

By the Committee on Rules & Calendar and Representative
Arnall

1 A bill to be entitled
2 An act relating to obsolete, expired, or
3 repealed provisions of law; repealing various
4 provisions of law that have become obsolete,
5 have had their effect, have served their
6 purpose, or have been impliedly repealed or
7 superseded; repealing s. 404.22(5)(c), F.S.,
8 relating to adoption of a fee schedule for
9 fiscal year 1981-1982 for registration and
10 inspection of radiation machines; repealing s.
11 458.349, F.S., relating to savings clauses
12 applicable to repeal and reenactment in 1979 of
13 ch. 458, F.S., relating to medical practice;
14 repealing s. 459.024, F.S., relating to savings
15 clauses applicable to repeal and reenactment in
16 1979 of ch. 459, F.S., relating to osteopathic
17 medicine; repealing s. 461.015, F.S., relating
18 to savings clauses applicable to repeal and
19 reenactment in 1979 of ch. 461, F.S., relating
20 to podiatric medicine; repealing s. 463.019,
21 F.S., relating to savings clauses applicable to
22 repeal and reenactment in 1986 of ch. 463,
23 F.S., relating to optometry; repealing s.
24 464.0035, F.S., relating to staggering of
25 initial terms on the joint committee appointed
26 to approve acts of medical diagnosis and
27 treatment, prescription, and operation that are
28 authorized as advanced or specialized nursing
29 practice; repealing s. 464.023, F.S., relating
30 to savings clauses applicable to repeal and
31 reenactment in 1979 of ch. 464, F.S., relating

1 to nursing; repealing s. 468.804, F.S.,
2 relating to the Orthotists and Prosthetists
3 Educational Programs Task Force; repealing s.
4 484.019, F.S., relating to savings clauses
5 applicable to repeal and reenactment in 1986 of
6 pt. I, ch. 484, F.S., relating to preparing and
7 dispensing of eyeglasses and other optical
8 devices; repealing ss. 499.018, 499.019,
9 499.02, 499.021, and 499.022, F.S., to abolish
10 the investigational drug program and the
11 Florida Drug Technical Review Panel; repealing
12 s. 499.003(16) and (28), F.S., relating to the
13 definitions of "investigational drug" and
14 "technical panel," to conform; amending ss.
15 381.0203, 499.015, 499.024, 499.03, 499.04,
16 499.041, and 499.067, F.S.; removing or
17 revising references and related provisions, to
18 conform; repealing s. 499.025(5), F.S.,
19 relating to applicability of provisions
20 establishing identification requirements for
21 drug products in finished, solid, oral dosage
22 form; repealing s. 103, ch. 97-261, Laws of
23 Florida, and s. 2, 98-226, Laws of Florida,
24 relating to the task force on the health care
25 practitioner credentialing program; repealing
26 s. 13, ch. 99-332, Laws of Florida, relating to
27 the Task Force on Home Health Services
28 Licensure Provisions; repealing s. 28, ch.
29 99-394, Laws of Florida, relating to the
30 certified nursing assistant study group;
31 repealing ss. 125 and 175, ch. 99-397, Laws of

1 Florida, relating to the Task Force for the
2 Study of Collaborative Drug Therapy Management
3 and the Task Force on Telehealth; providing an
4 effective date.

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

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8 Section 1. Paragraph (c) of subsection (5) of section
9 404.22, Florida Statutes, is repealed.

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

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

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

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

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

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

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

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

26 Section 10. Subsections (16) and (28) of section
27 499.003, Florida Statutes, and sections 499.018, 499.019,
28 499.02, 499.021, and 499.022, Florida Statutes, are repealed.

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

31 381.0203 Pharmacy services.--

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

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

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

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

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

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

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

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

22 b. Be of childbearing age with undesired fertility.

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

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

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

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

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

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

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

8 Section 12. Subsections (1) and (3) of section
9 499.015, Florida Statutes, are amended to read:

10 499.015 Registration of drugs, devices, and cosmetics;
11 issuance of certificates of free sale.--

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

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

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

30 499.024 Drug product classification.--The secretary
31 shall adopt rules to classify drug products intended for use

1 by humans which the United States Food and Drug Administration
2 has not classified in the federal act or the Code of Federal
3 Regulations.

4 ~~(1) The Florida Drug Technical Review Panel may review~~
5 ~~and make recommendations on products.~~

6 (1)~~(2)~~ Drug products must be classified as
7 proprietary, prescription, or investigational drugs.

8 (2)~~(3)~~ If a product is distributed without required
9 labeling, it is misbranded while held for sale.

10 (3)~~(4)~~ Any product that falls under the drug
11 definition, s. 499.003(11), may be classified under the
12 authority of this section. This section does not subject
13 portable emergency oxygen inhalators to classification;
14 however, this section does not exempt any person from ss.
15 499.01 and 499.015.

16 (4)~~(5)~~ Any product classified under the authority of
17 this section reverts to the federal classification, if
18 different, upon the federal regulation or act becoming
19 effective.

20 (5)~~(6)~~ The department may by rule reclassify drugs
21 subject to ss. 499.001-499.081 when such classification action
22 is necessary to protect the public health.

23 (6)~~(7)~~ The department may adopt rules that exempt from
24 any labeling or packaging requirements of ss. 499.001-499.081
25 drugs classified under this section if those requirements are
26 not necessary to protect the public health.

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

29 499.03 Possession of new drugs or legend drugs without
30 prescriptions unlawful; exemptions and exceptions.--

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1 (1) A person may not possess, or possess with intent
2 to sell, dispense, or deliver, any habit-forming, toxic,
3 harmful, or new drug subject to s. 499.003~~(21)(22)~~, or legend
4 drug as defined in s. 499.003(18), unless the possession of
5 the drug has been obtained by a valid prescription of a
6 practitioner licensed by law to prescribe the drug. However,
7 this section does not apply to the delivery of such drugs to
8 persons included in any of the classes named in this
9 subsection, or to the agents or employees of such persons, for
10 use in the usual course of their businesses or practices or in
11 the performance of their official duties, as the case may be;
12 nor does this section apply to the possession of such drugs by
13 those persons or their agents or employees for such use:
14 (a) A licensed pharmacist or any person under the
15 licensed pharmacist's supervision while acting within the
16 scope of the licensed pharmacist's practice;
17 (b) A licensed practitioner authorized by law to
18 prescribe legend drugs or any person under the licensed
19 practitioner's supervision while acting within the scope of
20 the licensed practitioner's practice;
21 (c) A qualified person who uses legend drugs for
22 lawful research, teaching, or testing, and not for resale;
23 (d) A licensed hospital or other institution that
24 procures such drugs for lawful administration or dispensing by
25 practitioners;
26 (e) An officer or employee of a federal, state, or
27 local government; or
28 (f) A person that holds a valid permit issued by the
29 department pursuant to ss. 499.001-499.081 which authorizes
30 that person to possess prescription drugs.
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1 Section 15. Section 499.04, Florida Statutes, is
2 amended to read:

3 499.04 Fee authority.--The department may collect fees
4 for all drug, device, and cosmetic applications, permits,
5 ~~investigational drug applications,~~ product registrations, and
6 free-sale certificates. The total amount of fees collected
7 from all permits, applications, product registrations, and
8 free-sale certificates must be adequate to fund the expenses
9 incurred by the department in carrying out ss.

10 499.001-499.081. The department shall, by rule, establish a
11 schedule of fees that are within the ranges provided in this
12 section and shall adjust those fees from time to time based on
13 the costs associated with administering ss. 499.001-499.081.
14 The fees are payable to the department to be deposited into
15 the Florida Drug, Device, and Cosmetic Trust Fund for the sole
16 purpose of carrying out the provisions of ss. 499.001-499.081.

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

19 499.041 Schedule of fees for drug, device, and
20 cosmetic applications and permits, ~~investigational drug~~
21 ~~applications,~~ product registrations, and free-sale
22 certificates, ~~trust fund.~~--

23 (1) The department shall assess applicants requiring a
24 manufacturing permit an annual fee within the ranges
25 established in this section for the specific type of
26 manufacturer.

27 (a) The fee for a prescription drug manufacturer's
28 permit may not be less than \$500 or more than \$600 annually.

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

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

3 (d) The fee for an over-the-counter drug
4 manufacturer's permit may not be less than \$300 or more than
5 \$400 annually.

6 (e) The fee for a compressed medical gas
7 manufacturer's permit may not be less than \$400 or more than
8 \$500 annually.

9 (f) A manufacturer may not be required to pay more
10 than one fee per establishment to obtain an additional
11 manufacturing permit, but each manufacturer must pay the
12 highest fee applicable to his or her operation in each
13 establishment.

14 (2) The department shall assess an applicant that is
15 required to have a wholesaling permit an annual fee within the
16 ranges established in this section for the specific type of
17 wholesaling.

18 (a) The fee for a prescription drug wholesaler's
19 permit may not be less than \$300 or more than \$400 annually;

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

22 (c) The fee for an out-of-state prescription drug
23 wholesaler's permit may not be less than \$200 or more than
24 \$300 annually;

25 (d) The fee for a retail pharmacy wholesaler's permit
26 may not be less than \$35 or more than \$50 annually.

27 (3) The department shall assess an applicant that is
28 required to have a retail establishment permit an annual fee
29 within the ranges established in this section for the specific
30 type of retail establishment.

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1 (a) The fee for a veterinary legend drug retail
2 establishment permit may not be less than \$200 or more than
3 \$300 annually;

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

6 (4) The department shall assess an applicant that is
7 required to have a restricted prescription drug distributor's
8 permit an annual fee of not less than \$200 or more than \$300.

9 (5) In addition to the fee charged for a permit
10 required by ss. 499.001-499.081, beginning January 1, 1993,
11 the department shall assess applicants an initial application
12 fee of \$150 for each new permit issued by the department which
13 requires an onsite inspection.

14 (6) A person that is required to register drugs,
15 devices, or cosmetic products under s. 499.015 shall pay an
16 annual product registration fee of not less than \$5 or more
17 than \$15 for each separate and distinct product in package
18 form. The registration fee is in addition to the fee charged
19 for a free-sale certificate.

20 (7) The department shall assess an applicant that
21 requests a free-sale certificate a fee of \$25. A fee of \$2
22 will be charged for each signature copy of a free-sale
23 certificate that is obtained at the same time the free-sale
24 certificate is issued.

25 ~~(8) The department shall assess an applicant that~~
26 ~~makes application for approval of an investigational drug~~
27 ~~pursuant to s. 499.018 a filing fee of not less than \$1,000 or~~
28 ~~more than \$1,100.~~

29 ~~(9) The department shall assess each individual~~
30 ~~applicant the fees for consulting contracts provided for in s.~~
31 ~~499.021. The consulting contracts must be completed by~~

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

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

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

13 Section 17. Paragraph (a) of subsection (1) of section
14 499.067, Florida Statutes, is amended to read:

15 499.067 Denial, suspension, or revocation of permit or
16 registration.--

17 (1)(a) The department may deny, suspend, or revoke a
18 permit if it finds that there has been a substantial failure
19 to comply with ss. 499.001-499.081 or chapter 465, chapter
20 501, or chapter 893, the rules adopted under any of those
21 sections or chapters, any final order of the department, ~~the~~
22 ~~procedures and protocols established for any investigational~~
23 ~~drug product by the department,~~ or applicable federal laws or
24 regulations or other state laws or rules governing drugs,
25 devices, or cosmetics.

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

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

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