

By the Committees on Health Care Licensing & Regulation,
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3 repealed provisions of law; repealing various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6 purpose, or have been impliedly repealed or
7 superseded; repealing s. 404.22(5)(c), F.S.,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.
11 408.02(5) and (6), F.S., relating to practice
12 parameters for certain services; amending ss.
13 627.6418 and 627.6613, F.S.; deleting
14 references, to conform; repealing s.
15 408.062(3), F.S., relating to annual assessment
16 and reporting on caesarean section rates and
17 the impact of practice parameters; repealing s.
18 458.349, F.S., relating to savings clauses
19 applicable to repeal and reenactment in 1979 of
20 ch. 458, F.S., relating to medical practice;
21 repealing s. 459.024, F.S., relating to savings
22 clauses applicable to repeal and reenactment in
23 1979 of ch. 459, F.S., relating to osteopathic
24 medicine; repealing s. 461.015, F.S., relating
25 to savings clauses applicable to repeal and
26 reenactment in 1979 of ch. 461, F.S., relating
27 to podiatric medicine; repealing s. 463.019,
28 F.S., relating to savings clauses applicable to
29 repeal and reenactment in 1986 of ch. 463,
30 F.S., relating to optometry; repealing s.
31 464.0035, F.S., relating to staggering of

1 initial terms on the joint committee appointed
2 to approve acts of medical diagnosis and
3 treatment, prescription, and operation that are
4 authorized as advanced or specialized nursing
5 practice; repealing s. 464.023, F.S., relating
6 to savings clauses applicable to repeal and
7 reenactment in 1979 of ch. 464, F.S., relating
8 to nursing; repealing s. 468.804, F.S.,
9 relating to the Orthotists and Prosthetists
10 Educational Programs Task Force; repealing s.
11 484.019, F.S., relating to savings clauses
12 applicable to repeal and reenactment in 1986 of
13 pt. I, ch. 484, F.S., relating to preparing and
14 dispensing of eyeglasses and other optical
15 devices; repealing ss. 499.018, 499.019,
16 499.02, 499.021, and 499.022, F.S., to abolish
17 the investigational drug program and the
18 Florida Drug Technical Review Panel; repealing
19 s. 499.003(16) and (28), F.S., relating to the
20 definitions of "investigational drug" and
21 "technical panel," to conform; amending ss.
22 381.0203, 499.015, 499.024, 499.03, 499.04,
23 499.041, and 499.067, F.S.; removing or
24 revising references and related provisions, to
25 conform; repealing s. 499.025(5), F.S.,
26 relating to applicability of provisions
27 establishing identification requirements for
28 drug products in finished, solid, oral dosage
29 form; repealing s. 103, ch. 97-261, Laws of
30 Florida, and s. 2, 98-226, Laws of Florida,
31 relating to the task force on the health care

1 practitioner credentialing program; repealing
2 s. 13, ch. 99-332, Laws of Florida, relating to
3 the Task Force on Home Health Services
4 Licensure Provisions; repealing s. 28, ch.
5 99-394, Laws of Florida, relating to the
6 certified nursing assistant study group;
7 repealing ss. 125 and 175, ch. 99-397, Laws of
8 Florida, relating to the Task Force for the
9 Study of Collaborative Drug Therapy Management
10 and the Task Force on Telehealth; providing an
11 effective date.

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

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15 Section 1. Paragraph (c) of subsection (5) of section
16 404.22, Florida Statutes, is repealed.

17 Section 2. Subsections (5) and (6) of section 408.02,
18 Florida Statutes, are repealed.

19 Section 3. Subsection (1) of section 627.6418, Florida
20 Statutes, is amended to read:

21 627.6418 Coverage for mammograms.--

22 (1) An accident or health insurance policy issued,
23 amended, delivered, or renewed in this state must provide
24 coverage for at least the following:

25 (a) A baseline mammogram for any woman who is 35 years
26 of age or older, but younger than 40 years of age.

27 (b) A mammogram every 2 years for any woman who is 40
28 years of age or older, but younger than 50 years of age, or
29 more frequently based on the patient's physician's
30 recommendation.

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1 (c) A mammogram every year for any woman who is 50
2 years of age or older.

3 (d) One or more mammograms a year, based upon a
4 physician's recommendation, for any woman who is at risk for
5 breast cancer because of a personal or family history of
6 breast cancer, because of having a history of biopsy-proven
7 benign breast disease, because of having a mother, sister, or
8 daughter who has or has had breast cancer, or because a woman
9 has not given birth before the age of 30.

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11 ~~It is the intent of the Legislature that, when practice~~
12 ~~parameters for the delivery of mammography services are~~
13 ~~developed pursuant to s. 408.02(7), the Legislature review the~~
14 ~~requirements of this section and conform to the practice~~
15 ~~parameters.~~

16 Section 4. Subsection (1) of section 627.6613, Florida
17 Statutes, is amended to read:

18 627.6613 Coverage for mammograms.--

19 (1) A group, blanket, or franchise accident or health
20 insurance policy issued, amended, delivered, or renewed in
21 this state must provide coverage for at least the following:

22 (a) A baseline mammogram for any woman who is 35 years
23 of age or older, but younger than 40 years of age.

24 (b) A mammogram every 2 years for any woman who is 40
25 years of age or older, but younger than 50 years of age, or
26 more frequently based on the patient's physician's
27 recommendation.

28 (c) A mammogram every year for any woman who is 50
29 years of age or older.

30 (d) One or more mammograms a year, based upon a
31 physician's recommendation, for any woman who is at risk for

1 breast cancer because of a personal or family history of
2 breast cancer, because of having a history of biopsy-proven
3 benign breast disease, because of having a mother, sister, or
4 daughter who has or has had breast cancer, or because a woman
5 has not given birth before the age of 30.
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7 ~~it is the intent of the Legislature that, when practice~~
8 ~~parameters for the delivery of mammography services are~~
9 ~~developed pursuant to s. 408.02(7), the Legislature review the~~
10 ~~requirements of this section and conform to the practice~~
11 ~~parameters.~~
12 Section 5. Subsection (3) of section 408.062, Florida
13 Statutes, is repealed.
14 Section 6. Section 458.349, Florida Statutes, is
15 repealed.
16 Section 7. Section 459.024, Florida Statutes, is
17 repealed.
18 Section 8. Section 461.015, Florida Statutes, is
19 repealed.
20 Section 9. Section 463.019, Florida Statutes, is
21 repealed.
22 Section 10. Section 464.0035, Florida Statutes, is
23 repealed.
24 Section 11. Section 464.023, Florida Statutes, is
25 repealed.
26 Section 12. Section 468.804, Florida Statutes, is
27 repealed.
28 Section 13. Section 484.019, Florida Statutes, is
29 repealed.
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1 Section 14. Subsections (16) and (28) of section
2 499.003, Florida Statutes, and sections 499.018, 499.019,
3 499.02, 499.021, and 499.022, Florida Statutes, are repealed.

4 Section 15. Subsection (2) of section 381.0203,
5 Florida Statutes, is amended to read:

6 381.0203 Pharmacy services.--

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

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

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

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

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

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

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

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

28 b. Be of childbearing age with undesired fertility.

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

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

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

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

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

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

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

14 Section 16. Subsections (1) and (3) of section
15 499.015, Florida Statutes, are amended to read:

16 499.015 Registration of drugs, devices, and cosmetics;
17 issuance of certificates of free sale.--

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

27 (3) Except for those persons exempted from the
28 definition in s. 499.003(20)~~(21)~~, a person may not sell any
29 product that he or she has failed to register in conformity
30 with this section. Such failure to register subjects such
31 drug, device, or cosmetic product to seizure and condemnation

1 as provided in ss. 499.062-499.064, and subjects such person
2 to the penalties and remedies provided in ss. 499.001-499.081.

3 Section 17. Section 499.024, Florida Statutes, is
4 amended to read:

5 499.024 Drug product classification.--The secretary
6 shall adopt rules to classify drug products intended for use
7 by humans which the United States Food and Drug Administration
8 has not classified in the federal act or the Code of Federal
9 Regulations.

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

12 (1)~~(2)~~ Drug products must be classified as
13 proprietary, prescription, or investigational drugs.

14 (2)~~(3)~~ If a product is distributed without required
15 labeling, it is misbranded while held for sale.

16 (3)~~(4)~~ Any product that falls under the drug
17 definition, s. 499.003(11), may be classified under the
18 authority of this section. This section does not subject
19 portable emergency oxygen inhalators to classification;
20 however, this section does not exempt any person from ss.
21 499.01 and 499.015.

22 (4)~~(5)~~ Any product classified under the authority of
23 this section reverts to the federal classification, if
24 different, upon the federal regulation or act becoming
25 effective.

26 (5)~~(6)~~ The department may by rule reclassify drugs
27 subject to ss. 499.001-499.081 when such classification action
28 is necessary to protect the public health.

29 (6)~~(7)~~ The department may adopt rules that exempt from
30 any labeling or packaging requirements of ss. 499.001-499.081

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1 drugs classified under this section if those requirements are
2 not necessary to protect the public health.

3 Section 18. Subsection (1) of section 499.03, Florida
4 Statutes, is amended to read:

5 499.03 Possession of new drugs or legend drugs without
6 prescriptions unlawful; exemptions and exceptions.--

7 (1) A person may not possess, or possess with intent
8 to sell, dispense, or deliver, any habit-forming, toxic,
9 harmful, or new drug subject to s. 499.003~~(21)~~~~(22)~~, or legend
10 drug as defined in s. 499.003(18), unless the possession of
11 the drug has been obtained by a valid prescription of a
12 practitioner licensed by law to prescribe the drug. However,
13 this section does not apply to the delivery of such drugs to
14 persons included in any of the classes named in this
15 subsection, or to the agents or employees of such persons, for
16 use in the usual course of their businesses or practices or in
17 the performance of their official duties, as the case may be;
18 nor does this section apply to the possession of such drugs by
19 those persons or their agents or employees for such use:

20 (a) A licensed pharmacist or any person under the
21 licensed pharmacist's supervision while acting within the
22 scope of the licensed pharmacist's practice;

23 (b) A licensed practitioner authorized by law to
24 prescribe legend drugs or any person under the licensed
25 practitioner's supervision while acting within the scope of
26 the licensed practitioner's practice;

27 (c) A qualified person who uses legend drugs for
28 lawful research, teaching, or testing, and not for resale;

29 (d) A licensed hospital or other institution that
30 procures such drugs for lawful administration or dispensing by
31 practitioners;

1 (e) An officer or employee of a federal, state, or
2 local government; or

3 (f) A person that holds a valid permit issued by the
4 department pursuant to ss. 499.001-499.081 which authorizes
5 that person to possess prescription drugs.

6 Section 19. Section 499.04, Florida Statutes, is
7 amended to read:

8 499.04 Fee authority.--The department may collect fees
9 for all drug, device, and cosmetic applications, permits,
10 ~~investigational drug applications~~, product registrations, and
11 free-sale certificates. The total amount of fees collected
12 from all permits, applications, product registrations, and
13 free-sale certificates must be adequate to fund the expenses
14 incurred by the department in carrying out ss.
15 499.001-499.081. The department shall, by rule, establish a
16 schedule of fees that are within the ranges provided in this
17 section and shall adjust those fees from time to time based on
18 the costs associated with administering ss. 499.001-499.081.
19 The fees are payable to the department to be deposited into
20 the Florida Drug, Device, and Cosmetic Trust Fund for the sole
21 purpose of carrying out the provisions of ss. 499.001-499.081.

22 Section 20. Section 499.041, Florida Statutes, is
23 amended to read:

24 499.041 Schedule of fees for drug, device, and
25 cosmetic applications and permits, ~~investigational drug~~
26 ~~applications~~, product registrations, and free-sale
27 certificates; ~~trust fund~~--

28 (1) The department shall assess applicants requiring a
29 manufacturing permit an annual fee within the ranges
30 established in this section for the specific type of
31 manufacturer.

- 1 (a) The fee for a prescription drug manufacturer's
2 permit may not be less than \$500 or more than \$600 annually.
- 3 (b) The fee for a device manufacturer's permit may not
4 be less than \$500 or more than \$600 annually.
- 5 (c) The fee for a cosmetic manufacturer's permit may
6 not be less than \$250 or more than \$400 annually.
- 7 (d) The fee for an over-the-counter drug
8 manufacturer's permit may not be less than \$300 or more than
9 \$400 annually.
- 10 (e) The fee for a compressed medical gas
11 manufacturer's permit may not be less than \$400 or more than
12 \$500 annually.
- 13 (f) A manufacturer may not be required to pay more
14 than one fee per establishment to obtain an additional
15 manufacturing permit, but each manufacturer must pay the
16 highest fee applicable to his or her operation in each
17 establishment.
- 18 (2) The department shall assess an applicant that is
19 required to have a wholesaling permit an annual fee within the
20 ranges established in this section for the specific type of
21 wholesaling.
- 22 (a) The fee for a prescription drug wholesaler's
23 permit may not be less than \$300 or more than \$400 annually;
- 24 (b) The fee for a compressed medical gas wholesaler's
25 permit may not be less than \$200 or more than \$300 annually;
- 26 (c) The fee for an out-of-state prescription drug
27 wholesaler's permit may not be less than \$200 or more than
28 \$300 annually;
- 29 (d) The fee for a retail pharmacy wholesaler's permit
30 may not be less than \$35 or more than \$50 annually.
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1 (3) The department shall assess an applicant that is
2 required to have a retail establishment permit an annual fee
3 within the ranges established in this section for the specific
4 type of retail establishment.

5 (a) The fee for a veterinary legend drug retail
6 establishment permit may not be less than \$200 or more than
7 \$300 annually;

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

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

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

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

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

29 ~~(8) The department shall assess an applicant that~~
30 ~~makes application for approval of an investigational drug~~

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1 ~~pursuant to s. 499.018 a filing fee of not less than \$1,000 or~~
2 ~~more than \$1,100.~~

3 ~~(9) The department shall assess each individual~~
4 ~~applicant the fees for consulting contracts provided for in s.~~
5 ~~499.021. The consulting contracts must be completed by~~
6 ~~contractors approved by the department. In awarding a~~
7 ~~consulting contract, preference must be given to the~~
8 ~~universities in the state and government laboratory resources,~~
9 ~~which must be contracted with when appropriate.~~

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

16 ~~(8)(11)~~ The department shall assess other fees as
17 provided in ss. 499.001-499.081.

18 Section 21. Paragraph (a) of subsection (1) of section
19 499.067, Florida Statutes, is amended to read:

20 499.067 Denial, suspension, or revocation of permit or
21 registration.--

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

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1 Section 22. Subsection (5) of section 499.025, Florida
2 Statutes, is repealed.
3 Section 23. Section 103 of chapter 97-261, Laws of
4 Florida, and section 2 of chapter 98-226, Laws of Florida, are
5 repealed.
6 Section 24. Section 13 of chapter 99-332, Laws of
7 Florida, is repealed.
8 Section 25. Section 28 of chapter 99-394, Laws of
9 Florida, is repealed.
10 Section 26. Sections 125 and 175 of chapter 99-397,
11 Laws of Florida, are repealed.
12 Section 27. This act shall take effect upon becoming a
13 law.
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