repealing s. 468.804, F.S., relating to the Orthotists and Prosthetists Educational Programs Task Force; repealing s. 484.019, F.S., relating to savings clauses applicable to repeal and reenactment in 1986 of pt. I, ch. 484, F.S., relating to preparing and dispensing of eyeglasses and other optical devices; repealing ss. 499.018, 499.019, 499.02, 499.021, and 499.022, F.S., to abolish the investigational drug program and the Florida Drug Technical Review Panel; repealing s. 499.003(16) and (28), F.S., relating to the definitions of "investigational drug" and "technical panel," to conform; amending ss. 381.0203, 499.015, 499.024, 499.03, 499.04, 499.041, and 499.067, F.S.; removing or revising references and related provisions, to conform; repealing s. 499.025(5), F.S., relating to applicability of provisions establishing identification requirements for drug products in finished, solid, oral dosage form; repealing s. 103, ch. 97-261, Laws of Florida, and s. 2, 98-226, Laws of Florida, relating to the task force on the health care practitioner credentialing program; repealing s. 13, ch. 99-332, F.S., relating to the Task Force on Home Health Services Licensure Provisions; repealing s. 28, ch. 99-394, Laws of Florida, relating to the certified nursing assistant study group; repealing ss. 125 and 175, ch. 99-397, Laws of Florida, relating to

the Task Force for the Study of Collaborative Drug Therapy Management and the Task Force on Telehealth; providing an effective date.

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

Section 1. Paragraph (c) of subsection (5) of section 404.22, Florida Statutes, is repealed.

Section 2. Section 458.349, Florida Statutes, is repealed.

Section 3. Section 459.024, Florida Statutes, is repealed.

Section 4. Section 461.015, Florida Statutes, is repealed.

Section 5. Section 463.019, Florida Statutes, is repealed.

Section 6. Section 464.0035, Florida Statutes, is repealed.

Section 7. Section 464.023, Florida Statutes, is repealed.

Section 8. Section 468.804, Florida Statutes, is repealed.

Section 9. Section 484.019, Florida Statutes, is repealed.

Section 10. Subsections (16) and (28) of section 499.003, Florida Statutes, and sections 499.018, 499.019, 499.02, 499.021, and 499.022, Florida Statutes, are repealed.

Section 11. Subsection (2) of section 381.0203, Florida Statutes, is amended to read:

381.0203 Pharmacy services.--

(2) The department may establish and maintain a pharmacy services program, including, but not limited to:

(a) A central pharmacy to support pharmaceutical services provided by the county health departments, including pharmaceutical repackaging, dispensing, and the purchase and distribution of immunizations and other pharmaceuticals.

(b) Regulation of drugs, cosmetics, and household products pursuant to chapter 499.

~~(c) An investigational drug program.~~

(c)~~(d)~~ Consultation to county health departments as required by s. 154.04(1)(c).

(d)~~(e)~~ A contraception distribution program which shall be implemented, to the extent resources permit, through the licensed pharmacies of county health departments. A woman who is eligible for participation in the contraceptive distribution program is deemed a patient of the county health department.

1. To be eligible for participation in the program a woman must:

a. Be a client of the department or the Department of Children and Family Services.

b. Be of childbearing age with undesired fertility.

c. Have an income between 150 and 200 percent of the federal poverty level.

d. Have no Medicaid benefits or applicable health insurance benefits.

e. Have had a medical examination by a licensed health care provider within the past 6 months.

f. Have a valid prescription for contraceptives that are available through the contraceptive distribution program.

g. Consent to the release of necessary medical information to the county health department.

2. Fees charged for the contraceptives under the program must cover the cost of purchasing and providing contraceptives to women participating in the program.

3. The department may adopt rules to administer this program.

Section 12. Subsections (1) and (3) of section 499.015, Florida Statutes, are amended to read:

499.015 Registration of drugs, devices, and cosmetics; issuance of certificates of free sale.--

(1) Except for those persons exempted from the definition in s. 499.003(20)~~(21)~~, any person who manufactures, packages, repackages, labels, or relabels a drug, device, or cosmetic in this state must register such drug, device, or cosmetic biennially with the department; pay a fee in accordance with the fee schedule provided by s. 499.041; and comply with this section. The registrant must list each separate and distinct drug, device, or cosmetic at the time of registration.

(3) Except for those persons exempted from the definition in s. 499.003(20)~~(21)~~, a person may not sell any product that he or she has failed to register in conformity with this section. Such failure to register subjects such drug, device, or cosmetic product to seizure and condemnation as provided in ss. 499.062-499.064, and subjects such person to the penalties and remedies provided in ss. 499.001-499.081.

Section 13. Section 499.024, Florida Statutes, is amended to read:

499.024 Drug product classification.--The secretary 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) The Florida Drug Technical Review Panel may review and make recommendations on products.~~

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

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

(3)~~(4)~~ Any product that falls under the drug definition, s. 499.003(11), 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)~~(5)~~ 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)~~(6)~~ The department may by rule reclassify drugs subject to ss. 499.001-499.081 when such classification action is necessary to protect the public health.

(6)~~(7)~~ The department may adopt rules that exempt from any labeling or packaging requirements of ss. 499.001-499.081 drugs classified under this section if those requirements are not necessary to protect the public health.

Section 14. Subsection (1) of section 499.03, Florida Statutes, is amended to read:

499.03 Possession of new drugs or legend 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(21)~~(22)~~, or legend drug as defined in s. 499.003(18), 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 legend 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 legend 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 ss. 499.001-499.081 which authorizes that person to possess prescription drugs.

Section 15. 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, ~~investigational drug applications,~~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 ss. 499.001-499.081. 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 ss. 499.001-499.081. The fees are payable to the department to be deposited into the Florida Drug, Device, and Cosmetic Trust Fund for the sole purpose of carrying out the provisions of ss. 499.001-499.081.

Section 16. Section 499.041, Florida Statutes, is amended to read:

499.041 Schedule of fees for drug, device, and cosmetic applications and permits, ~~investigational drug applications,~~product registrations, and free-sale certificates~~; trust fund~~.--

(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's permit may not be less than $500 or more than $600 annually.

(b) The fee for a device manufacturer's permit may not be less than $500 or more than $600 annually.

(c) The fee for a cosmetic manufacturer's permit may not be less than $250 or more than $400 annually.

(d) The fee for an over-the-counter drug manufacturer's permit may not be less than $300 or more than $400 annually.

(e) The fee for a compressed medical gas manufacturer's permit may not be less than $400 or more than $500 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 wholesaler's permit may not be less than $300 or more than $400 annually;

(b) The fee for a compressed medical gas wholesaler's permit may not be less than $200 or more than $300 annually;

(c) The fee for an out-of-state prescription drug wholesaler's permit may not be less than $200 or more than $300 annually;

(d) The fee for a retail pharmacy wholesaler's permit may not be less than $35 or more than $50 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 legend drug retail establishment permit may not be less than $200 or more than $300 annually;

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

(4) The department shall assess an applicant that is required to have a restricted prescription drug distributor's 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 ss. 499.001-499.081, beginning January 1, 1993, 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, devices, or cosmetic products 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 applicant that makes application for approval of an investigational drug pursuant to s. 499.018 a filing fee of not less than $1,000 or more than $1,100.~~

~~(9) The department shall assess each individual applicant the fees for consulting contracts provided for in s. 499.021. The consulting contracts must be completed by~~

~~contractors approved by the department. In awarding a consulting contract, preference must be given to the universities in the state and government laboratory resources, which must be contracted with when appropriate.~~

~~(10) Consulting contract fees must be set by the actual cost submitted by the contractor for each product application. All fees paid to the department, as provided in this section, must be placed in the Florida Drug, Device, and Cosmetic Trust Fund and used by the department for the administration of ss. 499.001-499.081.~~

(8)~~(11)~~ The department shall assess other fees as provided in ss. 499.001-499.081.

Section 17. Paragraph (a) of subsection (1) of section 499.067, Florida Statutes, is amended to read:

499.067 Denial, suspension, or revocation of permit 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 ss. 499.001-499.081 or chapter 465, chapter 501, or chapter 893, the rules adopted under any of those sections or chapters, any final order of the department, ~~the procedures and protocols established for any investigational drug product by the department,~~or applicable federal laws or regulations or other state laws or rules governing drugs, devices, or cosmetics.

Section 18. Subsection (5) of section 499.025, Florida Statutes, is repealed.

Section 19. Section 103 of chapter 97-261, Laws of Florida, and section 2 of chapter 98-226, Laws of Florida, are repealed.

Section 20. Section 13 of chapter 99-332, Laws of Florida, is repealed.

Section 21. Section 28 of chapter 99-394, Laws of Florida, is repealed.

Section 22. Sections 125 and 175 of chapter 99-397, Laws of Florida, are repealed.

Section 23. This act shall take effect upon becoming a law.

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LEGISLATIVE SUMMARY

Repeals various provisions of law that have become obsolete, have had their effect, have served their purpose, or have been impliedly repealed or superseded. Repeals or deletes provisions relating to adoption of a fee schedule for fiscal year 1981-1982 for registration and inspection of radiation machines; savings clauses applicable to repeal and reenactment of chs. 458, 459, 461, 463, and 464, F.S., relating to medical practice, osteopathic medicine, podiatric medicine, optometry, and nursing, and pt. I, ch. 484, F.S., relating to preparing and dispensing of eyeglasses and other optical devices; staggering of initial terms on the joint committee appointed to approve acts of medical diagnosis and treatment, prescription, and operation that are authorized as advanced or specialized nursing practice; the Orthotists and Prosthetists Educational Programs Task Force; the investigational drug program and the Florida Drug Technical Review Panel; applicability of provisions establishing identification requirements for drug products in finished, solid, oral dosage form; the task force on the health care practitioner credentialing program; the Task Force on Home Health Services Licensure Provisions; the certified nursing assistant study group; the Task Force for the Study of Collaborative Drug Therapy Management; and the Task Force on Telehealth.