

By the Committee on Health Care Licensing & Regulation and
Representative Fasano

1 A bill to be entitled
2 An act relating to rulemaking authority for the
3 Department of Health; amending s. 154.011,
4 F.S.; authorizing rules governing the operation
5 of primary care programs to include certain
6 provisions; amending s. 154.06, F.S.;
7 authorizing rules establishing fee schedules
8 for public health services rendered through the
9 county health departments to include certain
10 provisions; amending s. 381.003, F.S.;
11 authorizing rules relating to prevention and
12 control of communicable diseases to include
13 certain provisions; amending s. 381.004, F.S.;
14 authorizing rules implementing provisions for
15 the testing of human immunodeficiency virus to
16 include certain provisions; amending s.
17 381.0051, F.S.; authorizing rules implementing
18 provisions relating to family planning to
19 include certain provisions; amending s.
20 381.0056, F.S.; authorizing rules implementing
21 provisions relating to the school health
22 services program to include certain provisions;
23 amending s. 381.0057, F.S.; requiring services
24 provided by comprehensive school health
25 projects to focus on promoting student health
26 and reducing risk-taking behavior and teen
27 pregnancy; declaring school health service
28 funding provisions supplemental to other
29 provisions; amending s. 381.006, F.S.;
30 authorizing rules relating to group-care
31 facilities to include certain provisions;

1 amending s. 381.0062, F.S.; exempting certain
2 public water systems from obtaining an annual
3 operating permit; amending s. 381.0065, F.S.;
4 revising the definition of "onsite sewage
5 treatment and disposal system"; authorizing
6 rules administering regulation of onsite sewage
7 treatment and disposal systems to include
8 certain provisions; revising duties and powers
9 of the department relating to such regulation
10 to include reference to use and operation of
11 such systems and to disposition of system
12 byproducts; revising sewage flow restrictions
13 applicable to subdivisions and lots using such
14 systems; amending s. 381.0072, F.S.;
15 authorizing rules prescribing minimum
16 sanitation standards and manager certification
17 requirements which are to be enforced in food
18 service establishments to include certain
19 provisions; amending s. 381.0086, F.S.;
20 authorizing rules relating to protection of the
21 health and safety of migrant farm workers and
22 other migrant labor camp or residential migrant
23 housing occupants to cover field sanitation
24 facilities and include certain provisions;
25 amending s. 381.0098, F.S.; authorizing rules
26 relating to regulation of biomedical waste to
27 include certain provisions; revising provisions
28 relating to application for and transfer of a
29 biomedical waste permit; prohibiting transfer
30 of registration from one biomedical waste
31 transporter to another; providing application

1 requirements for registration of transporter
2 when ownership or name changes; amending s.
3 381.0101, F.S.; authorizing rules relating to
4 certification of environmental health
5 professionals to include definitions; amending
6 s. 381.0203, F.S.; authorizing adoption of
7 rules to implement provisions relating to the
8 purchase of drugs to be used by state agencies
9 and political subdivisions; amending s. 381.89,
10 F.S.; providing for issuance of a stop-use
11 order to remove a tanning device from service;
12 authorizing rules implementing regulation of
13 tanning facilities to include definitions;
14 amending s. 383.011, F.S.; authorizing rules
15 administering the maternal and child health
16 care program to include certain provisions;
17 amending s. 383.14, F.S.; authorizing rules
18 administering the infant metabolic screening
19 program to include definitions; amending s.
20 383.19, F.S.; authorizing rules relating to
21 standards for development and operation of a
22 regional perinatal intensive care center to
23 include certain provisions; amending s.
24 383.216, F.S.; providing that local prenatal
25 and infant health care coalitions need not be
26 recognized as having federal tax exempt status;
27 authorizing rules implementing regulation of
28 community-based prenatal and infant health care
29 coalitions to include certain provisions;
30 amending s. 384.33, F.S.; authorizing rules
31 relating to control of sexually transmissible

1 diseases to include certain provisions;
2 amending s. 385.207, F.S.; authorizing rules
3 relating to care and control of epilepsy to
4 include certain provisions; amending s.
5 391.026, F.S.; authorizing rules implementing
6 the Children's Medical Services Act to include
7 certain provisions; amending s. 392.66, F.S.;
8 authorizing rules relating to tuberculosis
9 control to include certain provisions; amending
10 s. 395.401, F.S.; providing for establishment
11 by rule of processes and procedures for
12 formation and approval of trauma agencies and
13 of minimum requirements for conduct and
14 submission of annual performance evaluations
15 thereof; amending s. 395.402, F.S.; providing
16 for allocation by rule of the number of trauma
17 centers needed for each trauma service area;
18 amending s. 401.35, F.S.; requiring rules
19 relating to regulation of medical
20 transportation services to include definitions
21 and requirements relating to staffing for air
22 ambulance services, certificates of public
23 convenience and necessity, medical direction,
24 and licensure and certification; amending s.
25 403.862, F.S.; authorizing rules relating to
26 regulation of private and public water systems
27 to include definitions; amending s. 404.056,
28 F.S.; providing for basic and advanced levels
29 of certification to perform radon gas or radon
30 progeny measurements; authorizing establishment
31 of enforcement procedures and denial of

1 applications for initial certification or
2 renewal thereof; providing for other
3 certification requirements; amending s. 404.22,
4 F.S.; providing for the adoption of rules
5 relating to inspection of and standards for
6 radiation machines and their operation;
7 amending s. 489.553, F.S.; providing for
8 adoption of rules to implement provisions
9 regulating septic tank contracting; amending
10 ss. 491.006 and 491.0145, F.S.; providing that
11 application fees for licensure as a clinical
12 social worker, marriage and family therapist,
13 or mental health counselor by endorsement and
14 application and examination fees for
15 certification as a master social worker are
16 nonrefundable; amending s. 499.003, F.S.;
17 defining "distribute" or "distribution" for
18 purposes of the Florida Drug and Cosmetic Act;
19 amending ss. 499.024 and 499.03, F.S.; revising
20 cross references, to conform; amending s.
21 499.005, F.S.; prohibiting the charging of a
22 dispensing fee for a prescription drug sample
23 and the dispensing, administering, or
24 distributing of an investigational drug except
25 pursuant to an approved protocol; reenacting s.
26 499.069, F.S., relating to punishment for
27 violations of s. 499.005, to incorporate the
28 amendment to s. 499.005, F.S., in references
29 thereto; providing penalties; amending s.
30 499.0054, F.S.; providing that the
31 representation or suggestion in labeling or

1 advertising that an article is approved under
2 the Florida Drug and Cosmetic Act is a
3 violation of such act; providing penalties;
4 amending s. 499.01, F.S.; requiring submission
5 of the name and address of a contact person
6 regarding access to records required to be
7 maintained under the Florida Drug and Cosmetic
8 Act when a permitted establishment closes;
9 amending s. 499.0121, F.S.; requiring vehicles
10 containing prescription drugs to be secured
11 from unauthorized access to such drugs;
12 amending s. 499.0122, F.S.; providing for
13 adoption of rules relating to prescription or
14 order requirements for medical oxygen and
15 veterinary legend drug retail establishments;
16 amending s. 499.013, F.S.; providing that a
17 device manufacturer's permit is not required if
18 the person is engaged only in the manufacture
19 or assembly of medical devices pursuant to a
20 practitioner's order for a specific patient;
21 requiring manufacturers of devices,
22 over-the-counter drugs, or cosmetics to
23 maintain certain records; amending s. 499.015,
24 F.S.; prohibiting registration of products not
25 in compliance with the Federal Food, Drug, and
26 Cosmetic Act and related federal regulations
27 and declaring that registration does not mean
28 compliance with all provisions of such act;
29 revising cross references; amending s. 499.05,
30 F.S.; restricting rules that implement and
31 enforce the Florida Drug and Cosmetic Act to

1 specified provisions; amending s. 499.701,
2 F.S.; revising provisions relating to rules
3 administering regulation of ether to include
4 certain provisions; amending s. 501.122, F.S.;
5 authorizing performance standards for lasers
6 and other radiation control to include
7 provisions relating to radiation surveys and
8 measurements; amending s. 513.05, F.S.;
9 authorizing rules regulating mobile home parks,
10 lodging parks, recreational vehicle parks, and
11 recreational camps to include definitions;
12 amending s. 514.021, F.S.; authorizing rules
13 regulating public swimming and bathing
14 facilities to include definitions; amending s.
15 766.1115, F.S., the Access to Health Care Act;
16 revising the definition of "health care
17 provider"; revising contract requirements to
18 cover instances in which a treated individual
19 is later found to be ineligible; requiring
20 acknowledgment in writing of receipt of the
21 notice of agency relationship; authorizing
22 rules implementing the act to include services
23 to be provided and authorized procedures;
24 providing an effective date.

25
26
27
28
29
30
31

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

Section 1. Subsection (5) of section 154.011, Florida Statutes, is amended to read:

154.011 Primary care services.--

1 (5) The department shall adopt rules to govern the
2 operation of primary care programs authorized by this section.
3 Such rules ~~may shall~~ include, but not be limited to, income
4 eligibility, income verification, continuity of care, client
5 services, client enrollment and disenrollment, eligibility,
6 intake, recordkeeping, coverage, quality control, quality of
7 care, case management, and Medicaid participation and shall be
8 developed by the State Health Officer. Rules governing
9 services to clients under 21 years of age shall be developed
10 in conjunction with children's medical services and shall at a
11 minimum include preventive services as set forth in s.
12 627.6579.

13 Section 2. Subsection (1) of section 154.06, Florida
14 Statutes, is amended to read:

15 154.06 Fees and services rendered; authority.--

16 (1) The Department of Health is authorized to
17 establish by rule fee schedules for public health services
18 rendered through the county health departments. Such rules may
19 include provisions for fee assessments, copayments, sliding
20 fee scales, fee waivers, and fee exemptions.In addition, the
21 department shall adopt by rule a uniform statewide fee
22 schedule for all regulatory activities performed through the
23 environmental health program. Each county may establish, and
24 each county health department may collect, fees for primary
25 care services, provided that a schedule of such fees is
26 established by resolution of the board of county commissioners
27 or by rule of the department, respectively. Fees for primary
28 care services and communicable disease control services may
29 not be less than Medicaid reimbursement rates unless otherwise
30 required by federal or state law or regulation.

31

1 Section 3. Subsection (2) of section 381.003, Florida
2 Statutes, is amended to read:

3 381.003 Communicable disease and acquired immune
4 deficiency syndrome prevention and control.--

5 (2) The department may adopt, repeal, and amend rules
6 related to the prevention and control of communicable
7 diseases, including procedures for investigating disease,
8 timeframes for reporting disease, definitions, procedures for
9 management of specific diseases, requirements for followup
10 reports of known or suspected exposure to disease, and
11 procedures for providing access to confidential information
12 necessary for disease investigations.

13 Section 4. Subsection (10) of section 381.004, Florida
14 Statutes, is amended to read:

15 381.004 Testing for human immunodeficiency virus.--

16 (10) RULES.--The Department of Health may adopt such
17 rules as are necessary to implement this section, including
18 definitions, procedures for accessing confidential
19 information, requirements for testing, and requirements for
20 registered testing sites.

21 Section 5. Subsection (7) of section 381.0051, Florida
22 Statutes, is amended to read:

23 381.0051 Family planning.--

24 (7) RULES.--The Department of Health may adopt rules
25 to implement this section, including rules regarding
26 definitions, eligibility, informed consent services, revisits,
27 temporary contraceptive methods, voluntary sterilization, and
28 infertility services.

29 Section 6. Subsection (8) of section 381.0056, Florida
30 Statutes, is amended to read:

31 381.0056 School health services program.--

1 (8) The Department of Health, in cooperation with the
2 Department of Education, may adopt rules necessary to
3 implement this section. The rules may include school health
4 service plans, school health screening, standards for meeting
5 emergency health needs, school health record maintenance, and
6 coordination requirements with exceptional student education
7 programs.

8 Section 7. Subsection (7) is added to section
9 381.0057, Florida Statutes, to read:

10 381.0057 Funding for school health services.--

11 (7) Services provided by comprehensive school health
12 projects shall focus on promoting the health of students,
13 reducing risk-taking behavior, and reducing teen pregnancy.
14 Services provided under this section are in addition to those
15 provided under s. 381.0056 and supplement rather than supplant
16 such services.

17 Section 8. Subsection (16) of section 381.006, Florida
18 Statutes, is amended to read:

19 381.006 Environmental health.--The department shall
20 conduct an environmental health program as part of fulfilling
21 the state's public health mission. The purpose of this program
22 is to detect and prevent disease caused by natural and manmade
23 factors in the environment. The environmental health program
24 shall include, but not be limited to:

25 (16) A group-care-facilities function, where a
26 group-care facility means any public or private school,
27 housing, building or buildings, section of a building, or
28 distinct part of a building or other place, whether operated
29 for profit or not, which undertakes, through its ownership or
30 management, to provide one or more personal services, care,
31 protection, and supervision to persons who require such

1 services and who are not related to the owner or
2 administrator. The department may adopt rules necessary to
3 protect the health and safety of residents, staff, and patrons
4 of group-care facilities, such as child care facilities,
5 family day-care homes, assisted-living facilities, adult
6 day-care centers, adult family-care homes, hospices,
7 residential treatment facilities, crisis-stabilization units,
8 pediatric extended-care centers, intermediate-care facilities
9 for the developmentally disabled, group-care homes, and,
10 jointly with the Department of Education, private and public
11 schools. These rules may include definitions;provisions
12 relating to operation and maintenance of facilities,
13 buildings, grounds, equipment, furnishings, and occupant-space
14 requirements; lighting; heating, cooling, and ventilation;
15 food service;water supply, plumbing; sewage; sanitary
16 facilities; insect and rodent control; garbage; safety;
17 personnel health, hygiene, and work practices; and other
18 matters the department finds are appropriate or necessary to
19 protect the safety and health of the residents, staff, or
20 patrons. The department may not adopt rules that conflict with
21 rules adopted by the licensing or certifying agency. The
22 department may enter and inspect at reasonable hours to
23 determine compliance with applicable statutes or rules. In
24 addition to any sanctions that the department may impose for
25 violations of rules adopted under this section, the department
26 shall also report such violations to any agency responsible
27 for licensing or certifying the group-care facility. The
28 licensing or certifying agency may also impose any sanction
29 based solely on the findings of the department.

30 Section 9. Subsection (6) of section 381.0062, Florida
31 Statutes, is amended to read:

1 381.0062 Supervision; private and certain public water
2 systems.--

3 (6) VARIANCES AND EXEMPTIONS.--

4 (a) The department may grant variances and exemptions
5 from the rules promulgated under the provisions of this
6 section through procedures set forth by the rule of the
7 department.

8 (b) Any establishment with a limited use commercial
9 public water system which does not make tap water available
10 for public consumption and meets the water quality standards
11 and installation requirements established by the department
12 shall be exempt from obtaining an annual operating permit from
13 the department, if the supplier of water:

14 1. Registers with the department; if the establishment
15 changes ownership or business activity, it must register; and
16 pay a \$15 registration fee; and

17 2. Performs an initial water quality clearance of the
18 water supply system.

19

20 A system exempt under this subsection may, in order to retain
21 potable water status, conduct annual testing for bacteria in
22 the form of one satisfactory microbiological sample per
23 calendar year.

24 Section 10. Paragraph (j) of subsection (2),
25 paragraphs (a), (b), (c), and (l) of subsection (3), and
26 paragraphs (a), (b), (c), and (g) of subsection (4) of section
27 381.0065, Florida Statutes, are amended to read:

28 381.0065 Onsite sewage treatment and disposal systems;
29 regulation.--

30 (2) DEFINITIONS.--As used in ss. 381.0065-381.0067,
31 the term:

1 (j) "Onsite sewage treatment and disposal system"
2 means a system that contains a standard subsurface, filled, or
3 mound drainfield system; an aerobic treatment unit; a
4 graywater system tank; a laundry wastewater system tank; a
5 septic tank; a grease interceptor; a pump dosing tank; a
6 solids or effluent pump; a waterless, incinerating, or organic
7 waste-composting toilet; or a sanitary pit privy that is
8 installed or proposed to be installed beyond the building
9 sewer on land of the owner or on other land to which the owner
10 has the legal right to install a system. The term includes any
11 item placed within or intended to be used as a part of or in
12 conjunction with the system. This term does not include
13 package sewage treatment facilities and other treatment works
14 regulated under chapter 403.

15 (3) DUTIES AND POWERS OF THE DEPARTMENT OF
16 HEALTH.--The department shall:

17 (a) Adopt rules to administer ss. 381.0065-381.0067,
18 including definitions consistent with these sections;
19 decreases to setback requirements where no health hazard
20 exists; increases for lot flow allowance for performance-based
21 systems; separation from water table elevation at the wettest
22 season; requirements for the design and construction of any
23 component part of an onsite sewage treatment and disposal
24 system; application and permit requirements for persons
25 maintaining an onsite sewage treatment and disposal system;
26 requirements for maintenance service agreements for aerobic
27 treatment units and performance-based treatment systems; and
28 system inspection standards.

29 (b) Perform application reviews and site evaluations,
30 issue permits, and conduct inspections and complaint
31 investigations associated with the construction, installation,

1 maintenance, modification, abandonment, operation, use, or
2 repair of an onsite sewage treatment and disposal system for a
3 residence or establishment with an estimated domestic sewage
4 flow of 10,000 gallons or less per day, or an estimated
5 commercial sewage flow of 5,000 gallons or less per day, which
6 is not currently regulated under chapter 403.

7 (c) Develop a comprehensive program to ensure that
8 onsite sewage treatment and disposal systems regulated by the
9 department are sized, designed, constructed, installed,
10 repaired, modified, abandoned, used, operated, and maintained
11 in compliance with this section and rules adopted under this
12 section to prevent groundwater contamination and surface water
13 contamination and to preserve the public health. The
14 department is the final administrative interpretive authority
15 regarding rule interpretation. In the event of a conflict
16 regarding rule interpretation, the Division Director for
17 Environmental Health of the department, or his or her
18 designee, shall timely assign a staff person to resolve the
19 dispute.

20 (1) Regulate and permit the sanitation, handling,
21 treatment, storage, reuse, and disposal of byproducts from any
22 system regulated under this chapter and ~~sewage-stabilization~~
23 and disposal facilities not regulated by the Department of
24 Environmental Protection.

25 (4) PERMITS; INSTALLATION; AND CONDITIONS.--A person
26 may not construct, repair, modify, abandon, or operate an
27 onsite sewage treatment and disposal system without first
28 obtaining a permit approved by the department. The department
29 may issue permits to carry out this section, but shall not
30 make the issuance of such permits contingent upon prior
31 approval by the Department of Environmental Protection. A

1 construction permit is valid for 18 months from the issuance
2 date and may be extended by the department for one 90-day
3 period under rules adopted by the department. A repair permit
4 is valid for 90 days from the date of issuance. An operating
5 permit must be obtained prior to the use of any aerobic
6 treatment unit or if the establishment generates commercial
7 waste. Buildings or establishments that use an aerobic
8 treatment unit or generate commercial waste shall be inspected
9 by the department at least annually to assure compliance with
10 the terms of the operating permit. The operating permit is
11 valid for 1 year from the date of issuance and must be renewed
12 annually. If all information pertaining to the siting,
13 location, and installation conditions or repair of an onsite
14 sewage treatment and disposal system remains the same, a
15 construction or repair permit for the onsite sewage treatment
16 and disposal system may be transferred to another person, if
17 the transferee files, within 60 days after the transfer of
18 ownership, an amended application providing all corrected
19 information and proof of ownership of the property. There is
20 no fee associated with the processing of this supplemental
21 information. A person may not contract to construct, modify,
22 alter, repair, service, abandon, or maintain any portion of an
23 onsite sewage treatment and disposal system without being
24 registered under part III of chapter 489. A property owner
25 who personally performs construction, maintenance, or repairs
26 to a system serving his or her own owner-occupied
27 single-family residence is exempt from registration
28 requirements for performing such construction, maintenance, or
29 repairs on that residence, but is subject to all permitting
30 requirements. A municipality or political subdivision of the
31 state may not issue a building or plumbing permit for any

1 building that requires the use of an onsite sewage treatment
2 and disposal system unless the owner or builder has received a
3 construction permit for such system from the department. A
4 building or structure may not be occupied and a municipality,
5 political subdivision, or any state or federal agency may not
6 authorize occupancy until the department approves the final
7 installation of the onsite sewage treatment and disposal
8 system. A municipality or political subdivision of the state
9 may not approve any change in occupancy or tenancy of a
10 building that uses an onsite sewage treatment and disposal
11 system until the department has reviewed the use of the system
12 with the proposed change, approved the change, and amended the
13 operating permit.

14 (a) Subdivisions and lots in which each lot has a
15 minimum area of at least one-half acre and either a minimum
16 dimension of 100 feet or a mean of at least 100 feet of the
17 side bordering the street and the distance formed by a line
18 parallel to the side bordering the street drawn between the
19 two most distant points of the remainder of the lot may be
20 developed with a water system regulated under s. 381.0062 and
21 onsite sewage treatment and disposal systems, provided the
22 projected daily ~~domestic~~ sewage flow does not exceed an
23 average of 1,500 gallons per acre per day, and provided
24 satisfactory drinking water can be obtained and all distance
25 and setback, soil condition, water table elevation, and other
26 related requirements of this section and rules adopted under
27 this section can be met.

28 (b) Subdivisions and lots using a public water system
29 as defined in s. 403.852 may use onsite sewage treatment and
30 disposal systems, provided there are no more than four lots
31 per acre, provided the projected daily ~~domestic~~ sewage flow

1 does not exceed an average of 2,500 gallons per acre per day,
2 and provided that all distance and setback, soil condition,
3 water table elevation, and other related requirements that are
4 generally applicable to the use of onsite sewage treatment and
5 disposal systems are met.

6 (c) Notwithstanding the provisions of paragraphs (a)
7 and (b), for subdivisions platted of record on or before
8 October 1, 1991, when a developer or other appropriate entity
9 has previously made or makes provisions, including financial
10 assurances or other commitments, acceptable to the Department
11 of Health, that a central water system will be installed by a
12 regulated public utility based on a density formula, private
13 potable wells may be used with onsite sewage treatment and
14 disposal systems until the agreed-upon densities are reached.
15 The department may consider assurances filed with the
16 Department of Business and Professional Regulation under
17 chapter 498 in determining the adequacy of the financial
18 assurance required by this paragraph. In a subdivision
19 regulated by this paragraph, the average daily ~~domestic~~ sewage
20 flow may not exceed 2,500 gallons per acre per day. This
21 section does not affect the validity of existing prior
22 agreements. After October 1, 1991, the exception provided
23 under this paragraph is not available to a developer or other
24 appropriate entity.

25 (g) All provisions of this section and rules adopted
26 under this section relating to soil condition, water table
27 elevation, distance, and other setback requirements must be
28 equally applied to all lots, with the following exceptions:

29 1. Any residential lot that was platted and recorded
30 on or after January 1, 1972, or that is part of a residential
31 subdivision that was approved by the appropriate permitting

1 agency on or after January 1, 1972, and that was eligible for
2 an onsite sewage treatment and disposal system construction
3 permit on the date of such platting and recording or approval
4 shall be eligible for an onsite sewage treatment and disposal
5 system construction permit, regardless of when the application
6 for a permit is made. If rules in effect at the time the
7 permit application is filed cannot be met, residential lots
8 platted and recorded or approved on or after January 1, 1972,
9 shall, to the maximum extent possible, comply with the rules
10 in effect at the time the permit application is filed. At a
11 minimum, however, those residential lots platted and recorded
12 or approved on or after January 1, 1972, but before January 1,
13 1983, shall comply with those rules in effect on January 1,
14 1983, and those residential lots platted and recorded or
15 approved on or after January 1, 1983, shall comply with those
16 rules in effect at the time of such platting and recording or
17 approval. In determining the maximum extent of compliance
18 with current rules that is possible, the department shall
19 allow structures and appurtenances thereto which were
20 authorized at the time such lots were platted and recorded or
21 approved.

22 2. Lots platted before 1972 are subject to a 50-foot
23 minimum surface water setback and are not subject to lot size
24 requirements. The projected daily flow for ~~domestic~~ onsite
25 sewage treatment and disposal systems for lots platted before
26 1972 may not exceed:

27 a. Two thousand five hundred gallons per acre per day
28 for lots served by public water systems as defined in s.
29 403.852.

30 b. One thousand five hundred gallons per acre per day
31 for lots served by water systems regulated under s. 381.0062.

1 Section 11. Paragraph (a) of subsection (2) of section
2 381.0072, Florida Statutes, is amended to read:

3 381.0072 Food service protection.--It shall be the
4 duty of the Department of Health to adopt and enforce
5 sanitation rules consistent with law to ensure the protection
6 of the public from food-borne illness. These rules shall
7 provide the standards and requirements for the storage,
8 preparation, serving, or display of food in food service
9 establishments as defined in this section and which are not
10 permitted or licensed under chapter 500 or chapter 509.

11 (2) DUTIES.--

12 (a) The department shall adopt rules, including
13 definitions, consistent with law prescribing minimum
14 sanitation standards and manager certification requirements as
15 prescribed in s. 509.039, which shall be enforced in food
16 service establishments as defined in this section. The
17 sanitation standards must address the construction, operation,
18 and maintenance of the establishment; lighting, ventilation,
19 laundry rooms, lockers, use and storage of toxic materials and
20 cleaning compounds, and first aid supplies; plan review;
21 design, construction, installation, location, maintenance,
22 sanitation, and storage of food equipment and utensils;
23 employee training, health, hygiene, and work practices; food
24 supplies, preparation, storage, transportation, and service,
25 including access to the areas associated with such; and
26 sanitary facilities and controls, including water supply and
27 sewage disposal; plumbing and toilet facilities; garbage and
28 refuse collection, storage, and disposal; and vermin control.
29 Public and private schools, hospitals licensed under chapter
30 395, nursing homes licensed under part II of chapter 400,
31 child care facilities as defined in s. 402.301, and

1 residential facilities colocated with a nursing home or
2 hospital if all food is prepared in a central kitchen that
3 complies with nursing or hospital regulations shall be exempt
4 from the rules developed for manager certification. The
5 department shall administer a comprehensive inspection,
6 monitoring, and sampling program to ensure such standards are
7 maintained. With respect to food service establishments
8 permitted or licensed under chapter 500 or chapter 509, the
9 department shall assist the Division of Hotels and Restaurants
10 of the Department of Business and Professional Regulation and
11 the Department of Agriculture and Consumer Services with
12 rulemaking by providing technical information.

13 Section 12. Subsection (1) of section 381.0086,
14 Florida Statutes, is amended to read:

15 381.0086 Rules; variances; penalties.--

16 (1) The department shall adopt rules necessary to
17 protect the health and safety of migrant farm workers and
18 other migrant labor camp or residential migrant housing
19 occupants and to regulate field sanitation facilities. These
20 rules must include definitions, provisions relating to plan
21 review of the construction of new, expanded, or remodeled
22 camp, sites, buildings, and structures, personal hygiene
23 facilities, lighting, sewage disposal, safety, minimum living
24 space per occupant, bedding, food equipment, storage, and
25 preparation, insect and rodent control, garbage, heating
26 equipment, water supply, maintenance and operation of the
27 camp, housing, or roads, and such other matters as the
28 department finds to be appropriate or necessary to protect the
29 life and health of the occupants. Housing operated by a
30 public housing authority is exempt from the provisions of any
31

1 administrative rule that conflicts with or is more stringent
2 than the federal standards applicable to the housing.

3 Section 13. Subsections (3), (4), and (5) of section
4 381.0098, Florida Statutes, are amended to read:

5 381.0098 Biomedical waste.--

6 (3) OPERATING STANDARDS.--The department shall adopt
7 rules necessary to protect the health, safety, and welfare of
8 the public and to carry out the purpose of this section. Such
9 rules shall address, but need not be limited to, definitions;
10 the packaging of biomedical waste, including specific
11 requirements for the segregation of the waste at the point of
12 generation; the safe packaging of sharps; the placement of the
13 waste in containers that will protect waste handlers and the
14 public from exposure; the appropriate labeling of containers
15 of waste; written operating plans for managing biomedical
16 waste; and the transport, storage, and treatment of biomedical
17 wastes.

18 (4) PERMITS AND FEES.--

19 (a) All persons who generate, store, or treat
20 biomedical waste shall obtain a permit from the department
21 prior to commencing operation, except that a biomedical waste
22 generator generating less than 25 pounds of biomedical waste
23 in each 30-day period shall be exempt from the registration
24 and fee requirements of this subsection. A biomedical waste
25 generator need not obtain a separate permit if such generator
26 works less than 6 hours in a 7-day period at a location
27 different than the location specified on the permit. The
28 department may issue combined permits for generation, storage,
29 and treatment as appropriate to streamline permitting
30 procedures. Application for such permit shall be made on an
31

1 application form provided by the department within the
2 timeframes and manner prescribed by department rule.

3 (b) Once the department determines that the person
4 generating, storing, or treating biomedical waste is capable
5 of constructing a facility or operating in compliance with
6 this section and the rules adopted under this section, the
7 department shall grant the permit.

8 (c) If the department determines that the person
9 generating, storing, or treating biomedical waste does not
10 meet the provisions outlined in this section or the rules
11 adopted under this section, the department shall deny the
12 application for the permit pursuant to provisions of chapter
13 120. Such denial shall be in writing and shall list the
14 circumstances for denial. Upon correction of such
15 circumstances the permit shall be issued.

16 (d) The permit for a biomedical waste facility
17 ~~generator~~ shall not be transferred ~~from one owner to another.~~
18 When the ownership, control, or name of a biomedical waste
19 facility generator is changed and continues to operate, the
20 new owner shall apply to the department, upon forms provided
21 by the department, for issuance of a permit in the timeframe
22 and manner prescribed by rule of the department.

23 ~~(e) A permit which the department may require by rule,~~
24 ~~for the storage or treatment of biomedical waste, may not be~~
25 ~~transferred by the permittee to any other entity, except in~~
26 ~~conformity with the requirements of this paragraph.~~

27 ~~1. Within 30 days after the sale or legal transfer of~~
28 ~~a permitted facility, the permittee shall file with the~~
29 ~~department an application for transfer of a permit on such~~
30 ~~form as the department shall establish by rule. The form must~~
31

1 ~~be completed with the notarized signatures of both the~~
2 ~~transferring permittee and the proposed permittee.~~

3 ~~2. The department shall approve the transfer of a~~
4 ~~permit unless it determines that the proposed permittee has~~
5 ~~not provided reasonable assurances that the proposed permittee~~
6 ~~has the administrative, technical, and financial capability to~~
7 ~~properly satisfy the requirements and conditions of the~~
8 ~~permit, as determined by department rule. The determination~~
9 ~~shall be limited solely to the ability of the proposed~~
10 ~~permittee to comply with the conditions of the existing~~
11 ~~permit, and it shall not concern the adequacy of the permit~~
12 ~~conditions. If the department proposes to deny the transfer,~~
13 ~~it shall provide both the transferring permittee and the~~
14 ~~proposed permittee a written objection to such transfer~~
15 ~~together with notice of a right to request a proceeding on~~
16 ~~such determination under chapter 120.~~

17 ~~3. Within 90 days after receiving a properly completed~~
18 ~~application for transfer of a permit, the department shall~~
19 ~~issue a final determination. The department may toll the time~~
20 ~~for making a determination on the transfer by notifying both~~
21 ~~the transferring permittee and the proposed permittee that~~
22 ~~additional information is required to adequately review the~~
23 ~~transfer request. Such notification shall be provided within~~
24 ~~30 days after receipt of an application for transfer of the~~
25 ~~permit, completed pursuant to this paragraph. If the~~
26 ~~department fails to take action to approve or deny the~~
27 ~~transfer within 90 days after receipt of the completed~~
28 ~~application or within 90 days after receipt of the last item~~
29 ~~of timely requested additional information, the transfer shall~~
30 ~~be deemed approved.~~

31

1 4. ~~The transferring permittee is encouraged to apply~~
2 ~~for a permit transfer well in advance of the sale or legal~~
3 ~~transfer of a permitted facility. However, the transfer of~~
4 ~~the permit shall not be effective prior to the sale or legal~~
5 ~~transfer of the facility.~~

6 5. ~~Until the transfer of the permit is approved by the~~
7 ~~department, the transferring permittee and any other person~~
8 ~~constructing, operating, or maintaining the permitted facility~~
9 ~~shall be liable for compliance with the terms of the permit.~~
10 ~~Nothing in this section shall relieve the transferring~~
11 ~~permittee of liability for corrective actions that may be~~
12 ~~required as a result of any violations occurring prior to the~~
13 ~~legal transfer of the permit.~~

14 (e)~~(f)~~ The department shall establish a schedule of
15 fees for such permits. Fees assessed under this section shall
16 be in an amount sufficient to meet the costs of carrying out
17 the provisions of this section and rules adopted under this
18 section. The fee schedule shall not be less than \$50 or more
19 than \$400 for each year the permit is valid. Fees may be
20 prorated on a quarterly basis when a facility will be in
21 operation for 6 months or less before the annual renewal date.
22 The department shall assess the minimum fees provided in this
23 subsection until a fee schedule is promulgated by rule of the
24 department. Facilities owned and operated by the state shall
25 be exempt from the payment of any fees.

26 (f)~~(g)~~ Fees collected by the department in accordance
27 with provisions of this section and the rules adopted under
28 this section shall be deposited into a trust fund administered
29 by the department for the payment of costs incurred in the
30 administration of this section.

31

1 ~~(g)(h)~~ Permits issued by the department shall be valid
2 for no more than 5 years. However, upon expiration, a new
3 permit may be issued by the department in accordance with this
4 section and the rules of the department.

5 ~~(h)(i)~~ The department is authorized to develop a
6 streamlined process for permitting biomedical waste storage
7 facilities that accept and store only sharps collected from
8 the public, which may include the issuance of a single permit
9 for each applicant which develops or sponsors a sharps
10 collection program.

11 (5) TRANSPORTERS.--Any person who transports
12 biomedical waste within the state must register with the
13 department prior to engaging in the transport of biomedical
14 waste in accordance with rules promulgated by the department.
15 Registrations shall not be transferred from one biomedical
16 waste transporter to another. When the ownership or name of a
17 biomedical waste transporter is changed and continues to
18 operate, the new owner shall apply to the department on
19 departmental forms within the timeframes and manner prescribed
20 by department rule.The department may charge registration
21 fees in the same manner as is provided in paragraphs (4)~~(e)(f)~~
22 and~~(f)(g)~~. The department may exempt from this requirement
23 any person who, or facility that, transports less than 25
24 pounds of such waste on any single occasion.

25 Section 14. Subsection (5) of section 381.0101,
26 Florida Statutes, is amended to read:

27 381.0101 Environmental health professionals.--

28 (5) STANDARDS FOR CERTIFICATION.--The department shall
29 adopt rules that establish definitions and minimum standards
30 of education, training, or experience for those persons
31 subject to this section. The rules shall also address the

1 process for application, examination, issuance, expiration,
2 and renewal of certification and ethical standards of practice
3 for the profession.

4 (a) Persons employed as environmental health
5 professionals shall exhibit a knowledge of rules and
6 principles of environmental and public health law in Florida
7 through examination. A person may not conduct environmental
8 health evaluations in a primary program area unless he or she
9 is currently certified in that program area or works under the
10 direct supervision of a certified environmental health
11 professional.

12 1. All persons who begin employment in a primary
13 environmental health program on or after September 21, 1994,
14 must be certified in that program within 6 months after
15 employment.

16 2. Persons employed in a primary environmental health
17 program prior to September 21, 1994, shall be considered
18 certified while employed in that position and shall be
19 required to adhere to any professional standards established
20 by the department pursuant to paragraph (b), complete any
21 continuing education requirements imposed under paragraph (d),
22 and pay the certificate renewal fee imposed under subsection
23 (7).

24 3. Persons employed in a primary environmental health
25 program prior to September 21, 1994, who change positions or
26 program areas and transfer into another primary environmental
27 health program area on or after September 21, 1994, must be
28 certified in that program within 6 months after such transfer,
29 except that they will not be required to possess the college
30 degree required under paragraph (e).

31

1 4. Registered sanitarians shall be considered
2 certified and shall be required to adhere to any professional
3 standards established by the department pursuant to paragraph
4 (b).

5 (b) At a minimum, the department shall establish
6 standards for professionals in the areas of food hygiene and
7 onsite sewage treatment and disposal.

8 (c) Those persons conducting primary environmental
9 health evaluations shall be certified by examination to be
10 knowledgeable in any primary area of environmental health in
11 which they are routinely assigned duties.

12 (d) Persons who are certified shall renew their
13 certification biennially by completing not less than 24
14 contact hours of continuing education for each program area in
15 which they maintain certification.

16 (e) Applicants for certification shall have graduated
17 from an accredited 4-year college or university with a degree
18 or major coursework in public health, environmental health,
19 environmental science, or a physical or biological science.

20 (f) A certificateholder shall notify the department
21 within 60 days after any change of name or address from that
22 which appears on the current certificate.

23 Section 15. Subsection (1) of section 381.0203,
24 Florida Statutes, is amended to read:

25 381.0203 Pharmacy services.--

26 (1) The department may contract on a statewide basis
27 for the purchase of drugs, as defined in s. 499.003, to be
28 used by state agencies and political subdivisions and may
29 adopt rules to implement this subsection.

30 Section 16. Subsections (12) and (13) of section
31 381.89, Florida Statutes, are amended to read:

1 381.89 Regulation of tanning facilities.--

2 (12) The department may institute legal action for
3 injunctive or other relief to enforce this section. For
4 violations of this section or rules adopted thereunder, the
5 department may issue a stop-use order, as prescribed by rule,
6 to remove a tanning device from service.

7 (13) The department shall adopt rules to implement
8 this section. The rules may include, but need not be limited
9 to, definitions; requirements for training tanning facility
10 operators and employees; the approval of training courses;
11 safety; plan review; and the design, construction, operation,
12 maintenance, and cleanliness of tanning facilities and tanning
13 devices.

14 Section 17. Paragraph (a) of subsection (2) of section
15 383.011, Florida Statutes, is amended to read:

16 383.011 Administration of maternal and child health
17 programs.--

18 (2) The Department of Health shall follow federal
19 requirements and may adopt any rules necessary for the
20 implementation of the maternal and child health care program,
21 the WIC program, and the Child Care Food Program.

22 (a) The department may adopt rules that are necessary
23 to administer the maternal and child health care program. The
24 rules may include, but need not be limited to, requirements
25 for client eligibility, program standards, service delivery,
26 system responsibilities of county health departments and
27 Healthy Start coalitions, system assurances, care
28 coordination, enhanced services, quality assurance, and
29 provider selection. Rules may also include identification,
30 screening, and intervention efforts by health care providers
31 prior to and following the birth of a child, and

1 responsibilities for interprogram coordination for prenatal
2 and infant care coalitions.

3 Section 18. Subsection (2) of section 383.14, Florida
4 Statutes, is amended to read:

5 383.14 Screening for metabolic disorders, other
6 hereditary and congenital disorders, and environmental risk
7 factors.--

8 (2) RULES.--After consultation with the Genetics and
9 Infant Screening Advisory Council, the department shall adopt
10 and enforce rules requiring that every infant born in this
11 state shall, prior to becoming 2 weeks of age, be subjected to
12 a test for phenylketonuria and, at the appropriate age, be
13 tested for such other metabolic diseases and hereditary or
14 congenital disorders as the department may deem necessary from
15 time to time. After consultation with the State Coordinating
16 Council for Early Childhood Services, the department shall
17 also adopt and enforce rules requiring every infant born in
18 this state to be screened for environmental risk factors that
19 place children and their families at risk for increased
20 morbidity, mortality, and other negative outcomes. The
21 department shall adopt such additional rules as are found
22 necessary for the administration of this section, including
23 rules relating to definitions, rules relating to the methods
24 used and time or times for testing as accepted medical
25 practice indicates, rules relating to charging and collecting
26 fees for screenings authorized by this section, and rules
27 requiring mandatory reporting of the results of tests and
28 screenings for these conditions to the department.

29 Section 19. Paragraphs (f) and (g) are added to
30 subsection (1) of section 383.19, Florida Statutes, to read:

31 383.19 Standards; funding; ineligibility.--

1 (1) The department shall adopt rules that specify
2 standards for development and operation of a center which
3 include, but are not limited to:

4 (f) Data collection.

5 (g) Definitions.

6 Section 20. Subsections (9) and (10) of section
7 383.216, Florida Statutes, are amended to read:

8 383.216 Community-based prenatal and infant health
9 care.--

10 (9) Local prenatal and infant health care coalitions
11 shall incorporate as not-for-profit corporations for the
12 purpose of seeking and receiving grants from federal, state,
13 and local government and other contributors, but need not be
14 recognized by the Internal Revenue Service as having exempt
15 status under s. 501(c)(3) of the Internal Revenue Code.

16 (10) The Department of Health shall adopt rules as
17 necessary to implement this section, including rules defining
18 acceptable "in-kind" contributions and rules providing other
19 definitions, coalition responsibilities, coalition operations
20 and standards, and conditions for establishing and approving
21 coalitions. Coalitions may not be direct providers of prenatal
22 and infant care services.

23 Section 21. Section 384.33, Florida Statutes, is
24 amended to read:

25 384.33 Rules.--The department may adopt rules pursuant
26 to ss. 120.536(1) and 120.54 to implement the provisions of
27 this chapter. The rules may include requirements for methods
28 of contacting a physician to determine the need for followup
29 services related to sexually transmissible diseases; standards
30 for screening, treatment, and contact investigations to
31 control the spread of sexually transmissible diseases;and

1 requirements for maintaining the security of confidential
2 information.

3 Section 22. Subsection (4) of section 385.207, Florida
4 Statutes, is amended to read:

5 385.207 Care and assistance of persons with epilepsy;
6 establishment of programs in epilepsy control.--

7 (4) The department shall adopt rules to implement this
8 section. The rules may include scope of service, eligibility
9 criteria, required reports, and forms.

10 Section 23. Subsection (18) of section 391.026,
11 Florida Statutes, is amended to read:

12 391.026 Powers and duties of the department.--The
13 department shall have the following powers, duties, and
14 responsibilities:

15 (18) To adopt rules pursuant to ss. 120.536(1) and
16 120.54 to implement the provisions of this act. The rules may
17 include definitions; program organization; program
18 description; selection process for an area medical director;
19 responsibilities of applicants and clients; service
20 application requirements, including medical and financial
21 information; initial treatment eligibility and continued
22 eligibility requirements, including financial and custody
23 issues; resource development and allocation methodologies,
24 including medical and financial considerations; reimbursement
25 services rendered to the client; billing and payment
26 requirements for providers; qualifications, appointments,
27 verifications, and emergency exceptions for health
28 professional consultants; general and diagnostic-specific
29 standards for diagnostic and treatment facilities; and
30 standards for the method of service delivery, including
31

1 consultants, respect for privacy, examination requirements,
2 family support plans, and clinic concept.

3 Section 24. Section 392.66, Florida Statutes, is
4 amended to read:

5 392.66 Rules.--The department shall adopt rules
6 pursuant to ss. 120.536(1) and 120.54 to implement the
7 provisions of this chapter. Such rules shall include
8 provisions for tuberculosis treatment and consequences for
9 noncompliance with treatment.

10 Section 25. Paragraphs (a) and (c) of subsection (2)
11 of section 395.401, Florida Statutes, are amended to read:

12 395.401 Trauma services system plans; verification of
13 trauma centers and pediatric trauma referral centers;
14 procedures; renewal.--

15 (2)(a) The local and regional trauma agencies shall
16 plan, implement, and evaluate trauma services systems, in
17 accordance with this section and ss. 395.4015, 395.404, and
18 395.4045, which consist of organized patterns of readiness and
19 response services based on public and private agreements and
20 operational procedures. The department shall establish, by
21 rule, processes and procedures for the formation and approval
22 by the department of a trauma agency.

23 (c) The department shall receive plans for the
24 implementation of inclusive trauma systems from trauma
25 agencies. The department may approve or not approve trauma
26 agency plans based on the conformance of the plan with this
27 section and ss. 395.4015, 395.404, and 395.4045 and the rules
28 adopted by the department, including definitions, pursuant to
29 those sections. The department shall approve or disapprove
30 the plans within 120 days after the date the plans are
31 submitted to the department. The department shall, by rule,

1 provide for application for the formation of a trauma agency.
2 The application shall, at a minimum, provide for submission of
3 a trauma agency plan, a process for the trauma agency review
4 of applications for state-approved trauma centers, a process
5 for the trauma agency review of trauma transport protocols,
6 and staffing requirements for the trauma agency. The
7 department shall, by rule, establish minimum requirements for
8 a trauma agency to conduct an annual performance evaluation
9 and submission of the results to the department.

10 Section 26. Paragraph (b) of subsection (3) of section
11 395.402, Florida Statutes, is amended to read:

12 395.402 Trauma service areas; number and location of
13 trauma centers.--

14 (3) Trauma service areas are to be used. The
15 department shall periodically review the assignment of the 67
16 counties to trauma service areas. These assignments are made
17 for the purpose of developing a system of trauma centers.
18 Revisions made by the department should take into
19 consideration the recommendations made as part of the regional
20 trauma system plans approved by the department, as well as the
21 recommendations made as part of the state trauma system plan.
22 These areas must, at a minimum, be reviewed in the year 2000
23 and every 5 years thereafter. Until the department completes
24 its initial review, the assignment of counties shall remain as
25 established pursuant to chapter 90-284, Laws of Florida.

26 (b) Each trauma service area should have at least one
27 Level I or Level II trauma center. The department shall
28 allocate, by rule, the number of trauma centers needed for
29 each trauma service area.

30 Section 27. Section 401.35, Florida Statutes, is
31 amended to read:

1 401.35 Rules.--The department shall adopt rules,
2 including definitions, necessary to carry out the purposes of
3 this part.

4 (1) The rules must provide at least minimum standards
5 governing:

6 (a) Sanitation, safety, and maintenance of basic life
7 support and advanced life support vehicles and air ambulances.

8 (b) Emergency medical technician, paramedic, and
9 driver training and qualifications.

10 (c) Ground ambulance and vehicle equipment and
11 supplies at least as comprehensive as those published in the
12 most current edition of the American College of Surgeons,
13 Committee on Trauma, list of essential equipment for
14 ambulances, as interpreted by rules of the department.

15 (d) Ground ambulance or vehicle design and
16 construction at least equal to those most currently
17 recommended by the United States General Services
18 Administration as interpreted by rules of the department.

19 (e) Staffing of basic life support and advanced life
20 support vehicles.

21 (f) Two-way communications for basic life support
22 services and advanced life support services.

23 (g) Advanced life support services equipment.

24 (h) Programs of training for emergency medical
25 technicians and paramedics.

26 (i) Vehicles, equipment, communications, and minimum
27 staffing qualifications for air ambulance services.

28 (j) Ambulance driver qualifications, training, and
29 experience.

30 (k) Optional use of telemetry by licensees.

31

- 1 (1) Licensees' security and storage of controlled
2 substances, medications, and fluids, not inconsistent with the
3 provisions of chapter 499 or chapter 893.
- 4 (m) Requirements for certificates of public
5 convenience and necessity.
- 6 (2) The rules must establish application requirements
7 for biennial licensure and certification. Pursuant thereto,
8 the department must develop application forms for basic life
9 support services and advanced life support services. An
10 application for each respective service license must include,
11 but is not limited to:
- 12 (a) The name and business address of the operator and
13 owner of the service or proposed service.
- 14 (b) The name under which the applicant will operate.
- 15 (c) A list of the names and addresses of all officers,
16 directors, and shareholders of the applicant.
- 17 (d) A description of each vehicle to be used,
18 including the make, model, year of manufacture, mileage, and
19 vehicle identification number (VIN); the state or federal
20 aviation or marine registration number, when applicable; and
21 the color scheme, insignia, name, monogram, or other
22 distinguishing characteristics to be used to designate the
23 applicant's vehicle or vehicles.
- 24 (e) The service location from which the service will
25 operate.
- 26 (f) A statement reasonably describing the geographic
27 area or areas to be served by the applicant.
- 28 (g) A statement certifying that the applicant will
29 provide continuous service 24 hours a day, 7 days a week, if a
30 basic life support service license or an advanced life support
31

1 service license is sought. Such service must be initiated
2 within 30 days after issuance of the license.

3 (h) Such other information as the department
4 determines reasonable and necessary.

5 (i) An oath, upon forms provided by the department
6 which shall contain such information as the department
7 reasonably requires, which may include affirmative evidence of
8 ability to comply with applicable laws and rules.

9 (3) The rules must establish specifications regarding
10 insignia and other ambulance identification. Any fire
11 department may retain its fire department identity and may use
12 such color scheme, insignia, name, monogram, or other
13 distinguishing characteristic that is acceptable to the fire
14 department for the purpose of designating its vehicles as
15 advanced life support vehicles. However, those advanced life
16 support service/fire rescue vehicles or ambulances operated by
17 fire departments which were purchased in whole or in part with
18 federal funds must comply with federal regulations pertaining
19 to color schemes, emblems, and markings.

20 (4) The rules must establish circumstances and
21 procedures under which emergency medical technicians and
22 paramedics may honor orders by the patient's physician not to
23 resuscitate and the documentation and reporting requirements
24 for handling such requests.

25 (5) The rules must establish requirements for medical
26 direction, including responsibilities and qualifications;
27 authority to determine medications; equipment and staffing;
28 development of protocols; and participation in operations of
29 quality assurance programs.

30 (6) The rules must establish requirements for
31 licensees and certificateholders to provide address

1 information; requirements for certification examinations,
2 grading, and passing scores; and requirements for determining
3 eligibility of convicted felon applicants for certification or
4 recertification.

5 Section 28. Paragraph (f) of subsection (1) of section
6 403.862, Florida Statutes, is amended to read:

7 403.862 Department of Health; public water supply
8 duties and responsibilities; coordinated budget requests with
9 department.--

10 (1) Recognizing that supervision and control of county
11 health departments of the Department of Health is retained by
12 the secretary of that agency, and that public health aspects
13 of the state public water supply program require joint
14 participation in the program by the Department of Health and
15 its units and the department, the Department of Health shall:

16 (f) Have general supervision and control over all
17 private water systems and all public water systems not
18 otherwise covered or included in this part. This shall include
19 the authority to adopt and enforce rules, including
20 definitions, to protect the health, safety, or welfare of
21 persons being served by all private water systems and all
22 public water systems not otherwise covered by this part.

23 Section 29. Paragraphs (a), (g), and (j) of subsection
24 (3) of section 404.056, Florida Statutes, are amended to read:

25 404.056 Environmental radiation standards and
26 programs; radon protection.--

27 (3) CERTIFICATION.--

28 (a) The department is authorized to certify persons
29 who perform radon gas or radon progeny measurements, including
30 sample collection, analysis, or interpretation of such
31 measurements, and who perform mitigation of buildings for

1 radon gas or radon progeny, and shall collect a fee for such
2 certification. Before performing radon measurement or radon
3 mitigation services, including collecting samples, performing
4 analysis, or interpreting measurement results, a certified
5 individual must own, be employed by, or be retained as a
6 consultant to a certified radon measurement or certified radon
7 mitigation business. The department may establish criteria for
8 the application, certification, and annual renewal of basic
9 and advanced levels of certification for individuals, which
10 may include requirements for education and experience,
11 approved training, examinations, and reporting. The department
12 may approve training courses for certification and establish
13 criteria for training courses and instructors. The department
14 may observe and evaluate training sessions, instructors, and
15 course material without charge.

16 (g) The department may establish enforcement
17 procedures, deny an initial or renewal certification
18 application, deny, suspend, or revoke a certification, or
19 impose an administrative fine not to exceed \$1,000 per
20 violation per day, for the violation of any provision of this
21 section or rule promulgated pursuant thereto.

22 (j) The department may set criteria and requirements
23 for the application, certification, and annual renewal of
24 certification for radon measurement and mitigation businesses,
25 which may include:

26 1. Requirements for measurement devices and
27 measurement procedures, including the disclosure of mitigation
28 materials, systems, and other mitigation services offered.

29 2. The identification of certified specialists and
30 technicians employed by the business and requirements for
31 specialist staffing and duties.

- 1 3. The analysis of measurement devices by proficient
2 analytical service providers.
- 3 4. Requirements for a quality assurance and quality
4 control program.
- 5 5. The disclosure of client measurement reporting
6 forms and warranties and operating instructions for mitigation
7 systems.
- 8 6. Requirements for radon services publications and
9 the identification of the radon business certification number
10 in advertisements.
- 11 7. Requirements for a worker health and safety
12 program.
- 13 8. Requirements for maintaining radon records.
- 14 9. The operation of branch office locations.
- 15 10. Requirements for supervising subcontractors who
16 install mitigation systems.
- 17 11. Requirements for building inspections and
18 evaluation and standards for the design and installation of
19 mitigation systems.
- 20 12. Prescribing conditions of premitigation and
21 postmitigation ~~mitigation~~ measurements.
- 22 13. Requirements for renewals received after the
23 automatic expiration date of certification.
- 24 14. Requirements for obtaining a duplicate or
25 replacement certificate, including a fee not to exceed the
26 cost of producing the duplicate or replacement certificate.
- 27 15. Requirements for reporting, including timeframes
28 and content.
- 29 Section 30. Subsection (1) of section 404.22, Florida
30 Statutes, is amended to read:
31

1 404.22 Radiation machines and components;
2 inspection.--
3 (1) The department and its duly authorized agents may
4 inspect in a lawful manner at all reasonable hours any
5 hospital or other health care facility or other place in the
6 state in which a radiation machine is installed for the
7 purpose of determining whether the facility, the radiation
8 machine and its components, the film and film processing
9 equipment, the techniques and procedures, any mechanical
10 holding devices, the warning labels and signs, the written
11 safety procedures, and the resultant image produced meet the
12 standards of the department as set forth in this chapter and
13 rules adopted pursuant thereto, including standards for
14 machine performance, surveys, calibrations, spot checks,
15 quality assurance programs, quality control programs, facility
16 electrical systems, safety alarms, radiation monitoring
17 equipment, dosimetry systems, visual and aural communication
18 with patients, facility radiation safety committees, and
19 qualifications of persons who cause the machine to be used,
20 who operate the machine, or who are responsible for ensuring
21 the machine complies with criteria as set forth in this
22 chapter and rules adopted pursuant thereto. If, in the opinion
23 of the department, a radiation machine which fails to meet
24 such standards can be made to meet the standards through an
25 adjustment or limitation upon the stations or range of the
26 radiation machine or through the purchase of a component
27 meeting the standards, the department shall order the owner of
28 the radiation machine to make the necessary adjustment or to
29 purchase the necessary component within 90 days of the date or
30 receipt of the order. However, if the radiation machine cannot
31 be made to meet the standards, the department shall order the

1 owner to cease the utilization of the radiation machine. The
2 department shall adopt rules to implement the provisions of
3 this subsection.

4 Section 31. Subsection (3) of section 489.553, Florida
5 Statutes, is amended to read:

6 489.553 Administration of part; registration
7 qualifications; examination.--

8 (3) The department shall adopt reasonable rules to
9 implement this part, including, but not limited to, rules
10 which establish ethical standards of practice, registration of
11 contractors, issuance of initial and renewal registration
12 certificates, disciplinary guidelines, and certification of
13 partnerships and corporations, and may amend or repeal the
14 same in accordance with the Administrative Procedure Act.

15 Section 32. Subsection (1) of section 491.006, Florida
16 Statutes, is amended to read:

17 491.006 Licensure or certification by endorsement.--

18 (1) The department shall license or grant a
19 certificate to a person in a profession regulated by this
20 chapter who, upon applying to the department and remitting the
21 appropriate nonrefundable fee, demonstrates to the board that
22 he or she:

23 (a) Has demonstrated, in a manner designated by rule
24 of the board, knowledge of the laws and rules governing the
25 practice of clinical social work, marriage and family therapy,
26 and mental health counseling.

27 (b)1. Holds an active valid license to practice and
28 has actively practiced the profession for which licensure is
29 applied in another state for 3 of the last 5 years immediately
30 preceding licensure.

31

1 2. Meets the education requirements of this chapter
2 for the profession for which licensure is applied.

3 3. Has passed a substantially equivalent licensing
4 examination in another state or has passed the licensure
5 examination in this state in the profession for which the
6 applicant seeks licensure.

7 4. Holds a license in good standing, is not under
8 investigation for an act which would constitute a violation of
9 this chapter, and has not been found to have committed any act
10 which would constitute a violation of this chapter.

11 Section 33. Subsections (1) and (5) of section
12 491.0145, Florida Statutes, are amended to read:

13 491.0145 Certified master social worker.--The
14 department may certify an applicant for a designation as a
15 certified master social worker upon the following conditions:

16 (1) The applicant completes an application to be
17 provided by the department and pays a nonrefundable fee not to
18 exceed \$250 to be established by rule of the department. The
19 completed application must be received by the department at
20 least 60 days before the date of the examination in order for
21 the applicant to qualify to take the scheduled exam.

22 (5) The applicant has passed an examination required
23 by the department for this purpose. The nonrefundable fee for
24 such examination shall not exceed \$250 as set by department
25 rule.

26 Section 34. Subsections (11) through (29) of section
27 499.003, Florida Statutes, are renumbered as subsections (12)
28 through (30), respectively, and a new subsection (11) is added
29 to said section to read:

30 499.003 Definitions of terms used in ss.
31 499.001-499.081.--As used in ss. 499.001-499.081, the term:

1 (11) "Distribute" or "distribution" means to sell,
2 offer to sell, give away, transfer, whether by passage of
3 title, physical movement, or both, deliver, or offer to
4 deliver, other than to administer or dispense.

5 Section 35. Subsection (4) of section 499.024, Florida
6 Statutes, is amended to read:

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

12 (4) Any product that falls under the drug definition,
13 s. 499.003(12)~~(11)~~, may be classified under the authority of
14 this section. This section does not subject portable
15 emergency oxygen inhalators to classification; however, this
16 section does not exempt any person from ss. 499.01 and
17 499.015.

18 Section 36. Subsection (1) of section 499.03, Florida
19 Statutes, is amended to read:

20 499.03 Possession of new drugs or legend drugs without
21 prescriptions unlawful; exemptions and exceptions.--

22 (1) A person may not possess, or possess with intent
23 to sell, dispense, or deliver, any habit-forming, toxic,
24 harmful, or new drug subject to s. 499.003(23)~~(22)~~, or legend
25 drug as defined in s. 499.003, unless the possession of the
26 drug has been obtained by a valid prescription of a
27 practitioner licensed by law to prescribe the drug. However,
28 this section does not apply to the delivery of such drugs to
29 persons included in any of the classes named in this
30 subsection, or to the agents or employees of such persons, for
31 use in the usual course of their businesses or practices or in

1 the performance of their official duties, as the case may be;
2 nor does this section apply to the possession of such drugs by
3 those persons or their agents or employees for such use:

4 (a) A licensed pharmacist or any person under the
5 licensed pharmacist's supervision while acting within the
6 scope of the licensed pharmacist's practice;

7 (b) A licensed practitioner authorized by law to
8 prescribe legend drugs or any person under the licensed
9 practitioner's supervision while acting within the scope of
10 the licensed practitioner's practice;

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

13 (d) A licensed hospital or other institution that
14 procures such drugs for lawful administration or dispensing by
15 practitioners;

16 (e) An officer or employee of a federal, state, or
17 local government; or

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

21 Section 37. Subsections (25) and (26) are added to
22 section 499.005, Florida Statutes, to read:

23 499.005 Prohibited acts.--It is unlawful to perform or
24 cause the performance of any of the following acts in this
25 state:

26 (25) Charging a dispensing fee for a prescription drug
27 sample.

28 (26) Dispensing, administering, or distributing an
29 investigational drug authorized under s. 499.018 except
30 pursuant to a protocol approved by the department.

31

1 Section 38. For the purpose of incorporating the
2 amendment to section 499.005, Florida Statutes, in references
3 thereto, section 499.069, Florida Statutes, is reenacted to
4 read:

5 499.069 Punishment for violations of s. 499.005;
6 dissemination of false advertisement.--

7 (1) Any person who violates any of the provisions of
8 s. 499.005 is guilty of a misdemeanor of the second degree,
9 punishable as provided in s. 775.082 or s. 775.083; but, if
10 the violation is committed after a conviction of such person
11 under this section has become final, such person is guilty of
12 a misdemeanor of the first degree, punishable as provided in
13 s. 775.082 or s. 775.083 or as otherwise provided in ss.
14 499.001-499.081, except that any person who violates
15 subsection (8), subsection (10), subsection (14), subsection
16 (15), or subsection (17) of s. 499.005 is guilty of a felony
17 of the third degree, punishable as provided in s. 775.082, s.
18 775.083, or s. 775.084, or as otherwise provided in ss.
19 499.001-499.081.

20 (2) A person is not subject to the penalties of
21 subsection (1) for having violated any of the provisions of s.
22 499.005 if he or she establishes a guaranty or undertaking,
23 which guaranty or undertaking is signed by and contains the
24 name and address of the person residing in the state, or the
25 manufacturer, from whom he or she received the article in good
26 faith, to the effect that such article is not adulterated or
27 misbranded within the meaning of ss. 499.001-499.081, citing
28 such sections.

29 (3) A publisher, radio broadcast licensee, or agency
30 or medium for the dissemination of an advertisement, except
31 the manufacturer, wholesaler, or seller of the article to

1 which a false advertisement relates, is not liable under this
2 section by reason of the dissemination by him or her of such
3 false advertisement, unless he or she has refused, on the
4 request of the department, to furnish to the department the
5 name and post office address of the manufacturer, wholesaler,
6 seller, or advertising agency that asked him or her to
7 disseminate such advertisement.

8 Section 39. Subsection (8) is added to section
9 499.0054, Florida Statutes, to read:

10 499.0054 Advertising and labeling of drugs, devices,
11 and cosmetics.--It is a violation of the Florida Drug and
12 Cosmetic Act to perform or cause the performance of any of the
13 following acts:

14 (8) The representation or suggestion in labeling or
15 advertising that an article is approved under ss.
16 499.001-499.081.

17 Section 40. Subsection (2) and paragraph (d) of
18 subsection (4) of section 499.01, Florida Statutes, are
19 amended to read:

20 499.01 Permits; applications; renewal; general
21 requirements.--

22 (2) The department shall establish, by rule, the form
23 and content of the application to obtain or renew a permit.
24 The applicant must submit to the department with the
25 application a statement that swears or affirms that the
26 information is true and correct.

27 (a) Information that an applicant must provide
28 includes, but need not be limited to:

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

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

- 1 3. The address, telephone numbers, and the names of
2 contact persons for each facility used by the applicant for
3 the storage, handling, and distribution of prescription drugs;
- 4 4. The type of ownership or operation, such as a
5 partnership, corporation, or sole proprietorship; and
- 6 5. The names of the owner and the operator of the
7 establishment, including:
- 8 a. If an individual, the name of the individual;
- 9 b. If a partnership, the name of each partner and the
10 name of the partnership;
- 11 c. If a corporation, the name and title of each
12 corporate officer and director, the corporate names, and the
13 name of the state of incorporation;
- 14 d. If a sole proprietorship, the full name of the sole
15 proprietor and the name of the business entity; and
- 16 e. Any other relevant information that the department
17 requires.
- 18 (b) Upon approval of the application by the department
19 and payment of the required fee, the department shall issue a
20 permit to the applicant, if the applicant meets the
21 requirements of ss. 499.001-499.081 and rules adopted under
22 those sections.
- 23 (c) Any change in information required under paragraph
24 (a) must be submitted to the department before the change
25 occurs.
- 26 (d) The department shall consider, at a minimum, the
27 following factors in reviewing the qualifications of persons
28 to be permitted under ss. 499.001-499.081:
- 29 1. The applicant's having been found guilty,
30 regardless of adjudication, in a court of this state or other
31 jurisdiction, of a violation of a law that directly relates to

1 a drug, device, or cosmetic. A plea of nolo contendere
2 constitutes a finding of guilt for purposes of this
3 subparagraph.

4 2. The applicant's having been disciplined by a
5 regulatory agency in any state for any offense that would
6 constitute a violation of ss. 499.001-499.081.

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

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

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

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

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

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

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

27 (4) A permit issued by the department is
28 nontransferable. Each permit is valid only for the person or
29 governmental unit to which it is issued and is not subject to
30 sale, assignment, or other transfer, voluntarily or
31 involuntarily; nor is a permit valid for any establishment

1 other than the establishment for which it was originally
2 issued.

3 (d) If an establishment permitted under ss.
4 499.001-499.081 closes, the owner must notify the department
5 in writing before the effective date of closure and must:

- 6 1. Return the permit to the department;
- 7 2. If the permittee is authorized to distribute legend
8 drugs, indicate the disposition of such drugs, including the
9 name, address, and inventory, and the name and address of a
10 person to contact regarding access to records required to be
11 maintained under ss. 499.001-499.081. Transfer of ownership
12 of legend drugs may be made only to persons authorized to
13 possess legend drugs under ss. 499.001-499.081.

14 Section 41. Paragraph (c) is added to subsection (2)
15 of section 499.0121, Florida Statutes, to read:

16 499.0121 Storage and handling of prescription
17 drugs.--The department shall adopt rules to implement this
18 section as necessary to protect the public health, safety, and
19 welfare. Such rules shall include, but not be limited to,
20 requirements for the storage and handling of prescription
21 drugs and for the establishment and maintenance of
22 prescription drug distribution records.

23 (2) SECURITY.--

24 (c) Vehicles containing prescription drugs must be
25 secured from unauthorized access to the prescription drugs
26 therein.

27 Section 42. Paragraph (b) of subsection (2) of section
28 499.0122, Florida Statutes, is amended to read:

29 499.0122 Medical oxygen and veterinary legend drug
30 retail establishments; definitions, permits, general
31 requirements.--

1 (2)

2 (b) The department shall adopt rules relating to
3 information required from each retail establishment pursuant
4 to s. 499.01(2) and prescription and order requirements.

5 Section 43. Paragraph (d) of subsection (2) of section
6 499.013, Florida Statutes, is amended, and subsection (4) is
7 added to said section, to read:

8 499.013 Manufacturers of drugs, devices, and
9 cosmetics; definitions, permits, and general requirements.--

10 (2) Any person that engages in the manufacture of
11 drugs, devices, or cosmetics in this state must first obtain
12 one of the following permits and may engage only in the
13 activity allowed under that permit:

14 (d) A device manufacturer's permit is required for any
15 person that engages in the manufacture or assembly of medical
16 devices for human use in this state, except that a permit is
17 not required if the person is engaged only in the manufacture
18 or assembly of medical devices pursuant to a practitioner's
19 order for a specific patient.

20 1. A manufacturer of medical devices in this state
21 must comply with all appropriate state and federal good
22 manufacturing practices.

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

26 (4) Manufacturers of devices, over-the-counter drugs,
27 or cosmetics must maintain records that include the following
28 information: the name and principal address of the seller or
29 transferor, the address of the location from which the product
30 was shipped, the date of the transaction, the name and

31

1 quantity of the product involved, and the name and principal
2 address of the person purchasing the product.

3 Section 44. Subsections (1) and (3) of section
4 499.015, Florida Statutes, are amended to read:

5 499.015 Registration of drugs, devices, and cosmetics;
6 issuance of certificates of free sale.--

7 (1)(a) Except for those persons exempted from the
8 definition in s. 499.003(22)(21), any person who manufactures,
9 packages, repackages, labels, or relabels a drug, device, or
10 cosmetic in this state must register such drug, device, or
11 cosmetic biennially with the department; pay a fee in
12 accordance with the fee schedule provided by s. 499.041; and
13 comply with this section. The registrant must list each
14 separate and distinct drug, device, or cosmetic at the time of
15 registration.

16 (b) The department shall not register products that
17 are not in compliance with the provisions of the Federal Food,
18 Drug, and Cosmetic Act, as amended, and Title 21, C.F.R., or
19 which are not approved investigational drugs as provided for
20 in s. 499.018. Registration of a product by the department
21 does not mean that the product does in fact comply with all
22 provisions of the Federal Food, Drug, and Cosmetic Act, as
23 amended.

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

31

1 Section 45. Subsection (1) of section 499.05, Florida
2 Statutes, is amended to read:

3 499.05 Rules.--

4 (1) The department shall adopt rules to implement and
5 enforce ss. 499.001-499.081 related to or determining the
6 following:-

7 (a) Definitions of terms used in ss. 499.001-499.081
8 and the rules adopted thereunder.

9 (b) Labeling requirements for drugs, devices, and
10 cosmetics.

11 (c) Applications, protocols, reporting requirements,
12 and submission of other information required for oversight by
13 the department and the Florida Drug Technical Review Panel
14 related to the Florida Investigational Drug Program.

15 (d) Fees authorized in ss. 499.001-499.081.

16 (e) Identification of permits requiring an initial
17 application fee and onsite inspection or other prerequisites
18 for permitting which demonstrate that the establishment and
19 person are in compliance with the requirements of ss.
20 499.001-499.081.

21 (f) Product registration application processes and
22 forms.

23 (g) Procedures for requesting and issuing certificates
24 of free sale.

25 (h) Inspections and investigations conducted pursuant
26 to s. 499.051 and the identification of information claimed as
27 trade secret as provided in s. 499.051(5).

28 (i) Establishing a range of penalties, as provided in
29 s. 499.066, to put people on notice of potential impact for
30 violations of ss. 499.001-499.081 and a process for
31 uncontested settlement of alleged violations.

1 (j) Additional conditions that qualify as emergency
2 medical reasons under s. 499.012(1)(a)2.b.

3 Section 46. Section 499.701, Florida Statutes, is
4 amended to read:

5 499.701 Adoption of rules by the department.--

6 (1) The department shall adopt and enforce rules
7 necessary to the administration of its authority under this
8 part. Said rules shall be such as are reasonably necessary for
9 the protection of the health, welfare, and safety of the
10 public and persons manufacturing, distributing, dealing, and
11 possessing ether and shall address application forms and
12 procedures, recordkeeping requirements, and security. The
13 rules and shall be in substantial conformity with generally
14 accepted standards of safety concerning such subject matter.

15 (2) The department may adopt rules regarding
16 recordkeeping and security for methyl ethyl ketone (MEK) or
17 butyl acetate as needed. These products and records are open
18 to inspection in the same manner as are ether products and
19 records.

20 Section 47. Paragraph (d) of subsection (2) of section
21 501.122, Florida Statutes, is amended to read:

22 501.122 Control of nonionizing radiations; laser;
23 penalties.--

24 (2) AUTHORITY TO ISSUE REGULATIONS.--Except for
25 electrical transmission and distribution lines and substation
26 facilities subject to regulation by the Department of
27 Environmental Protection pursuant to chapter 403, the
28 Department of Health shall adopt rules as necessary to protect
29 the health and safety of persons exposed to laser devices and
30 other nonionizing radiation, including the user or any others
31

1 who might come in contact with such radiation. The Department
2 of Health may:

3 (d) Establish and prescribe performance standards for
4 lasers and other radiation control, including requirements for
5 radiation surveys and measurements and the methods and
6 instruments used to perform surveys;the qualifications,
7 duties, and training of users; the posting of warning signs
8 and labels for facilities and devices; recordkeeping; and
9 reports to the department, if it determines that such
10 standards are necessary for the protection of the public
11 health.

12 Section 48. Section 513.05, Florida Statutes, is
13 amended to read:

14 513.05 Rules.--The department may adopt rules
15 pertaining to the location, construction, modification,
16 equipment, and operation of mobile home parks, lodging parks,
17 recreational vehicle parks, and recreational camps except as
18 provided in s. 633.022, as necessary to implement this
19 chapter. Such rules may include definitions,requirements for
20 plan reviews of proposed and existing parks and camps; plan
21 reviews of parks that consolidate space or change space size;
22 water supply; sewage collection and disposal; plumbing and
23 backflow prevention; garbage and refuse storage, collection,
24 and disposal; insect and rodent control; space requirements;
25 heating facilities; food service; lighting; sanitary
26 facilities; bedding; an occupancy equivalency to spaces for
27 permits for recreational camps; sanitary facilities in
28 recreational vehicle parks; and the owners' responsibilities
29 at recreational vehicle parks and recreational camps.

30 Section 49. Section 514.021, Florida Statutes, is
31 amended to read:

1 514.021 Department authorization.--The department is
2 authorized to adopt and enforce rules, including definitions,
3 to protect the health, safety, or welfare of persons using
4 public swimming pools and bathing places. The department
5 shall review and revise such rules as necessary, but not less
6 than biannually. Sanitation and safety standards shall
7 include, but not be limited to, matters relating to structure;
8 appurtenances; operation; source of water supply;
9 bacteriological, chemical, and physical quality of water in
10 the pool or bathing area; method of water purification,
11 treatment, and disinfection; lifesaving apparatus; measures to
12 ensure safety of bathers; and measures to ensure the personal
13 cleanliness of bathers.

14 Section 50. Paragraph (d) of subsection (3) and
15 subsections (4), (5), and (10) of section 766.1115, Florida
16 Statutes, are amended to read:

17 766.1115 Health care providers; creation of agency
18 relationship with governmental contractors.--

19 (3) DEFINITIONS.--As used in this section, the term:

20 (d) "Health care provider" or "provider" means:

21 1. A birth center licensed under chapter 383.

22 2. An ambulatory surgical center licensed under
23 chapter 395.

24 3. A hospital licensed under chapter 395.

25 4. A physician or physician assistant licensed under
26 chapter 458.

27 5. An osteopathic physician or osteopathic physician
28 assistant licensed under chapter 459.

29 6. A chiropractic physician licensed under chapter
30 460.

31 7. A podiatric physician licensed under chapter 461.

1 8. A registered nurse, nurse midwife, licensed
2 practical nurse, or advanced registered nurse practitioner
3 licensed or registered under chapter 464 or any facility which
4 employs nurses licensed or registered under chapter 464 to
5 supply all or part of the care delivered under this section.

6 9. A midwife licensed under chapter 467.

7 10. A health maintenance organization certificated
8 under part I of chapter 641.

9 11. A health care professional association and its
10 employees or a corporate medical group and its employees.

11 12. Any other medical facility the primary purpose of
12 which is to deliver human medical diagnostic services or which
13 delivers nonsurgical human medical treatment, and which
14 includes an office maintained by a provider.

15 13. A dentist or dental hygienist licensed under
16 chapter 466.

17 14. Any other health care professional, practitioner,
18 provider, or facility under contract with a governmental
19 contractor, including any student involved in an accredited
20 program that prepares the student for licensure as a
21 professional described in subparagraphs 4.-9.

22
23 The term includes any nonprofit corporation qualified as
24 exempt from federal income taxation under s. 501(c) of the
25 Internal Revenue Code which delivers health care services
26 provided by licensed professionals listed in this paragraph,
27 any federally funded community health center, and any
28 volunteer corporation or volunteer health care provider that
29 delivers health care services.

30 (4) CONTRACT REQUIREMENTS.--A health care provider
31 that executes a contract with a governmental contractor to

1 deliver health care services on or after April 17, 1992, as an
2 agent of the governmental contractor is an agent for purposes
3 of s. 768.28(9), while acting within the scope of duties
4 pursuant to the contract, if the contract complies with the
5 requirements of this section, even if the individual treated
6 is later found to be ineligible. A health care provider under
7 contract with the state may not be named as a defendant in any
8 action arising out of the medical care or treatment provided
9 on or after April 17, 1992, pursuant to contracts entered into
10 under this section. The contract must provide that:

11 (a) The right of dismissal or termination of any
12 health care provider delivering services pursuant to the
13 contract is retained by the governmental contractor.

14 (b) The governmental contractor has access to the
15 patient records of any health care provider delivering
16 services pursuant to the contract.

17 (c) Adverse incidents and information on treatment
18 outcomes must be reported by any health care provider to the
19 governmental contractor if such incidents and information
20 pertain to a patient treated pursuant to the contract. The
21 health care provider shall annually submit an adverse incident
22 report that includes all information required by s.

23 395.0197(6)(a), unless the adverse incident involves a result
24 described by s. 395.0197(8), in which case it shall be
25 reported within 15 days after the occurrence of such incident.
26 If an incident involves a professional licensed by the
27 Department of Health or a facility licensed by the Agency for
28 Health Care Administration, the governmental contractor shall
29 submit such incident reports to the appropriate department or
30 agency, which shall review each incident and determine whether
31 it involves conduct by the licensee that is subject to

1 disciplinary action. All patient medical records and any
2 identifying information contained in adverse incident reports
3 and treatment outcomes which are obtained by governmental
4 entities pursuant to this paragraph are confidential and
5 exempt from the provisions of s. 119.07(1) and s. 24(a), Art.
6 I of the State Constitution.

7 (d) Patient selection and initial referral must be
8 made solely by the governmental contractor, and the provider
9 must accept all referred patients. However, the number of
10 patients that must be accepted may be limited by the contract,
11 and patients may not be transferred to the provider based on a
12 violation of the antidumping provisions of the Omnibus Budget
13 Reconciliation Act of 1989, the Omnibus Budget Reconciliation
14 Act of 1990, or chapter 395.

15 (e) If emergency care is required, the patient need
16 not be referred before receiving treatment, but must be
17 referred within 48 hours after treatment is commenced or
18 within 48 hours after the patient has the mental capacity to
19 consent to treatment, whichever occurs later.

20 (f) Patient care, including any followup or hospital
21 care, is subject to approval by the governmental contractor.

22 (g) The provider is subject to supervision and regular
23 inspection by the governmental contractor.

24
25 A governmental contractor that is also a health care provider
26 is not required to enter into a contract under this section
27 with respect to the health care services delivered by its
28 employees.

29 (5) NOTICE OF AGENCY RELATIONSHIP.--The governmental
30 contractor must provide written notice to, receipt of which is
31 acknowledged in writing by, each patient, or the patient's

1 legal representative, that the provider is an agent of the
2 governmental contractor and that the exclusive remedy for
3 injury or damage suffered as the result of any act or omission
4 of the provider or of any employee or agent thereof acting
5 within the scope of duties pursuant to the contract is by
6 commencement of an action pursuant to the provisions of s.
7 768.28. With respect to any federally funded community health
8 center, the notice requirements may be met by posting in a
9 place conspicuous to all persons a notice that the federally
10 funded community health center is an agent of the governmental
11 contractor and that the exclusive remedy for injury or damage
12 suffered as the result of any act or omission of the provider
13 or of any employee or agent thereof acting within the scope of
14 duties pursuant to the contract is by commencement of an
15 action pursuant to the provisions of s. 768.28.

16 (10) RULES.--The department shall adopt rules designed
17 to implement this section in a manner consistent with its
18 purpose to provide and facilitate access to appropriate, safe,
19 and cost-effective health care services and to maintain health
20 care quality. The rules may include services to be provided
21 and authorized procedures.

22 Section 51. This act shall take effect upon becoming a
23 law.

24
25 *****

26 HOUSE SUMMARY

27 Provides, pursuant to the directive in s. 120.536(2)(b),
28 Florida Statutes, specific legislation to enact into law
29 the substance of rules of the Department of Health that
30 exceed rulemaking authority under the Administrative
31 Procedure Act and that the department has decided not to
repeal. See bill for details.