

By the Committee on Health, Aging and Long-Term Care; and
Senator Myers

317-2044-00

1 A bill to be entitled
2 An act relating to rulemaking authority of the
3 Department of Health (RAB); amending s.
4 154.011, F.S., relating to primary care
5 services; requiring the department to adopt
6 certain rules developed by the State Health
7 Officer; amending s. 154.06, F.S.; requiring
8 the adoption of rules with respect to fees for
9 services rendered through county health
10 departments; amending s. 381.003, F.S.,
11 relating to prevention and control of
12 communicable diseases and acquired immune
13 deficiency syndrome; authorizing rules
14 governing procedures for managing diseases;
15 amending s. 381.004, F.S., relating to testing
16 for human immunodeficiency virus; providing
17 additional rulemaking authority; amending s.
18 381.0051, F.S., relating to family planning
19 services; providing for rules administering the
20 provision of such services; amending s.
21 381.0056, F.S., relating to the school health
22 services program; authorizing the department to
23 adopt rules in cooperation with the Department
24 of Education; amending s. 381.0057, F.S.;
25 providing requirements for the services
26 provided by school health programs; amending s.
27 381.006, F.S., relating to public health;
28 providing additional rulemaking authority;
29 amending s. 381.0062, F.S., relating to the
30 regulation of water systems; providing
31 additional requirements for obtaining an

1 exemption from the department; amending s.
2 381.0065, F.S.; redefining the term "onsite
3 sewage treatment and disposal system";
4 providing additional rulemaking authority;
5 revising requirements for sewage treatment and
6 disposal systems; amending s. 381.0072, F.S.;
7 requiring the department to adopt additional
8 rules with respect to food service protection;
9 amending s. 381.0086, F.S.; requiring the
10 department to adopt additional rules with
11 respect to the health and safety of migrant
12 farm workers; amending s. 381.0098, F.S.;
13 prohibiting the transfer of a permit for a
14 biomedical waste facility or a biomedical waste
15 transporter; providing requirements for a
16 permit application; amending s. 381.0101, F.S.,
17 relating to environmental health professionals;
18 providing additional rulemaking authority with
19 respect to standards for certification;
20 amending s. 381.0203, F.S.; authorizing the
21 department to adopt rules governing pharmacy
22 services; amending s. 381.89, F.S.; authorizing
23 the department to issue a stop-use order
24 against a tanning facility; amending s.
25 383.011, F.S., relating to maternal and child
26 health programs; providing additional
27 rulemaking authority; amending s. 383.14, F.S.;
28 providing for rules governing screening for
29 metabolic disorders, hereditary disorders, and
30 environmental risk factors; amending s. 383.19,
31 F.S.; providing for rules governing perinatal

1 intensive care centers; amending s. 383.216,
2 F.S.; revising requirements for prenatal and
3 infant health care coalitions; providing
4 additional rulemaking authority; amending s.
5 384.33, F.S.; authorizing rules governing
6 screenings and investigations to control the
7 spread of sexually transmitted diseases;
8 amending s. 385.207, F.S., relating to care and
9 assistance of persons with epilepsy; providing
10 additional rulemaking authority; amending s.
11 391.026, F.S., relating to the Children's
12 Medical Services Act; requiring the department
13 to adopt rules to administer the act; amending
14 s. 392.66, F.S.; requiring the department to
15 adopt rules to administer the Tuberculosis
16 Control Act; amending ss. 395.401, 395.402,
17 F.S.; requiring the department to adopt rules
18 governing the procedures for establishing a
19 trauma agency and for performance evaluations;
20 requiring the department to establish the
21 number of trauma centers within each service
22 area; amending s. 401.35, F.S.; requiring the
23 department to adopt rules governing medical
24 transportation services; amending s. 403.862,
25 F.S.; authorizing the department to adopt rules
26 governing water systems; amending s. 404.056,
27 F.S., relating to environmental radiation
28 standards and programs; providing additional
29 rulemaking authority; amending s. 404.22, F.S.;
30 authorizing the department to adopt rules
31 governing the operation of radiation machines

1 and components; amending s. 489.553, F.S.,
2 relating to septic tank contracting; providing
3 additional rulemaking authority; amending ss.
4 491.006, 491.0145, F.S., relating to clinical,
5 counseling, and psychotherapy services;
6 providing for nonrefundable application fees;
7 amending s. 499.003, F.S.; defining the terms
8 "distribute or distribution" for purposes of
9 ch. 499, F.S., relating to the Florida Drug and
10 Cosmetic Act; amending s. 499.005, F.S.;
11 prohibiting charging certain fees or dispensing
12 certain drugs; amending s. 499.0054, F.S.;
13 prohibiting certain labels or advertisements;
14 amending s. 499.01, F.S.; providing additional
15 requirements for closing an establishment
16 permitted under the Florida Drug and Cosmetic
17 Act; amending s. 499.0121, F.S.; providing
18 additional requirements for a vehicle that
19 contains prescription drugs; amending s.
20 499.0122, F.S., relating to medical oxygen and
21 veterinary legend drugs; providing additional
22 rulemaking authority; amending s. 499.013,
23 F.S., relating to manufacturers of drugs,
24 devices, and cosmetics; exempting manufacturers
25 of a device for a specific patient from certain
26 requirements; requiring that manufacturers
27 maintain certain records; amending ss. 499.015,
28 499.024, 499.03, F.S.; providing certain
29 limitations on the registration of products or
30 drugs; conforming cross-references to changes
31 made by the act; amending s. 499.05, F.S.;

1 requiring the department to adopt additional
2 rules to administer the Florida Drug and
3 Cosmetic Act; amending s. 499.701, F.S.,
4 relating to the regulation of ether; providing
5 additional rulemaking authority; amending s.
6 501.122, F.S.; requiring the department to
7 adopt rules governing radiation surveys;
8 amending s. 513.05, F.S., relating to mobile
9 home and recreational vehicle parks; providing
10 additional rulemaking authority; amending s.
11 514.021, F.S.; authorizing the department to
12 adopt rules governing public swimming and
13 bathing facilities; amending s. 766.1115, F.S.,
14 relating to the Access to Health Care Act;
15 providing for rules governing services and
16 procedures; providing an effective date.

17

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

19

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

22 154.011 Primary care services.--

23 (5) The department shall adopt rules to govern the
24 operation of primary care programs authorized by this section.
25 Such rules may ~~shall~~ include, but need not be limited to,
26 requirements for income eligibility, income verification,
27 continuity of care, client services, client enrollment and
28 disenrollment, eligibility, intake, recordkeeping, coverage,
29 quality control, quality of care, case management, and
30 Medicaid participation and shall be developed by the State
31 Health Officer. Rules governing services to clients under 21

1 years of age shall be developed in conjunction with children's
2 medical services and shall at a minimum include preventive
3 services as set forth in s. 627.6579.

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

6 154.06 Fees and services rendered; authority.--

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

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

24 381.003 Communicable disease and acquired immune
25 deficiency syndrome prevention and control.--

26 (2) The department may adopt, repeal, and amend rules
27 related to the prevention and control of communicable
28 diseases, including procedures for investigating disease,
29 timeframes for reporting disease, definitions, procedures for
30 managing specific diseases, requirements for followup reports
31 of known or suspected exposure to disease, and procedures for

1 providing access to confidential information necessary for
2 disease investigations.

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

5 381.004 Testing for human immunodeficiency virus.--

6 (10) RULES.--The Department of Health may adopt ~~such~~
7 rules ~~as are necessary~~ to implement this section, including
8 definitions of terms, procedures for accessing confidential
9 information, requirements for testing, and requirements for
10 registered testing sites.

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

13 381.0051 Family planning.--

14 (7) RULES.--The Department of Health may adopt rules
15 to implement this section, including rules regarding
16 definitions of terms and requirements for eligibility,
17 informed-consent services, revisits, temporary contraceptive
18 methods, voluntary sterilization, and infertility services.

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

21 381.0056 School health services program.--

22 (8) The Department of Health, in cooperation with the
23 Department of Education, may adopt rules necessary to
24 implement this section. The rules may include standards and
25 requirements for developing school health services plans,
26 conducting school health screening, meeting emergency health
27 needs, maintaining school health records, and coordinating
28 with education programs for exceptional students.

29 Section 7. Subsection (7) is added to section
30 381.0057, Florida Statutes, to read:

31 381.0057 Funding for school health services.--

1 (7) The services provided by a comprehensive school
2 health program must focus attention on promoting the health of
3 students, reducing risk-taking behavior, and reducing teen
4 pregnancy. Services provided under this section are in
5 addition to the services provided under s. 381.0056 and are
6 intended to supplement, rather than supplant, those services.

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

9 381.006 Environmental health.--The department shall
10 conduct an environmental health program as part of fulfilling
11 the state's public health mission. The purpose of this program
12 is to detect and prevent disease caused by natural and manmade
13 factors in the environment. The environmental health program
14 shall include, but not be limited to:

15 (16) A group-care-facilities function, where a
16 group-care facility means any public or private school,
17 housing, building or buildings, section of a building, or
18 distinct part of a building or other place, whether operated
19 for profit or not, which undertakes, through its ownership or
20 management, to provide one or more personal services, care,
21 protection, and supervision to persons who require such
22 services and who are not related to the owner or
23 administrator. The department may adopt rules necessary to
24 protect the health and safety of residents, staff, and patrons
25 of group-care facilities, such as child care facilities,
26 family day-care homes, assisted-living facilities, adult
27 day-care centers, adult family-care homes, hospices,
28 residential treatment facilities, crisis-stabilization units,
29 pediatric extended-care centers, intermediate-care facilities
30 for the developmentally disabled, group-care homes, and,
31 jointly with the Department of Education, private and public

1 schools. These rules may include definitions of terms;
2 provisions relating to operation and maintenance of
3 facilities, buildings, grounds, equipment, furnishings, and
4 occupant-space requirements; lighting; heating, cooling, and
5 ventilation; food service; water supply and, plumbing; sewage;
6 sanitary facilities; insect and rodent control; garbage;
7 safety; personnel health, hygiene, and work practices; and
8 other matters the department finds are appropriate or
9 necessary to protect the safety and health of the residents,
10 staff, or patrons. The department may not adopt rules that
11 conflict with rules adopted by the licensing or certifying
12 agency. The department may enter and inspect at reasonable
13 hours to determine compliance with applicable statutes or
14 rules. In addition to any sanctions that the department may
15 impose for violations of rules adopted under this section, the
16 department shall also report such violations to any agency
17 responsible for licensing or certifying the group-care
18 facility. The licensing or certifying agency may also impose
19 any sanction based solely on the findings of the department.

20
21 The department may adopt rules to carry out the provisions of
22 this section.

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

25 381.0062 Supervision; private and certain public water
26 systems.--

27 (6) VARIANCES AND EXEMPTIONS.--

28 (a) The department may grant variances and exemptions
29 from the rules adopted ~~promulgated~~ ~~under the provisions of~~
30 this section through procedures set forth by the rule of the
31 department.

1 (b) Any establishment with a limited use commercial
2 public water system which does not make tap water available
3 for public consumption and meets the water quality standards
4 and installation requirements established by the department
5 shall be exempt from obtaining an annual operating permit from
6 the department, if the supplier of water:

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

10 2. Performs an initial water quality clearance of the
11 water supply system.

12
13 A system exempt under this subsection may, in order to retain
14 potable water status, conduct annual testing for bacteria in
15 the form of one satisfactory microbiological sample per
16 calendar year.

17 Section 10. Subsections (2), (3), and (4) of section
18 381.0065, Florida Statutes, are amended to read:

19 381.0065 Onsite sewage treatment and disposal systems;
20 regulation.--

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

23 (a) "Available," as applied to a publicly owned or
24 investor-owned sewerage system, means that the publicly owned
25 or investor-owned sewerage system is capable of being
26 connected to the plumbing of an establishment or residence, is
27 not under a Department of Environmental Protection moratorium,
28 and has adequate permitted capacity to accept the sewage to be
29 generated by the establishment or residence; and:

30 1. For a residential subdivision lot, a single-family
31 residence, or an establishment, any of which has an estimated

1 sewage flow of 1,000 gallons per day or less, a gravity sewer
2 line to maintain gravity flow from the property's drain to the
3 sewer line, or a low pressure or vacuum sewage collection line
4 in those areas approved for low pressure or vacuum sewage
5 collection, exists in a public easement or right-of-way that
6 abuts the property line of the lot, residence, or
7 establishment.

8 2. For an establishment with an estimated sewage flow
9 exceeding 1,000 gallons per day, a sewer line, force main, or
10 lift station exists in a public easement or right-of-way that
11 abuts the property of the establishment or is within 50 feet
12 of the property line of the establishment as accessed via
13 existing rights-of-way or easements.

14 3. For proposed residential subdivisions with more
15 than 50 lots, for proposed commercial subdivisions with more
16 than 5 lots, and for areas zoned or used for an industrial or
17 manufacturing purpose or its equivalent, a sewerage system
18 exists within one-fourth mile of the development as measured
19 and accessed via existing easements or rights-of-way.

20 4. For repairs or modifications within areas zoned or
21 used for an industrial or manufacturing purpose or its
22 equivalent, a sewerage system exists within 500 feet of an
23 establishment's or residence's sewer stub-out as measured and
24 accessed via existing rights-of-way or easements.

25 (b) "Blackwater" means that part of domestic sewage
26 carried off by toilets, urinals, and kitchen drains.

27 (c) "Domestic sewage" means human body waste and
28 wastewater, including bath and toilet waste, residential
29 laundry waste, residential kitchen waste, and other similar
30 waste from appurtenances at a residence or establishment.

31

1 (d) "Graywater" means that part of domestic sewage
2 that is not blackwater, including waste from the bath,
3 lavatory, laundry, and sink, except kitchen sink waste.

4 (e) "Florida Keys" means those islands of the state
5 located within the boundaries of Monroe County.

6 (f) "Injection well" means an open vertical hole at
7 least 90 feet in depth, cased and grouted to at least 60 feet
8 in depth which is used to dispose of effluent from an onsite
9 sewage treatment and disposal system.

10 (g) "Innovative system" means an onsite sewage
11 treatment and disposal system that, in whole or in part,
12 employs materials, devices, or techniques that are novel or
13 unique and that have not been successfully field-tested under
14 sound scientific and engineering principles under climatic and
15 soil conditions found in this state.

16 (h) "Lot" means a parcel or tract of land described by
17 reference to recorded plats or by metes and bounds, or the
18 least fractional part of subdivided lands having limited fixed
19 boundaries or an assigned number, letter, or any other legal
20 description by which it can be identified.

21 (i) "Mean annual flood line" means the elevation
22 determined by calculating the arithmetic mean of the
23 elevations of the highest yearly flood stage or discharge for
24 the period of record, to include at least the most recent
25 10-year period. If at least 10 years of data is not available,
26 the mean annual flood line shall be as determined based upon
27 the data available and field verification conducted by a
28 certified professional surveyor and mapper with experience in
29 the determination of flood water elevation lines or, at the
30 option of the applicant, by department personnel. Field
31 verification of the mean annual flood line shall be performed

1 using a combination of those indicators listed in
2 subparagraphs 1. through 7. that are present on the site, and
3 that reflect flooding that recurs on an annual basis. In those
4 situations where any one or more of these indicators reflect a
5 rare or aberrant event, such indicator or indicators shall not
6 be utilized in determining the mean annual flood line. The
7 indicators that may be considered are:

- 8 1. Water stains on the ground surface, trees, and
9 other fixed objects;
- 10 2. Hydric adventitious roots;
- 11 3. Drift lines;
- 12 4. Rafted debris;
- 13 5. Aquatic mosses and liverworts;
- 14 6. Moss collars; and
- 15 7. Lichen lines.

16 (j) "Onsite sewage treatment and disposal system"
17 means a system that contains a standard subsurface, filled, or
18 mound drainfield system; an aerobic treatment unit; a
19 graywater system tank; a laundry wastewater system tank; a
20 septic tank; a grease interceptor; a pump dosing tank; a
21 solids or effluent pump; a waterless, incinerating, or organic
22 waste-composting toilet; or a sanitary pit privy that is
23 installed or proposed to be installed beyond the building
24 sewer on land of the owner or on other land to which the owner
25 has the legal right to install a system. The term includes any
26 item placed within, or intended to be used as a part of or in
27 conjunction with, the system.This term does not include
28 package sewage treatment facilities and other treatment works
29 regulated under chapter 403.

30 (k) "Permanent nontidal surface water body" means a
31 perennial stream, a perennial river, an intermittent stream, a

1 perennial lake, a submerged marsh or swamp, a submerged wooded
2 marsh or swamp, a spring, or a seep, as identified on the most
3 recent quadrangle map, 7.5 minute series (topographic),
4 produced by the United States Geological Survey. "Permanent
5 nontidal surface water body" shall also mean an artificial
6 surface water body that does not have an impermeable bottom
7 and side and that is designed to hold, or does hold, visible
8 standing water for at least 180 days of the year. However, a
9 nontidal surface water body that is drained, either naturally
10 or artificially, where the intent or the result is that such
11 drainage be temporary, shall be considered a permanent
12 nontidal surface water body. A nontidal surface water body
13 that is drained of all visible surface water, where the lawful
14 intent or the result of such drainage is that such drainage
15 will be permanent, shall not be considered a permanent
16 nontidal surface water body. The boundary of a permanent
17 nontidal surface water body shall be the mean annual flood
18 line.

19 (1) "Potable water line" means any water line that is
20 connected to a potable water supply source, but the term does
21 not include an irrigation line with any of the following types
22 of backflow devices:

23 1. For irrigation systems into which chemicals are not
24 injected, any atmospheric or pressure vacuum breaker or double
25 check valve or any detector check assembly.

26 2. For irrigation systems into which chemicals such as
27 fertilizers, pesticides, or herbicides are injected, any
28 reduced pressure backflow preventer.

29 (m) "Septage" means a mixture of sludge, fatty
30 materials, human feces, and wastewater removed during the
31 pumping of an onsite sewage treatment and disposal system.

1 (n) "Subdivision" means, for residential use, any
2 tract or plot of land divided into two or more lots or parcels
3 of which at least one is 1 acre or less in size for sale,
4 lease, or rent. A subdivision for commercial or industrial
5 use is any tract or plot of land divided into two or more lots
6 or parcels of which at least one is 5 acres or less in size
7 and which is for sale, lease, or rent. A subdivision shall be
8 deemed to be proposed until such time as an application is
9 submitted to the local government for subdivision approval or,
10 in those areas where no local government subdivision approval
11 is required, until such time as a plat of the subdivision is
12 recorded.

13 (o) "Tidally influenced surface water body" means a
14 body of water that is subject to the ebb and flow of the tides
15 and has as its boundary a mean high-water line as defined by
16 s. 177.27(15).

17 (p) "Toxic or hazardous chemical" means a substance
18 that poses a serious danger to human health or the
19 environment.

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

22 (a) Adopt rules to administer ss. 381.0065-381.0067,
23 including definitions that are consistent with the definitions
24 in this section, decreases to setback requirements where no
25 health hazard exists, increases for the lot-flow allowance for
26 performance-based systems, requirements for separation from
27 water table elevation during the wettest season, requirements
28 for the design and construction of any component part of an
29 onsite sewage treatment and disposal system, application and
30 permit requirements for persons who maintain an onsite sewage
31 treatment and disposal system, requirements for maintenance

1 and service agreements for aerobic treatment units and
2 performance-based treatment systems, and standards for system
3 inspection.

4 (b) Perform application reviews and site evaluations,
5 issue permits, and conduct inspections and complaint
6 investigations associated with the construction, installation,
7 maintenance, modification, abandonment, operation, use, or
8 repair of an onsite sewage treatment and disposal system for a
9 residence or establishment with an estimated domestic sewage
10 flow of 10,000 gallons or less per day, or an estimated
11 commercial sewage flow of 5,000 gallons or less per day, which
12 is not currently regulated under chapter 403.

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

26 (d) Grant variances in hardship cases under the
27 conditions prescribed in this section and rules adopted under
28 this section.

29 (e) Permit the use of a limited number of innovative
30 systems for a specific period of time, when there is
31 compelling evidence that the system will function properly and

1 reliably to meet the requirements of this section and rules
2 adopted under this section.

3 (f) Issue annual operating permits under this section.

4 (g) Establish and collect fees as established under s.
5 381.0066 for services provided with respect to onsite sewage
6 treatment and disposal systems.

7 (h) Conduct enforcement activities, including imposing
8 fines, issuing citations, suspensions, revocations,
9 injunctions, and emergency orders for violations of this
10 section, part I of chapter 386, or part III of chapter 489 or
11 for a violation of any rule adopted under this section, part I
12 of chapter 386, or part III of chapter 489.

13 (i) Provide or conduct education and training of
14 department personnel, service providers, and the public
15 regarding onsite sewage treatment and disposal systems.

16 (j) Supervise research on, demonstration of, and
17 training on the performance, environmental impact, and public
18 health impact of onsite sewage treatment and disposal systems
19 within this state. Research fees collected under s.
20 381.0066(2)(k) must be used to develop and fund hands-on
21 training centers designed to provide practical information
22 about onsite sewage treatment and disposal systems to septic
23 tank contractors, master septic tank contractors, contractors,
24 inspectors, engineers, and the public and must also be used to
25 fund research projects which focus on improvements of onsite
26 sewage treatment and disposal systems, including use of
27 performance-based standards and reduction of environmental
28 impact. Research projects shall be initially approved by the
29 technical advisory panel and shall be applicable to and
30 reflect the soil conditions specific to Florida. Such
31 projects shall be awarded through competitive negotiation,

1 using the procedures provided in s. 287.055, to public or
2 private entities that have experience in onsite sewage
3 treatment and disposal systems in Florida and that are
4 principally located in Florida. Research projects shall not
5 be awarded to firms or entities that employ or are associated
6 with persons who serve on either the technical advisory panel
7 or the research review and advisory committee.

8 (k) Approve the installation of individual graywater
9 disposal systems in which blackwater is treated by a central
10 sewerage system.

11 (l) Regulate and permit the sanitation, handling,
12 treatment, storage, reuse, and disposal of byproducts from any
13 system regulated under this chapter and ~~septage-stabilization~~
14 and disposal facilities not regulated by the Department of
15 Environmental Protection.

16 (m) Permit and inspect portable or temporary toilet
17 services and holding tanks. The department shall review
18 applications, perform site evaluations, and issue permits for
19 the temporary use of holding tanks, privies, portable toilet
20 services, or any other toilet facility that is intended for
21 use on a permanent or nonpermanent basis, including facilities
22 placed on construction sites when workers are present. The
23 department may specify standards for the construction,
24 maintenance, use, and operation of any such facility for
25 temporary use.

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

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

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

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

29 (b) Subdivisions and lots using a public water system
30 as defined in s. 403.852 may use onsite sewage treatment and
31 disposal systems, provided there are no more than four lots

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

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

26 (d) Paragraphs (a) and (b) do not apply to any
27 proposed residential subdivision with more than 50 lots or to
28 any proposed commercial subdivision with more than 5 lots
29 where a publicly owned or investor-owned sewerage system is
30 available. It is the intent of this paragraph not to allow
31 development of additional proposed subdivisions in order to

1 evade the requirements of this paragraph. The department
2 shall report to the Legislature by February 1 of each
3 odd-numbered year concerning the success in meeting this
4 intent.

5 (e) Onsite sewage treatment and disposal systems must
6 not be placed closer than:

- 7 1. Seventy-five feet from a private potable well.
- 8 2. Two hundred feet from a public potable well serving
9 a residential or nonresidential establishment having a total
10 sewage flow of greater than 2,000 gallons per day.
- 11 3. One hundred feet from a public potable well serving
12 a residential or nonresidential establishment having a total
13 sewage flow of less than or equal to 2,000 gallons per day.
- 14 4. Fifty feet from any nonpotable well.
- 15 5. Ten feet from any storm sewer pipe, to the maximum
16 extent possible, but in no instance shall the setback be less
17 than 5 feet.
- 18 6. Seventy-five feet from the mean high-water line of
19 a tidally influenced surface water body;
- 20 7. Seventy-five feet from the normal annual flood line
21 of a permanent nontidal surface water body;
- 22 8. Fifteen feet from the design high-water line of
23 retention areas, detention areas, or swales designed to
24 contain standing or flowing water for less than 72 hours after
25 a rainfall or the design high-water level of normally dry
26 drainage ditches or normally dry individual lot stormwater
27 retention areas.

28 (f) Except as provided under paragraphs (e) and (t),
29 no limitations shall be imposed by rule, relating to the
30 distance between an onsite disposal system and any area that
31 either permanently or temporarily has visible surface water.

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

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

29 2. Lots platted before 1972 are subject to a 50-foot
30 minimum surface water setback and are not subject to lot size
31 requirements. The projected daily flow for ~~domestic~~ onsite

1 sewage treatment and disposal systems for lots platted before
2 1972 may not exceed:

3 a. Two thousand five hundred gallons per acre per day
4 for lots served by public water systems as defined in s.
5 403.852.

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

8 (h)1. The department may grant variances in hardship
9 cases which may be less restrictive than the provisions
10 specified in this section. If a variance is granted and the
11 onsite sewage treatment and disposal system construction
12 permit has been issued, the variance may be transferred with
13 the system construction permit, if the transferee files,
14 within 60 days after the transfer of ownership, an amended
15 construction permit application providing all corrected
16 information and proof of ownership of the property and if the
17 same variance would have been required for the new owner of
18 the property as was originally granted to the original
19 applicant for the variance. There is no fee associated with
20 the processing of this supplemental information. A variance
21 may not be granted under this section until the department is
22 satisfied that:

23 a. The hardship was not caused intentionally by the
24 action of the applicant;

25 b. No reasonable alternative, taking into
26 consideration factors such as cost, exists for the treatment
27 of the sewage; and

28 c. The discharge from the onsite sewage treatment and
29 disposal system will not adversely affect the health of the
30 applicant or the public or significantly degrade the
31 groundwater or surface waters.

1
2 Where soil conditions, water table elevation, and setback
3 provisions are determined by the department to be
4 satisfactory, special consideration must be given to those
5 lots platted before 1972.

6 2. The department shall appoint and staff a variance
7 review and advisory committee, which shall meet monthly to
8 recommend agency action on variance requests. The committee
9 shall make its recommendations on variance requests at the
10 meeting in which the application is scheduled for
11 consideration, except for an extraordinary change in
12 circumstances, the receipt of new information that raises new
13 issues, or when the applicant requests an extension. The
14 committee shall consider the criteria in subparagraph 1. in
15 its recommended agency action on variance requests and shall
16 also strive to allow property owners the full use of their
17 land where possible. The committee consists of the following:

18 a. The Division Director for Environmental Health of
19 the department or his or her designee.

20 b. A representative from the county health
21 departments.

22 c. A representative from the home building industry
23 recommended by the Florida Home Builders Association.

24 d. A representative from the septic tank industry
25 recommended by the Florida Septic Tank Association.

26 e. A representative from the Department of
27 Environmental Protection.

28 f. A representative from the real estate industry who
29 is also a developer in this state who develops lots using
30 onsite sewage treatment and disposal systems, recommended by
31 the Florida Association of Realtors.

1 g. A representative from the engineering profession
2 recommended by the Florida Engineering Society.

3
4 Members shall be appointed for a term of 3 years, with such
5 appointments being staggered so that the terms of no more than
6 two members expire in any one year. Members shall serve
7 without remuneration, but if requested, shall be reimbursed
8 for per diem and travel expenses as provided in s. 112.061.

9 (i) A construction permit may not be issued for an
10 onsite sewage treatment and disposal system in any area zoned
11 or used for industrial or manufacturing purposes, or its
12 equivalent, where a publicly owned or investor-owned sewage
13 treatment system is available, or where a likelihood exists
14 that the system will receive toxic, hazardous, or industrial
15 waste. An existing onsite sewage treatment and disposal
16 system may be repaired if a publicly owned or investor-owned
17 sewerage system is not available within 500 feet of the
18 building sewer stub-out and if system construction and
19 operation standards can be met. This paragraph does not
20 require publicly owned or investor-owned sewerage treatment
21 systems to accept anything other than domestic wastewater.

22 1. A building located in an area zoned or used for
23 industrial or manufacturing purposes, or its equivalent, when
24 such building is served by an onsite sewage treatment and
25 disposal system, must not be occupied until the owner or
26 tenant has obtained written approval from the department. The
27 department shall not grant approval when the proposed use of
28 the system is to dispose of toxic, hazardous, or industrial
29 wastewater or toxic or hazardous chemicals.

30 2. Each person who owns or operates a business or
31 facility in an area zoned or used for industrial or

1 manufacturing purposes, or its equivalent, or who owns or
2 operates a business that has the potential to generate toxic,
3 hazardous, or industrial wastewater or toxic or hazardous
4 chemicals, and uses an onsite sewage treatment and disposal
5 system that is installed on or after July 5, 1989, must obtain
6 an annual system operating permit from the department. A
7 person who owns or operates a business that uses an onsite
8 sewage treatment and disposal system that was installed and
9 approved before July 5, 1989, need not obtain a system
10 operating permit. However, upon change of ownership or
11 tenancy, the new owner or operator must notify the department
12 of the change, and the new owner or operator must obtain an
13 annual system operating permit, regardless of the date that
14 the system was installed or approved.

15 3. The department shall periodically review and
16 evaluate the continued use of onsite sewage treatment and
17 disposal systems in areas zoned or used for industrial or
18 manufacturing purposes, or its equivalent, and may require the
19 collection and analyses of samples from within and around such
20 systems. If the department finds that toxic or hazardous
21 chemicals or toxic, hazardous, or industrial wastewater have
22 been or are being disposed of through an onsite sewage
23 treatment and disposal system, the department shall initiate
24 enforcement actions against the owner or tenant to ensure
25 adequate cleanup, treatment, and disposal.

26 (j) An onsite sewage treatment and disposal system for
27 a single-family residence that is designed by a professional
28 engineer registered in the state and certified by such
29 engineer as complying with performance criteria adopted by the
30 department must be approved by the department subject to the
31 following:

1 1. The performance criteria applicable to
2 engineer-designed systems must be limited to those necessary
3 to ensure that such systems do not adversely affect the public
4 health or significantly degrade the groundwater or surface
5 water. Such performance criteria shall include consideration
6 of the quality of system effluent, the proposed total sewage
7 flow per acre, wastewater treatment capabilities of the
8 natural or replaced soil, water quality classification of the
9 potential surface-water-receiving body, and the structural and
10 maintenance viability of the system for the treatment of
11 domestic wastewater. However, performance criteria shall
12 address only the performance of a system and not a system's
13 design.

14 2. The technical review and advisory panel shall
15 assist the department in the development of performance
16 criteria applicable to engineer-designed systems. Workshops
17 on the development of the rules delineating such criteria
18 shall commence not later than September 1, 1996, and the
19 department shall advertise such rules for public hearing no
20 later than October 1, 1997.

21 3. A person electing to utilize an engineer-designed
22 system shall, upon completion of the system design, submit
23 such design, certified by a registered professional engineer,
24 to the county health department. The county health department
25 may utilize an outside consultant to review the
26 engineer-designed system, with the actual cost of such review
27 to be borne by the applicant. Within 5 working days after
28 receiving an engineer-designed system permit application, the
29 county health department shall request additional information
30 if the application is not complete. Within 15 working days
31 after receiving a complete application for an

1 engineer-designed system, the county health department either
2 shall issue the permit or, if it determines that the system
3 does not comply with the performance criteria, shall notify
4 the applicant of that determination and refer the application
5 to the department for a determination as to whether the system
6 should be approved, disapproved, or approved with
7 modification. The department engineer's determination shall
8 prevail over the action of the county health department. The
9 applicant shall be notified in writing of the department's
10 determination and of the applicant's rights to pursue a
11 variance or seek review under the provisions of chapter 120.

12 4. The owner of an engineer-designed performance-based
13 system must obtain an annual system operating permit from the
14 department. The department shall inspect the system at least
15 annually and may collect system-effluent samples if
16 appropriate to determine compliance with the performance
17 criteria. The fee for the annual operating permit shall be
18 collected beginning with the second year of system operation.

19 5. If an engineer-designed system fails to properly
20 function or fails to meet performance standards, the system
21 shall be re-engineered, if necessary, to bring the system into
22 compliance with the provisions of this section.

23 (k) An innovative system may be approved in
24 conjunction with an engineer-designed site-specific system
25 which is certified by the engineer to meet the
26 performance-based criteria adopted by the department.

27 (l) For the Florida Keys, the department shall adopt a
28 special rule for the construction, installation, modification,
29 operation, repair, maintenance, and performance of onsite
30 sewage treatment and disposal systems which considers the
31 unique soil conditions and which considers water table

1 elevations, densities, and setback requirements. On lots
2 where a setback distance of 75 feet from surface waters,
3 saltmarsh, and buttonwood association habitat areas cannot be
4 met, an injection well, approved and permitted by the
5 department, may be used for disposal of effluent from onsite
6 sewage treatment and disposal systems.

7 (m) No product sold in the state for use in onsite
8 sewage treatment and disposal systems may contain any
9 substance in concentrations or amounts that would interfere
10 with or prevent the successful operation of such system, or
11 that would cause discharges from such systems to violate
12 applicable water quality standards. The department shall
13 publish criteria for products known or expected to meet the
14 conditions of this paragraph. In the event a product does not
15 meet such criteria, such product may be sold if the
16 manufacturer satisfactorily demonstrates to the department
17 that the conditions of this paragraph are met.

18 (n) Evaluations for determining the seasonal
19 high-water table elevations or the suitability of soils for
20 the use of a new onsite sewage treatment and disposal system
21 shall be performed by department personnel, professional
22 engineers registered in the state, or such other persons with
23 expertise, as defined by rule, in making such evaluations.
24 Evaluations for determining mean annual flood lines shall be
25 performed by those persons identified in paragraph (2)(i). The
26 department shall accept evaluations submitted by professional
27 engineers and such other persons as meet the expertise
28 established by this section or by rule unless the department
29 has a reasonable scientific basis for questioning the accuracy
30 or completeness of the evaluation.

31

1 (o) The department shall appoint a research review and
2 advisory committee, which shall meet at least semiannually.
3 The committee shall advise the department on directions for
4 new research, review and rank proposals for research
5 contracts, and review draft research reports and make
6 comments. The committee is comprised of:

7 1. A representative of the Division of Environmental
8 Health of the Department of Health.

9 2. A representative from the septic tank industry.

10 3. A representative from the home building industry.

11 4. A representative from an environmental interest
12 group.

13 5. A representative from the State University System,
14 from a department knowledgeable about onsite sewage treatment
15 and disposal systems.

16 6. A professional engineer registered in this state
17 who has work experience in onsite sewage treatment and
18 disposal systems.

19 7. A representative from the real estate profession.

20 8. A representative from the restaurant industry.

21 9. A consumer.
22

23 Members shall be appointed for a term of 3 years, with the
24 appointments being staggered so that the terms of no more than
25 four members expire in any one year. Members shall serve
26 without remuneration, but are entitled to reimbursement for
27 per diem and travel expenses as provided in s. 112.061.

28 (p) An application for an onsite sewage treatment and
29 disposal system permit shall be completed in full, signed by
30 the owner or the owner's authorized representative, or by a
31 contractor licensed under chapter 489, and shall be

1 accompanied by all required exhibits and fees. No specific
2 documentation of property ownership shall be required as a
3 prerequisite to the review of an application or the issuance
4 of a permit. The issuance of a permit does not constitute
5 determination by the department of property ownership.

6 (q) The department may not require any form of
7 subdivision analysis of property by an owner, developer, or
8 subdivider prior to submission of an application for an onsite
9 sewage treatment and disposal system.

10 (r) Nothing in this section limits the power of a
11 municipality or county to enforce other laws for the
12 protection of the public health and safety.

13 (s) In the siting of onsite sewage treatment and
14 disposal systems, including drainfields, shoulders, and
15 slopes, guttering shall not be required on single-family
16 residential dwelling units for systems located greater than 5
17 feet from the roof drip line of the house. If guttering is
18 used on residential dwelling units, the downspouts shall be
19 directed away from the drainfield.

20 (t) Notwithstanding the provisions of subparagraph
21 (f)1., onsite sewage treatment and disposal systems located in
22 floodways of the Suwannee and Aucilla Rivers must adhere to
23 the following requirements:

24 1. The absorption surface of the drainfield shall not
25 be subject to flooding based on 10-year flood elevations.
26 Provided, however, for lots or parcels created by the
27 subdivision of land in accordance with applicable local
28 government regulations prior to January 17, 1990, if an
29 applicant cannot construct a drainfield system with the
30 absorption surface of the drainfield at an elevation equal to
31 or above 10-year flood elevation, the department shall issue a

1 permit for an onsite sewage treatment and disposal system
2 within the 10-year floodplain of rivers, streams, and other
3 bodies of flowing water if all of the following criteria are
4 met:

5 a. The lot is at least one-half acre in size;
6 b. The bottom of the drainfield is at least 36 inches
7 above the 2-year flood elevation; and
8 c. The applicant installs either: a waterless,
9 incinerating, or organic waste composting toilet and a
10 graywater system and drainfield in accordance with department
11 rules; an aerobic treatment unit and drainfield in accordance
12 with department rules; a system approved by the State Health
13 Office that is capable of reducing effluent nitrate by at
14 least 50 percent; or a system approved by the county health
15 department pursuant to department rule other than a system
16 using alternative drainfield materials. The United States
17 Department of Agriculture Soil Conservation Service soil maps,
18 State of Florida Water Management District data, and Federal
19 Emergency Management Agency Flood Insurance maps are resources
20 that shall be used to identify flood-prone areas.

21 2. The use of fill or mounding to elevate a drainfield
22 system out of the 10-year floodplain of rivers, streams, or
23 other bodies of flowing water shall not be permitted if such a
24 system lies within a regulatory floodway of the Suwannee and
25 Aucilla Rivers. In cases where the 10-year flood elevation
26 does not coincide with the boundaries of the regulatory
27 floodway, the regulatory floodway will be considered for the
28 purposes of this subsection to extend at a minimum to the
29 10-year flood elevation.

30 Section 11. Paragraph (a) of subsection (2) of section
31 381.0072, Florida Statutes, is amended to read:

1 381.0072 Food service protection.--It shall be the
2 duty of the Department of Health to adopt and enforce
3 sanitation rules consistent with law to ensure the protection
4 of the public from food-borne illness. These rules shall
5 provide the standards and requirements for the storage,
6 preparation, serving, or display of food in food service
7 establishments as defined in this section and which are not
8 permitted or licensed under chapter 500 or chapter 509.

9 (2) DUTIES.--

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

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

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

14 381.0086 Rules; variances; penalties.--

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

1 is more stringent than the federal standards applicable to the
2 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 of terms, the packaging of biomedical waste, including
11 specific requirements for the segregation of the waste at the
12 point of generation; the safe packaging of sharps; the
13 placement of the waste in containers that will protect waste
14 handlers and the public from exposure; the appropriate
15 labeling of containers of waste; written operating plans for
16 managing biomedical waste; and the transport, storage, and
17 treatment of biomedical 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 and within the
2 timeframes and in the 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 may
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 adopted ~~promulgated~~ by rule
24 of the department. Facilities owned and operated by the state
25 shall 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 may ~~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 that ~~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 adopted ~~promulgated~~ by the
15 department. A registration may not be transferred from one
16 biomedical waste transporter to another. If the ownership or
17 name of a biomedical waste transporter is changed and the
18 owner intends to continue operation of the transporter, the
19 owner must apply to the department on departmental forms
20 within the timeframes and in the manner prescribed by
21 department rule.The department may charge registration fees
22 in the same manner as is provided in paragraphs(4)(e) and (f)
23 ~~(4)(f) and (g)~~. The department may exempt from this
24 requirement any person who, or facility that, transports less
25 than 25 pounds of such waste on any single occasion.

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

28 381.0101 Environmental health professionals.--

29 (5) STANDARDS FOR CERTIFICATION.--The department shall
30 adopt rules that establish definitions of terms and minimum
31 standards of education, training, or experience for those

1 persons subject to this section. The rules must ~~shall~~ also
2 address the process for application, examination, issuance,
3 expiration, and renewal of certification and ethical standards
4 of practice for the profession.

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

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

17 2. Persons employed in a primary environmental health
18 program prior to September 21, 1994, shall be considered
19 certified while employed in that position and shall be
20 required to adhere to any professional standards established
21 by the department pursuant to paragraph (b), complete any
22 continuing education requirements imposed under paragraph (d),
23 and pay the certificate renewal fee imposed under subsection
24 (7).

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

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 administer this section.

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. If a
4 tanning facility or other person violates this section or any
5 rule adopted under this section, the department may issue a
6 stop-use order, as prescribed by rule, to remove a tanning
7 device from service.

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

15 Section 17. Paragraph (a) of subsection (2) of section
16 383.011, Florida Statutes, is amended to read:

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

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

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

1 health care providers prior to and following the birth of a
2 child and responsibilities for the interprogram coordination
3 of prenatal and infant care coalitions.

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

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

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

30 Section 19. Subsection (1) of section 383.19, Florida
31 Statutes, is amended to read:

1 383.19 Standards; funding; ineligibility.--

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

5 (a) The need to provide services through a regional
6 perinatal intensive care center and the requirements of the
7 population to be served.

8 (b) Equipment.

9 (c) Facilities.

10 (d) Staffing and qualifications of personnel.

11 (e) Transportation services.

12 (f) Data collection.

13 (g) Definitions of terms.

14 Section 20. Subsections (9) and (10) of section
15 383.216, Florida Statutes, are amended to read:

16 383.216 Community-based prenatal and infant health
17 care.--

18 (9) Local prenatal and infant health care coalitions
19 shall incorporate as not-for-profit corporations for the
20 purpose of seeking and receiving grants from federal, state,
21 and local government and other contributors. However, a
22 coalition need not be designated as a tax-exempt organization
23 under s. 501(c)(3) of the Internal Revenue Code.

24 (10) The Department of Health shall adopt rules ~~as~~
25 necessary to administer ~~implement~~ this section, including
26 rules defining acceptable "in-kind" contributions and rules
27 providing definitions of terms, coalition responsibilities,
28 coalition operations and standards, and conditions for
29 establishing and approving a coalition. A coalition may not be
30 a direct provider of prenatal and infant-care services.

31

1 Section 21. Section 384.33, Florida Statutes, is
2 amended to read:

3 384.33 Rules.--The department may adopt rules pursuant
4 to ss. 120.536(1) and 120.54 to implement the provisions of
5 this chapter. The rules may include requirements for methods
6 of contacting a physician to determine the need for followup
7 services related to sexually transmissible diseases; standards
8 for screening, treating, and performing contact investigations
9 to control the spread of sexually transmitted diseases; and
10 requirements for maintaining the security of confidential
11 information.

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

14 385.207 Care and assistance of persons with epilepsy;
15 establishment of programs in epilepsy control.--

16 (4) The department shall adopt rules to administer
17 ~~implement~~ this section. The rules may include requirements for
18 the scope of service, criteria for eligibility, and
19 requirements for reports and forms.

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

22 391.026 Powers and duties of the department.--The
23 department shall have the following powers, duties, and
24 responsibilities:

25 (18) To adopt rules pursuant to ss. 120.536(1) and
26 120.54 to administer ~~implement~~ the Children's Medical Services
27 ~~provisions of this Act.~~ The rules may include requirements for
28 definitions of terms, program organization, and program
29 description; a process for selecting an area medical director;
30 responsibilities of applicants and clients; requirements for
31 service applications, including required medical and financial

1 information; eligibility requirements for initial treatment
2 and for continued eligibility, including financial and custody
3 issues; methodologies for resource development and allocation,
4 including medical and financial considerations; requirements
5 for reimbursement services rendered to a client; billing and
6 payment requirements for providers; requirements for
7 qualification, appointments, verification, and emergency
8 exceptions for health-professional consultants; general and
9 diagnostic-specific standards for diagnostic and treatment
10 facilities; and standards for the method of service delivery,
11 including consultant services, respect-for-privacy
12 considerations, examination requirements, family support
13 plans, and clinic design.

14 Section 24. Section 392.66, Florida Statutes, is
15 amended to read:

16 392.66 Rules.--The department shall adopt rules
17 pursuant to ss. 120.536(1) and 120.54 to administer ~~implement~~
18 ~~the provisions of~~ this chapter. The rules must include
19 requirements for tuberculosis treatment and provide
20 consequences if a person who has active tuberculosis fails to
21 comply with treatment requirements.

22 Section 25. Subsection (2) of section 395.401, Florida
23 Statutes, is amended to read:

24 395.401 Trauma services system plans; verification of
25 trauma centers and pediatric trauma referral centers;
26 procedures; renewal.--

27 (2)(a) The local and regional trauma agencies shall
28 plan, implement, and evaluate trauma services systems, in
29 accordance with this section and ss. 395.4015, 395.404, and
30 395.4045, which consist of organized patterns of readiness and
31 response services based on public and private agreements and

1 operational procedures. The department shall establish, by
2 rule, processes and procedures for establishing a trauma
3 agency and obtaining its approval from the department.

4 (b) The local and regional trauma agencies shall
5 develop and submit to the department plans for local and
6 regional trauma services systems. The plans must include, at a
7 minimum, the following components:

8 1. The organizational structure of the trauma system.

9 2. Prehospital care management guidelines for triage
10 and transportation of trauma cases.

11 3. Flow patterns of trauma cases and transportation
12 system design and resources, including air transportation
13 services, and provision for interfacility transfer.

14 4. The number and location of needed state-approved
15 trauma centers based on local needs, population, and location
16 and distribution of resources.

17 5. Data collection regarding system operation and
18 patient outcome.

19 6. Periodic performance evaluation of the trauma
20 system and its components.

21 7. The use of air transport services within the
22 jurisdiction of the local trauma agency.

23 8. Public information and education about the trauma
24 system.

25 9. Emergency medical services communication system
26 usage and dispatching.

27 10. The coordination and integration between the
28 verified trauma care facility and the nonverified health care
29 facilities.

30 11. Medical control and accountability.

31 12. Quality control and system evaluation.

1 (c) The department shall receive plans for the
2 implementation of inclusive trauma systems from trauma
3 agencies. The department may approve or not approve trauma
4 agency plans based on the conformance of the plan with this
5 section and ss. 395.4015, 395.404, and 395.4045 and the rules
6 and definitions adopted by the department pursuant to those
7 sections. The department shall approve or disapprove the
8 plans within 120 days after the date the plans are submitted
9 to the department. The department shall, by rule, provide an
10 application process for establishing a trauma agency. The
11 application must, at a minimum, provide requirements for the
12 trauma agency plan submitted for review, a process for
13 reviewing the application for a state-approved trauma agency,
14 a process for reviewing the trauma transport protocols for the
15 trauma agency, and a process for reviewing the staffing
16 requirements for the agency. The department shall, by rule,
17 establish minimum requirements for a trauma agency to conduct
18 an annual performance evaluation and submit the results to the
19 department.

20 (d) A trauma agency shall not operate unless the
21 department has approved the local or regional trauma services
22 system plan of the agency.

23 (e) The department may grant an exception to a portion
24 of the rules adopted pursuant to this section or s. 395.4015
25 if the local or regional trauma agency proves that, as defined
26 in the rules, compliance with that requirement would not be in
27 the best interest of the persons served within the affected
28 local or regional trauma area.

29 (f) A local or regional trauma agency may implement a
30 trauma care system only if the system meets the minimum
31 standards set forth in the rules for implementation

1 established by the department and if the plan has been
2 submitted to, and approved by, the department. At least 60
3 days before the local or regional trauma agency submits the
4 plan for the trauma care system to the department, the local
5 or regional trauma agency shall hold a public hearing and give
6 adequate notice of the public hearing to all hospitals and
7 other interested parties in the area to be included in the
8 proposed system.

9 (g) Local or regional trauma agencies may enter into
10 contracts for the purpose of implementing the local or
11 regional plan. If local or regional agencies contract with
12 hospitals for trauma services, such agencies must contract
13 only with hospitals which are verified trauma centers.

14 (h) Local or regional trauma agencies providing
15 service for more than one county shall, as part of their
16 formation, establish interlocal agreements between or among
17 the several counties in the regional system.

18 (i) This section does not restrict the authority of a
19 health care facility to provide service for which it has
20 received a license pursuant to this chapter.

21 (j) Any hospital which is verified as a trauma center
22 shall accept all trauma victims that are appropriate for the
23 facility regardless of race, sex, creed, or ability to pay.

24 (k) It is unlawful for any hospital or other facility
25 to hold itself out as a trauma center unless it has been so
26 verified.

27 (l) A county, upon the recommendations of the local or
28 regional trauma agency, may adopt ordinances governing the
29 transport of a patient who is receiving care in the field from
30 prehospital emergency medical personnel when the patient meets
31 specific criteria for trauma, burn, or pediatric centers

1 adopted by the local or regional trauma agency. These
2 ordinances must be consistent with s. 395.4045, ordinances
3 adopted under s. 401.25(6), and the local or regional trauma
4 system plan and, to the furthest possible extent, must ensure
5 that individual patients receive appropriate medical care
6 while protecting the interests of the community at large by
7 making maximum use of available emergency medical care
8 resources.

9 (m) The local or regional trauma agency shall,
10 consistent with the regional trauma system plan, coordinate
11 and otherwise facilitate arrangements necessary to develop a
12 trauma services system.

13 (n) After the submission of the initial trauma system
14 plan, each trauma agency shall, every 5th year, submit to the
15 department for approval an updated plan that identifies the
16 changes, if any, to be made in the regional trauma system.

17 (o) This section does not preclude a local or regional
18 trauma agency from adopting trauma care system standards.

19 Section 26. Paragraph (b) of subsection (3) of section
20 395.402, Florida Statutes, is amended to read:

21 395.402 Trauma service areas; number and location of
22 trauma centers.--

23 (3) Trauma service areas are to be used. The
24 department shall periodically review the assignment of the 67
25 counties to trauma service areas. These assignments are made
26 for the purpose of developing a system of trauma centers.
27 Revisions made by the department should take into
28 consideration the recommendations made as part of the regional
29 trauma system plans approved by the department, as well as the
30 recommendations made as part of the state trauma system plan.
31 These areas must, at a minimum, be reviewed in the year 2000

1 and every 5 years thereafter. Until the department completes
2 its initial review, the assignment of counties shall remain as
3 established pursuant to chapter 90-284, Laws of Florida.

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

8 Section 27. Section 401.35, Florida Statutes, is
9 amended to read:

10 401.35 Rules.--The department shall adopt rules,
11 including definitions of terms,necessary to carry out the
12 purposes of this part.

13 (1) The rules must provide at least minimum standards
14 governing:

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

17 (b) Emergency medical technician, paramedic, and
18 driver training and qualifications.

19 (c) Ground ambulance and vehicle equipment and
20 supplies at least as comprehensive as those published in the
21 most current edition of the American College of Surgeons,
22 Committee on Trauma, list of essential equipment for
23 ambulances, as interpreted by rules of the department.

24 (d) Ground ambulance or vehicle design and
25 construction at least equal to those most currently
26 recommended by the United States General Services
27 Administration as interpreted by rules of the department.

28 (e) Staffing of basic life support and advanced life
29 support vehicles.

30 (f) Two-way communications for basic life support
31 services and advanced life support services.

- 1 (g) Advanced life support services equipment.
- 2 (h) Programs of training for emergency medical
3 technicians and paramedics.
- 4 (i) Vehicles, equipment, communications, and minimum
5 staffing qualifications for air ambulance services.
- 6 (j) Ambulance driver qualifications, training, and
7 experience.
- 8 (k) Optional use of telemetry by licensees.
- 9 (l) Licensees' security and storage of controlled
10 substances, medications, and fluids, not inconsistent with the
11 provisions of chapter 499 or chapter 893.
- 12 (2) The rules must establish application requirements
13 for licensure and certification. Pursuant thereto, the
14 department must develop application forms for basic life
15 support services and advanced life support services. An
16 application for each respective service license must include,
17 but is not limited to:
- 18 (a) The name and business address of the operator and
19 owner of the service or proposed service.
- 20 (b) The name under which the applicant will operate.
- 21 (c) A list of the names and addresses of all officers,
22 directors, and shareholders of the applicant.
- 23 (d) A description of each vehicle to be used,
24 including the make, model, year of manufacture, mileage, and
25 vehicle identification number (VIN); the state or federal
26 aviation or marine registration number, when applicable; and
27 the color scheme, insignia, name, monogram, or other
28 distinguishing characteristics to be used to designate the
29 applicant's vehicle or vehicles.
- 30 (e) The service location from which the service will
31 operate.

1 (f) A statement reasonably describing the geographic
2 area or areas to be served by the applicant.

3 (g) A statement certifying that the applicant will
4 provide continuous service 24 hours a day, 7 days a week, if a
5 basic life support service license or an advanced life support
6 service license is sought. Such service must be initiated
7 within 30 days after issuance of the license.

8 (h) Such other information as the department
9 determines reasonable and necessary.

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

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

25 (4) The rules must establish circumstances and
26 procedures under which emergency medical technicians and
27 paramedics may honor orders by the patient's physician not to
28 resuscitate and the documentation and reporting requirements
29 for handling such requests.

30 (5) The rules must establish requirements for
31 licensees and certificateholders with respect to providing

1 address information to the department; requirements for
2 examinations, grading, and passing scores for certification;
3 and requirements for determining whether a convicted felon
4 whose civil rights have not been restored is eligible for
5 certification or recertification.

6 Section 28. Paragraph (f) of subsection (1) of section
7 403.862, Florida Statutes, is amended to read:

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

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

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

25 Section 29. Subsection (3) of section 404.056, Florida
26 Statutes, is amended to read:

27 404.056 Environmental radiation standards and
28 programs; radon protection.--

29 (3) CERTIFICATION.--

30 (a) The department may ~~is authorized to~~ certify
31 persons who perform radon gas or radon progeny measurements,

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

18 (b) A person may not participate in performing radon
19 gas or radon progeny measurements, including sample
20 collection, analysis, or interpretation of such measurements,
21 or perform mitigation of buildings for radon gas or radon
22 progeny, and charge a fee or obtain other remuneration as
23 benefit for such services or devices, unless that person is
24 certified by the department. A certification issued in
25 accordance with this section automatically expires at the end
26 of the certification period stated on the certificate. An
27 uncertified commercial business may subcontract radon
28 measurements to a certified radon business. The uncertified
29 commercial business must provide the complete radon report
30 from the certified radon business to the client and direct all
31

1 the client's questions about the measurements or radon report
2 to the certified radon business.

3 (c) The results of measurements of radon gas or radon
4 progeny performed by persons certified under the provisions of
5 this subsection shall be reported to the department and
6 persons contracting for the service. Upon request, the
7 results of measurements of radon gas or radon progeny which
8 are performed to evaluate the effectiveness of a radon
9 mitigation system shall be reported to the certified business
10 that installed the mitigation system. The report must include
11 the radon levels detected; the location, age, and description
12 of the building; the name and certification numbers of the
13 certified radon measurement business and individual who
14 performed the measurements; and other information determined
15 by the department to meet the requirements of the protocols
16 and procedures for the type of measurement performed. Each
17 installation of a radon mitigation system performed by a
18 person certified under this section must be reported to the
19 department according to the schedule set by the department.
20 The report must include the premitigation and postmitigation
21 radon levels; the type or types of systems installed; the
22 location, age, and description of the building; and the name
23 and certification number of the certified mitigation business
24 that performed the mitigation.

25 (d) Authorized representatives of the department may
26 ~~have the authority to~~ inspect the business and records of any
27 person certified under the provisions of this subsection, at
28 all reasonable times, to examine records and test procedures
29 to determine compliance with or violation of the provisions of
30 this section.

31

1 (e) Any person who practices fraud, deception, or
2 misrepresentation in performing radon gas or radon progeny
3 measurements or in performing mitigation of buildings for
4 radon gas or radon progeny is subject to the penalties
5 provided in s. 404.161.

6 (f) The department may ~~is authorized to~~ charge and
7 collect nonrefundable fees for the certification and annual
8 recertification of persons who perform radon gas or radon
9 progeny measurements or who perform mitigation of buildings
10 for radon gas or radon progeny. The amount of the initial
11 application fee and certification shall be not less than \$200
12 or more than \$900. The amount of the annual recertification
13 fee shall be not less than \$200 or more than \$900. Effective
14 July 1, 1988, the fee amounts shall be the minimum fee
15 prescribed in this paragraph, and such fee amounts shall
16 remain in effect until the effective date of a fee schedule
17 promulgated by rule by the department. The fees collected
18 shall be deposited in the Radiation Protection Trust Fund and
19 shall be used only to implement the provisions of this
20 section. The surcharge established pursuant to subsection (3)
21 may be used to supplement the fees established in this
22 paragraph in carrying out the provisions of this subsection.

23 (g) The department may establish enforcement
24 procedures; deny an application for initial or renewal
25 certification; deny, suspend, or revoke a certification; or
26 impose an administrative fine not to exceed \$1,000 per
27 violation per day, for the violation of any provision of this
28 section or rule adopted under this section promulgated
29 ~~pursuant thereto~~.

30 (h) A certificateholder in good standing remains in
31 good standing when he or she becomes a member of the Armed

1 Forces of the United States on active duty without payment of
2 renewal fees as long as he or she is a member of the Armed
3 Forces on active duty and for a period of 6 months after his
4 or her discharge from active duty, if he or she is not engaged
5 in practicing radon measurement or radon mitigation in the
6 private sector for profit. The certificateholder must pay a
7 renewal fee to renew the certificate.

8 (i) A certificateholder who is in good standing
9 remains in good standing if he or she is absent from the state
10 because of his or her spouse's active duty with the Armed
11 Forces of the United States. The certificateholder remains in
12 good standing without payment of renewal fees as long as his
13 or her spouse is a member of the Armed Forces on active duty
14 and for a period of 6 months after the spouse's discharge from
15 active duty, if the certificateholder is not engaged in
16 practicing radon measurement or radon mitigation in the
17 private sector for profit. The certificateholder must pay a
18 renewal fee to renew the certificate.

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

23 1. Requirements for measurement devices and
24 measurement procedures, including the disclosure of mitigation
25 materials, systems, and other mitigation services offered.

26 2. The identification of certified specialists and
27 technicians employed by the business and requirements for
28 specialist staffing and duties.

29 3. The analysis of measurement devices by proficient
30 analytical service providers.

31

1 4. Requirements for a quality assurance and quality
2 control program.

3 5. The disclosure of client measurement reporting
4 forms and warranties and operating instructions for mitigation
5 systems.

6 6. Requirements for radon services publications and
7 the identification of the radon business certification number
8 in advertisements.

9 7. Requirements for a worker health and safety
10 program.

11 8. Requirements for maintaining radon records.

12 9. The operation of branch office locations.

13 10. Requirements for supervising subcontractors who
14 install mitigation systems.

15 11. Requirements for building inspections and
16 evaluation and standards for the design and installation of
17 mitigation systems.

18 12. Prescribing conditions of premitigation and
19 postmitigation ~~mitigation~~ measurements.

20 13. Requirements for renewals received after the
21 automatic expiration date of certification.

22 14. Requirements for obtaining a duplicate or
23 replacement certificate, including a fee not to exceed the
24 cost of producing the duplicate or replacement certificate.

25 15. Requirements for reporting, including timeframes
26 and content.

27 (k) Any change in the information provided to the
28 department in the original business application to be reported
29 within 10 days after the change.

30 Section 30. Subsection (1) of section 404.22, Florida
31 Statutes, is amended to read:

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 to this chapter ~~thereto~~. Such rules may
14 include standards for radiation machine performance, surveys,
15 calibrations, and spot checks; requirements for quality
16 assurance programs and quality control programs; standards for
17 facility electrical systems, safety alarms,
18 radiation-monitoring equipment, and dosimetry systems;
19 requirements for visual and aural communication with patients;
20 procedures for establishing radiation-safety committees for a
21 facility; and qualifications of persons who cause a radiation
22 machine to be used, who operate a radiation machine, and who
23 ensure that a radiation machine complies with the requirements
24 of this chapter and with rules of the department.If, in the
25 opinion of the department, a radiation machine that ~~which~~
26 fails to meet such standards can be made to meet the standards
27 through an adjustment or limitation upon the stations or range
28 of the radiation machine or through the purchase of a
29 component meeting the standards, the department shall order
30 the owner of the radiation machine to make the necessary
31 adjustment or to purchase the necessary component within 90

1 days after ~~of~~ the date or receipt of the order. However, if
2 the radiation machine cannot be made to meet the standards,
3 the department shall order the owner to cease the use
4 ~~utilization~~ of the radiation machine.

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

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

9 (3) The department shall adopt reasonable rules,
10 including, but not limited to, rules that ~~which~~ establish
11 ethical standards of practice, requirements for registering as
12 a contractor, requirements for obtaining an initial or renewal
13 certificate of registration, disciplinary guidelines, and
14 requirements for the certification of partnerships and
15 corporations. The department ~~and~~ may amend or repeal the rules
16 ~~same~~ in accordance with the Administrative Procedure Act.

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

19 491.006 Licensure or certification by endorsement.--

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

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

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

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 that ~~which~~ would constitute a
9 violation of this chapter, and has not been found to have
10 committed any act that ~~which~~ would constitute a violation of
11 this chapter. The fees paid by any applicant for certification
12 as a master social worker under this section are
13 nonrefundable.

14 Section 33. Subsections (1) and (5) of section
15 491.0145, Florida Statutes, are amended to read:

16 491.0145 Certified master social worker.--The
17 department may certify an applicant for a designation as a
18 certified master social worker upon the following conditions:

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

25 (5) The applicant has passed an examination required
26 by the department for this purpose. The nonrefundable fee for
27 such examination may ~~shall~~ not exceed \$250 as set by
28 department rule.

29 Section 34. Present subsections (11) through (29) of
30 section 499.003, Florida Statutes, are redesignated as
31

1 subsections (12) through (30), respectively, and a new
2 subsection (11) is added to that section, to read:

3 499.003 Definitions of terms used in ss.
4 499.001-499.081.--As used in ss. 499.001-499.081, the term:
5 (11) "Distribute or distribution" means to sell; offer
6 to sell; give away; transfer, whether by passage of title,
7 physical movement, or both; deliver; or offer to deliver. The
8 term does not mean to administer or dispense.

9 Section 35. Subsections (25) and (26) are added to
10 section 499.005, Florida Statutes, to read:

11 499.005 Prohibited acts.--It is unlawful to perform or
12 cause the performance of any of the following acts in this
13 state:

14 (25) Charging a dispensing fee for dispensing,
15 administering, or distributing a prescription drug sample.

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

19 Section 36. Subsection (8) is added to section
20 499.0054, Florida Statutes, to read:

21 499.0054 Advertising and labeling of drugs, devices,
22 and cosmetics.--It is a violation of the Florida Drug and
23 Cosmetic Act to perform or cause the performance of any of the
24 following acts:

25 (8) The representation or suggestion in labeling or
26 advertising that an article is approved under ss.
27 499.001-499.081, when such is not the case.

28 Section 37. Subsection (2) and paragraph (d) of
29 subsection (4) of section 499.01, Florida Statutes, are
30 amended to read:

31

1 499.01 Permits; applications; renewal; general
2 requirements.--

3 (2) The department shall establish, by rule, the form
4 and content of the application to obtain or renew a permit.
5 The applicant must submit to the department with the
6 application a statement that swears or affirms that the
7 information is true and correct.

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

- 10 1. The name, full business address, and telephone
11 number of the applicant;
- 12 2. All trade or business names used by the applicant;
- 13 3. The address, telephone numbers, and the names of
14 contact persons for each facility used by the applicant for
15 the storage, handling, and distribution of prescription drugs;
- 16 4. The type of ownership or operation, such as a
17 partnership, corporation, or sole proprietorship; and
- 18 5. The names of the owner and the operator of the
19 establishment, including:
 - 20 a. If an individual, the name of the individual;
 - 21 b. If a partnership, the name of each partner and the
22 name of the partnership;
 - 23 c. If a corporation, the name and title of each
24 corporate officer and director, the corporate names, and the
25 name of the state of incorporation;
 - 26 d. If a sole proprietorship, the full name of the sole
27 proprietor and the name of the business entity; and
 - 28 e. Any other relevant information that the department
29 requires.

30 (b) Upon approval of the application by the department
31 and payment of the required fee, the department shall issue a

1 permit to the applicant, if the applicant meets the
2 requirements of ss. 499.001-499.081 and rules adopted under
3 those sections.

4 (c) Any change in information required under paragraph
5 (a) must be submitted to the department before the change
6 occurs.

7 (d) The department shall consider, at a minimum, the
8 following factors in reviewing the qualifications of persons
9 to be permitted under ss. 499.001-499.081:

10 1. The applicant's having been found guilty,
11 regardless of adjudication, in a court of this state or other
12 jurisdiction, of a violation of a law that directly relates to
13 a drug, device, or cosmetic. A plea of nolo contendere
14 constitutes a finding of guilt for purposes of this
15 subparagraph.

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

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

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

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

26 6. Suspension or revocation by a federal, state, or
27 local government of any permit currently or previously held by
28 the applicant for the manufacture or distribution of any
29 drugs, devices, or cosmetics;

30 7. Compliance with permitting requirements under any
31 previously granted permits;

1 8. Compliance with requirements to maintain or make
2 available to the state permitting authority or to federal,
3 state, or local law enforcement officials those records
4 required under this section; and

5 9. Any other factors or qualifications the department
6 considers relevant to and consistent with the public health
7 and safety.

8 (4) A permit issued by the department is
9 nontransferable. Each permit is valid only for the person or
10 governmental unit to which it is issued and is not subject to
11 sale, assignment, or other transfer, voluntarily or
12 involuntarily; nor is a permit valid for any establishment
13 other than the establishment for which it was originally
14 issued.

15 (d) If an establishment permitted under ss.
16 499.001-499.081 closes, the owner must notify the department
17 in writing before the effective date of closure and must:

- 18 1. Return the permit to the department;
19 2. If the permittee is authorized to distribute legend
20 drugs, indicate the disposition of such drugs, including the
21 name, address, and inventory, and provide the name and address
22 of a person to contact regarding access to records that are
23 required to be maintained under ss. 499.001-499.081. Transfer
24 of ownership of legend drugs may be made only to persons
25 authorized to possess legend drugs under ss. 499.001-499.081.

26 Section 38. Paragraph (c) is added to subsection (2)
27 of section 499.0121, Florida Statutes, to read:

28 499.0121 Storage and handling of prescription
29 drugs.--The department shall adopt rules to implement this
30 section as necessary to protect the public health, safety, and
31 welfare. Such rules shall include, but not be limited to,

1 requirements for the storage and handling of prescription
2 drugs and for the establishment and maintenance of
3 prescription drug distribution records.

4 (2) SECURITY.--

5 (c) Any vehicle that contains prescription drugs must
6 be secure from unauthorized access to the prescription drugs
7 in the vehicle.

8 Section 39. Paragraph (b) of subsection (2) of section
9 499.0122, Florida Statutes, is amended to read:

10 499.0122 Medical oxygen and veterinary legend drug
11 retail establishments; definitions, permits, general
12 requirements.--

13 (2)

14 (b) The department shall adopt rules relating to
15 information required from each retail establishment pursuant
16 to s. 499.01(2), including requirements for prescriptions or
17 orders.

18 Section 40. Paragraph (d) of subsection (2) of section
19 499.013, Florida Statutes, is amended, and subsection (4) is
20 added to that section, to read:

21 499.013 Manufacturers of drugs, devices, and
22 cosmetics; definitions, permits, and general requirements.--

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

27 (d) A device manufacturer's permit is required for any
28 person that engages in the manufacture or assembly of medical
29 devices for human use in this state, except that a permit is
30 not required if the person is engaged only in manufacturing or
31

1 assembling a medical device pursuant to a practitioner's order
2 for a specific patient.

3 1. A manufacturer of medical devices in this state
4 must comply with all appropriate state and federal good
5 manufacturing practices.

6 2. The department shall adopt rules related to
7 storage, handling, and recordkeeping requirements for
8 manufacturers of medical devices for human use.

9 (4) Each manufacturer of medical devices,
10 over-the-counter drugs, or cosmetics must maintain records
11 that include the name and principal address of the seller or
12 transferor of the product, the address of the location from
13 which the product was shipped, the date of the transaction,
14 the name and quantity of the product involved, and the name
15 and principal address of the person who purchased the product.

16 Section 41. Subsections (1) and (3) of section
17 499.015, Florida Statutes, are amended to read:

18 499.015 Registration of drugs, devices, and cosmetics;
19 issuance of certificates of free sale.--

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

29 (b) The department may not register any product that
30 does not comply with the Federal Food, Drug, and Cosmetic Act,
31 as amended, or Title 21 C.F.R., or that is not an approved

1 investigational drug as provided for in s. 499.018.
2 Registration of a product by the department does not mean that
3 the product does in fact comply with all provisions of the
4 Federal Food, Drug, and Cosmetic Act, as amended.

5 (3) Except for those persons exempted from the
6 definition in s. 499.003(22)~~s. 499.003(21)~~, a person may not
7 sell any product that he or she has failed to register in
8 conformity with this section. Such failure to register
9 subjects such drug, device, or cosmetic product to seizure and
10 condemnation as provided in ss. 499.062-499.064, and subjects
11 such person to the penalties and remedies provided in ss.
12 499.001-499.081.

13 Section 42. Subsection (4) of section 499.024, Florida
14 Statutes, is amended to read:

15 499.024 Drug product classification.--The secretary
16 shall adopt rules to classify drug products intended for use
17 by humans which the United States Food and Drug Administration
18 has not classified in the federal act or the Code of Federal
19 Regulations.

20 (4) Any product that falls under the drug definition,
21 s. 499.003(12)~~s. 499.003(11)~~, may be classified under the
22 authority of this section. This section does not subject
23 portable emergency oxygen inhalators to classification;
24 however, this section does not exempt any person from ss.
25 499.01 and 499.015.

26 Section 43. Subsection (1) of section 499.03, Florida
27 Statutes, is amended to read:

28 499.03 Possession of new drugs or legend drugs without
29 prescriptions unlawful; exemptions and exceptions.--

30 (1) A person may not possess, or possess with intent
31 to sell, dispense, or deliver, any habit-forming, toxic,

1 harmful, or new drug subject to s. 499.003(23)~~s. 499.003(22)~~,
2 or legend drug as defined in s. 499.003, unless the possession
3 of the drug has been obtained by a valid prescription of a
4 practitioner licensed by law to prescribe the drug. However,
5 this section does not apply to the delivery of such drugs to
6 persons included in any of the classes named in this
7 subsection, or to the agents or employees of such persons, for
8 use in the usual course of their businesses or practices or in
9 the performance of their official duties, as the case may be;
10 nor does this section apply to the possession of such drugs by
11 those persons or their agents or employees for such use:

12 (a) A licensed pharmacist or any person under the
13 licensed pharmacist's supervision while acting within the
14 scope of the licensed pharmacist's practice;

15 (b) A licensed practitioner authorized by law to
16 prescribe legend drugs or any person under the licensed
17 practitioner's supervision while acting within the scope of
18 the licensed practitioner's practice;

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

21 (d) A licensed hospital or other institution that
22 procures such drugs for lawful administration or dispensing by
23 practitioners;

24 (e) An officer or employee of a federal, state, or
25 local government; or

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

29 Section 44. Subsection (1) of section 499.05, Florida
30 Statutes, is amended to read:

31 499.05 Rules.--

1 (1) The department shall adopt rules to implement and
2 enforce ss. 499.001-499.081 with respect to:-

3 (a) The definition of terms used in ss.
4 499.001-499.081, and used in the rules adopted under ss.
5 499.001-499.081, when the use of the term is not its usual and
6 ordinary meaning.

7 (b) Labeling requirements for drugs, devices, and
8 cosmetics.

9 (c) Application requirements, protocols, reporting
10 requirements, and requirements for submitting other
11 information to the department and the Florida Drug Technical
12 Review Panel, as required under the investigational drug
13 program.

14 (d) The establishment of fees authorized in ss.
15 499.001-499.081.

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

21 (f) The application processes and forms for product
22 registration.

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

25 (h) Inspections and investigations conducted under s.
26 499.051, and the identification of information claimed to be a
27 trade secret and exempt from the public records law as
28 provided in s. 499.051(5).

29 (i) The establishment of a range of penalties, as
30 provided in s. 499.006; requirements for notifying persons of
31 the potential impact of a violation of ss. 499.001-499.081;

1 and a process for the uncontested settlement of alleged
2 violations.

3 (j) Additional conditions that qualify as an emergency
4 medical reason under s. 499.012(1)(a)2.b.

5 Section 45. Section 499.701, Florida Statutes, is
6 amended to read:

7 499.701 Adoption of rules by the department.--

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

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

23 Section 46. Paragraph (d) of subsection (2) of section
24 501.122, Florida Statutes, is amended to read:

25 501.122 Control of nonionizing radiations; laser;
26 penalties.--

27 (2) AUTHORITY TO ISSUE REGULATIONS.--Except for
28 electrical transmission and distribution lines and substation
29 facilities subject to regulation by the Department of
30 Environmental Protection pursuant to chapter 403, the
31 Department of Health shall adopt rules as necessary to protect

1 the health and safety of persons exposed to laser devices and
2 other nonionizing radiation, including the user or any others
3 who might come in contact with such radiation. The Department
4 of Health may:

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

14 Section 47. Section 513.05, Florida Statutes, is
15 amended to read:

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

31

1 owners' responsibilities at recreational vehicle parks and
2 recreational camps.

3 Section 48. Section 514.021, Florida Statutes, is
4 amended to read:

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

18 Section 49. Section 766.1115, Florida Statutes, is
19 amended to read:

20 766.1115 Health care providers; creation of agency
21 relationship with governmental contractors.--

22 (1) SHORT TITLE.--This section may be cited as the
23 "Access to Health Care Act."

24 (2) FINDINGS AND INTENT.--The Legislature finds that a
25 significant proportion of the residents of this state who are
26 uninsured or Medicaid recipients are unable to access needed
27 health care because health care providers fear the increased
28 risk of medical malpractice liability. It is the intent of
29 the Legislature that access to medical care for indigent
30 residents be improved by providing governmental protection to
31 health care providers who offer free quality medical services

1 to underserved populations of the state. Therefore, it is the
2 intent of the Legislature to ensure that health care
3 professionals who contract to provide such services as agents
4 of the state are provided sovereign immunity.

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

6 (a) "Contract" means an agreement executed in
7 compliance with this section between a health care provider
8 and a governmental contractor. This contract shall allow the
9 health care provider to deliver health care services to
10 low-income recipients as an agent of the governmental
11 contractor. The contract must be for volunteer, uncompensated
12 services.

13 (b) "Department" means the Department of Health.

14 (c) "Governmental contractor" means the department,
15 county health departments, a special taxing district with
16 health care responsibilities, or a hospital owned and operated
17 by a governmental entity.

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

19 1. A birth center licensed under chapter 383.

20 2. An ambulatory surgical center licensed under
21 chapter 395.

22 3. A hospital licensed under chapter 395.

23 4. A physician or physician assistant licensed under
24 chapter 458.

25 5. An osteopathic physician or osteopathic physician
26 assistant licensed under chapter 459.

27 6. A chiropractic physician licensed under chapter
28 460.

29 7. A podiatric physician licensed under chapter 461.

30 8. A registered nurse, nurse midwife, licensed
31 practical nurse, or advanced registered nurse practitioner

1 licensed or registered under chapter 464 or any facility which
2 employs nurses licensed or registered under chapter 464 to
3 supply all or part of the care delivered under this section.

4 9. A midwife licensed under chapter 467.

5 10. A health maintenance organization certificated
6 under part I of chapter 641.

7 11. A health care professional association and its
8 employees or a corporate medical group and its employees.

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

13 13. A dentist or dental hygienist licensed under
14 chapter 466.

15 14. Any other health care professional, practitioner,
16 provider, or facility under contract with a governmental
17 contractor, including a student enrolled in an accredited
18 program that prepares the student for licensure as any one of
19 the professionals listed in subparagraphs 4. through 9.

20
21 The term includes any nonprofit corporation qualified as
22 exempt from federal income taxation under s. 501(c) of the
23 Internal Revenue Code which delivers health care services
24 provided by licensed professionals listed in this paragraph,
25 any federally funded community health center, and any
26 volunteer corporation or volunteer health care provider that
27 delivers health care services.

28 (e) "Low-income" means:

29 1. A person who is Medicaid-eligible under Florida
30 law;

31

1 2. A person who is without health insurance and whose
2 family income does not exceed 150 percent of the federal
3 poverty level as defined annually by the federal Office of
4 Management and Budget; or

5 3. Any client of the department who voluntarily
6 chooses to participate in a program offered or approved by the
7 department and meets the program eligibility guidelines of the
8 department.

9 (4) CONTRACT REQUIREMENTS.--A health care provider
10 that executes a contract with a governmental contractor to
11 deliver health care services on or after April 17, 1992, as an
12 agent of the governmental contractor is an agent for purposes
13 of s. 768.28(9), while acting within the scope of duties
14 pursuant to the contract, if the contract complies with the
15 requirements of this section and regardless of whether the
16 individual treated is later found to be ineligible. A health
17 care provider under contract with the state may not be named
18 as a defendant in any action arising out of the medical care
19 or treatment provided on or after April 17, 1992, pursuant to
20 contracts entered into under this section. The contract must
21 provide that:

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

25 (b) The governmental contractor has access to the
26 patient records of any health care provider delivering
27 services pursuant to the contract.

28 (c) Adverse incidents and information on treatment
29 outcomes must be reported by any health care provider to the
30 governmental contractor if such incidents and information
31 pertain to a patient treated pursuant to the contract. The

1 health care provider shall annually submit an adverse incident
2 report that includes all information required by s.
3 395.0197(6)(a), unless the adverse incident involves a result
4 described by s. 395.0197(8), in which case it shall be
5 reported within 15 days after the occurrence of such incident.
6 If an incident involves a professional licensed by the
7 Department of Health or a facility licensed by the Agency for
8 Health Care Administration, the governmental contractor shall
9 submit such incident reports to the appropriate department or
10 agency, which shall review each incident and determine whether
11 it involves conduct by the licensee that is subject to
12 disciplinary action. All patient medical records and any
13 identifying information contained in adverse incident reports
14 and treatment outcomes which are obtained by governmental
15 entities pursuant to this paragraph are confidential and
16 exempt from the provisions of s. 119.07(1) and s. 24(a), Art.
17 I of the State Constitution.

18 (d) Patient selection and initial referral must be
19 made solely by the governmental contractor, and the provider
20 must accept all referred patients. However, the number of
21 patients that must be accepted may be limited by the contract,
22 and patients may not be transferred to the provider based on a
23 violation of the antidumping provisions of the Omnibus Budget
24 Reconciliation Act of 1989, the Omnibus Budget Reconciliation
25 Act of 1990, or chapter 395.

26 (e) If emergency care is required, the patient need
27 not be referred before receiving treatment, but must be
28 referred within 48 hours after treatment is commenced or
29 within 48 hours after the patient has the mental capacity to
30 consent to treatment, whichever occurs later.

31

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

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

5
6 A governmental contractor that is also a health care provider
7 is not required to enter into a contract under this section
8 with respect to the health care services delivered by its
9 employees.

10 (5) NOTICE OF AGENCY RELATIONSHIP.--The governmental
11 contractor must provide written notice to each patient, or the
12 patient's legal representative, receipt of which must be
13 acknowledged in writing, that the provider is an agent of the
14 governmental contractor and that the exclusive remedy for
15 injury or damage suffered as the result of any act or omission
16 of the provider or of any employee or agent thereof acting
17 within the scope of duties pursuant to the contract is by
18 commencement of an action pursuant to the provisions of s.
19 768.28. With respect to any federally funded community health
20 center, the notice requirements may be met by posting in a
21 place conspicuous to all persons a notice that the federally
22 funded community health center is an agent of the governmental
23 contractor and that the exclusive remedy for injury or damage
24 suffered as the result of any act or omission of the provider
25 or of any employee or agent thereof acting within the scope of
26 duties pursuant to the contract is by commencement of an
27 action pursuant to the provisions of s. 768.28.

28 (6) QUALITY ASSURANCE PROGRAM REQUIRED.--The
29 governmental contractor shall establish a quality assurance
30 program to monitor services delivered under any contract
31

1 between an agency and a health care provider pursuant to this
2 section.

3 (7) RISK MANAGEMENT REPORT.--The Division of Risk
4 Management of the Department of Insurance shall annually
5 compile a report of all claims statistics for all entities
6 participating in the risk management program administered by
7 the division, which shall include the number and total of all
8 claims pending and paid, and defense and handling costs
9 associated with all claims brought against contract providers
10 under this section. This report shall be forwarded to the
11 department and included in the annual report submitted to the
12 Legislature pursuant to this section.

13 (8) REPORT TO THE LEGISLATURE.--Annually, the
14 department shall report to the President of the Senate, the
15 Speaker of the House of Representatives, and the minority
16 leaders and relevant substantive committee chairpersons of
17 both houses, summarizing the efficacy of access and treatment
18 outcomes with respect to providing health care services for
19 low-income persons pursuant to this section.

20 (9) MALPRACTICE LITIGATION COSTS.--Governmental
21 contractors other than the department are responsible for
22 their own costs and attorney's fees for malpractice litigation
23 arising out of health care services delivered pursuant to this
24 section.

25 (10) RULES.--The department shall adopt rules ~~designed~~
26 to administer ~~implement~~ this section in a manner consistent
27 with its purpose to provide and facilitate access to
28 appropriate, safe, and cost-effective health care services and
29 to maintain health care quality. The rules may include
30 services to be provided and authorized procedures.

31

1 (11) APPLICABILITY.--This section applies to incidents
2 occurring on or after April 17, 1992. This section does not
3 apply to any health care contract entered into by the
4 Department of Corrections which is subject to s.
5 768.28(10)(a). Nothing in this section in any way reduces or
6 limits the rights of the state or any of its agencies or
7 subdivisions to any benefit currently provided under s.
8 768.28.

9 Section 50. This act shall take effect upon becoming a
10 law.

11
12 STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN
13 COMMITTEE SUBSTITUTE FOR
14 Senate Bill 2628

15 The bill removes provisions granting rulemaking authority to
16 the Department of Health for establishing requirements for
17 emergency medical services medical directors, including
18 responsibilities, qualifications, and authorization to
19 determine medications, equipment, and staffing, requirements
20 for developing protocols, and participation requirements for
21 quality assurance programs; and requirements relating to
22 certificates of public convenience and necessity for emergency
23 medical services providers. The bill revises rulemaking
24 authority extended to the department for determining whether a
25 convicted felon is eligible for certification or
26 recertification as an emergency medical technician or
27 paramedic.