

By Senator Myers

27-1328-00

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, procedures for managing  
30 specific diseases, requirements for followup reports of known  
31 or suspected exposure to disease, and procedures for providing

1 access to confidential information necessary for disease  
2 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, fire  
23 protection, safety, minimum living space per occupant,  
24 bedding, food equipment, food storage and preparation, insect  
25 and rodent control, garbage, heating equipment, water supply,  
26 maintenance and operation of the camp, housing, or roads, and  
27 such other matters as the department finds to be appropriate  
28 or necessary to protect the life and health of the occupants.  
29 Housing operated by a public housing authority is exempt from  
30 the provisions of any administrative rule that conflicts with  
31

1 or is more stringent than the federal standards applicable to  
2 the housing.

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

5 381.0098 Biomedical waste.--

6 (3) OPERATING STANDARDS.--The department shall adopt  
7 rules necessary to protect the health, safety, and welfare of  
8 the public and to carry out the purpose of this section. Such  
9 rules shall address, but need not be limited to, definitions  
10 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 (m) Requirements for obtaining a certificate of public  
13 convenience and necessity.
- 14 (2) The rules must establish application requirements  
15 for licensure and certification. Pursuant thereto, the  
16 department must develop application forms for basic life  
17 support services and advanced life support services. An  
18 application for each respective service license must include,  
19 but is not limited to:
- 20 (a) The name and business address of the operator and  
21 owner of the service or proposed service.
- 22 (b) The name under which the applicant will operate.
- 23 (c) A list of the names and addresses of all officers,  
24 directors, and shareholders of the applicant.
- 25 (d) A description of each vehicle to be used,  
26 including the make, model, year of manufacture, mileage, and  
27 vehicle identification number (VIN); the state or federal  
28 aviation or marine registration number, when applicable; and  
29 the color scheme, insignia, name, monogram, or other  
30 distinguishing characteristics to be used to designate the  
31 applicant's vehicle or vehicles.

1           (e) The service location from which the service will  
2 operate.

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

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

10          (h) Such other information as the department  
11 determines reasonable and necessary.

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

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

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

1           (5) The rules must establish requirements for medical  
2 directors, including responsibilities, qualifications, and  
3 authorization to determine medications, equipment, and  
4 staffing; requirements for developing protocols; and  
5 participation requirements for operating quality assurance  
6 programs.

7           (6) The rules must establish requirements for  
8 licensees and certificateholders with respect to providing  
9 address information to the department; requirements for  
10 examinations, grading, and passing scores for certification;  
11 and requirements for determining whether a convicted felon is  
12 eligible for certification or recertification.

13           Section 28. Paragraph (f) of subsection (1) of section  
14 403.862, Florida Statutes, is amended to read:

15           403.862 Department of Health; public water supply  
16 duties and responsibilities; coordinated budget requests with  
17 department.--

18           (1) Recognizing that supervision and control of county  
19 health departments of the Department of Health is retained by  
20 the secretary of that agency, and that public health aspects  
21 of the state public water supply program require joint  
22 participation in the program by the Department of Health and  
23 its units and the department, the Department of Health shall:

24           (f) Have general supervision and control over all  
25 private water systems and all public water systems not  
26 otherwise covered or included in this part. This shall include  
27 the authority to adopt and enforce rules, including  
28 definitions of terms, to protect the health, safety, or  
29 welfare of persons being served by all private water systems  
30 and all public water systems not otherwise covered by this  
31 part.

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

3           404.056 Environmental radiation standards and  
4 programs; radon protection.--

5           (3) CERTIFICATION.--

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

25           (b) A person may not participate in performing radon  
26 gas or radon progeny measurements, including sample  
27 collection, analysis, or interpretation of such measurements,  
28 or perform mitigation of buildings for radon gas or radon  
29 progeny, and charge a fee or obtain other remuneration as  
30 benefit for such services or devices, unless that person is  
31 certified by the department. A certification issued in



1 accordance with this section automatically expires at the end  
2 of the certification period stated on the certificate. An  
3 uncertified commercial business may subcontract radon  
4 measurements to a certified radon business. The uncertified  
5 commercial business must provide the complete radon report  
6 from the certified radon business to the client and direct all  
7 the client's questions about the measurements or radon report  
8 to the certified radon business.

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

31

1           (d) Authorized representatives of the department may  
2 ~~have the authority to~~ inspect the business and records of any  
3 person certified under the provisions of this subsection, at  
4 all reasonable times, to examine records and test procedures  
5 to determine compliance with or violation of the provisions of  
6 this section.

7           (e) Any person who practices fraud, deception, or  
8 misrepresentation in performing radon gas or radon progeny  
9 measurements or in performing mitigation of buildings for  
10 radon gas or radon progeny is subject to the penalties  
11 provided in s. 404.161.

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

29           (g) The department may establish enforcement  
30 procedures; deny an application for initial or renewal  
31 certification; deny, suspend, or revoke a certification; or

1 impose an administrative fine not to exceed \$1,000 per  
2 violation per day, for the violation of any provision of this  
3 section or rule adopted under this section ~~promulgated~~  
4 ~~pursuant thereto~~.

5 (h) A certificateholder in good standing remains in  
6 good standing when he or she becomes a member of the Armed  
7 Forces of the United States on active duty without payment of  
8 renewal fees as long as he or she is a member of the Armed  
9 Forces on active duty and for a period of 6 months after his  
10 or her discharge from active duty, if he or she is not engaged  
11 in practicing radon measurement or radon mitigation in the  
12 private sector for profit. The certificateholder must pay a  
13 renewal fee to renew the certificate.

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

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

29 1. Requirements for measurement devices and  
30 measurement procedures, including the disclosure of mitigation  
31 materials, systems, and other mitigation services offered.

- 1           2. The identification of certified specialists and  
2 technicians employed by the business and requirements for  
3 specialist staffing and duties.
- 4           3. The analysis of measurement devices by proficient  
5 analytical service providers.
- 6           4. Requirements for a quality assurance and quality  
7 control program.
- 8           5. The disclosure of client measurement reporting  
9 forms and warranties and operating instructions for mitigation  
10 systems.
- 11          6. Requirements for radon services publications and  
12 the identification of the radon business certification number  
13 in advertisements.
- 14          7. Requirements for a worker health and safety  
15 program.
- 16          8. Requirements for maintaining radon records.
- 17          9. The operation of branch office locations.
- 18          10. Requirements for supervising subcontractors who  
19 install mitigation systems.
- 20          11. Requirements for building inspections and  
21 evaluation and standards for the design and installation of  
22 mitigation systems.
- 23          12. Prescribing conditions of premitigation and  
24 postmitigation ~~mitigation~~ measurements.
- 25          13. Requirements for renewals received after  
26 expiration of the automatic certification date.
- 27          14. Requirements for obtaining a duplicate or  
28 replacement certificate, including a fee.
- 29          15. Requirements for reporting, including timeframes  
30 and content.
- 31

1 (k) Any change in the information provided to the  
2 department in the original business application to be reported  
3 within 10 days after the change.

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

6 404.22 Radiation machines and components;  
7 inspection.--

8 (1) The department and its duly authorized agents may  
9 inspect in a lawful manner at all reasonable hours any  
10 hospital or other health care facility or other place in the  
11 state in which a radiation machine is installed for the  
12 purpose of determining whether the facility, the radiation  
13 machine and its components, the film and film processing  
14 equipment, the techniques and procedures, any mechanical  
15 holding devices, the warning labels and signs, the written  
16 safety procedures, and the resultant image produced meet the  
17 standards of the department as set forth in this chapter and  
18 rules adopted pursuant to this chapter ~~thereto~~. Such rules may  
19 include standards for radiation machine performance, surveys,  
20 calibrations, and spot checks; requirements for quality  
21 assurance programs and quality control programs; standards for  
22 facility electrical systems, safety alarms,  
23 radiation-monitoring equipment, and dosimetry systems;  
24 requirements for visual and aural communication with patients;  
25 procedures for establishing radiation-safety committees for a  
26 facility; and qualifications of persons who cause a radiation  
27 machine to be used, who operate a radiation machine, and who  
28 ensure that a radiation machine complies with the requirements  
29 of this chapter and with rules of the department. If, in the  
30 opinion of the department, a radiation machine ~~that~~ which  
31 fails to meet such standards can be made to meet the standards

1 through an adjustment or limitation upon the stations or range  
2 of the radiation machine or through the purchase of a  
3 component meeting the standards, the department shall order  
4 the owner of the radiation machine to make the necessary  
5 adjustment or to purchase the necessary component within 90  
6 days after ~~of~~ the date or receipt of the order. However, if  
7 the radiation machine cannot be made to meet the standards,  
8 the department shall order the owner to cease the use  
9 ~~utilization~~ of the radiation machine.

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

12 489.553 Administration of part; registration  
13 qualifications; examination.--

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

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

24 491.006 Licensure or certification by endorsement.--

25 (1) The department shall license or grant a  
26 certificate to a person in a profession regulated by this  
27 chapter who, upon applying to the department and remitting the  
28 appropriate nonrefundable fee, demonstrates to the board that  
29 he or she:

30 (a) Has demonstrated, in a manner designated by rule  
31 of the board, knowledge of the laws and rules governing the

1 practice of clinical social work, marriage and family therapy,  
2 and mental health counseling.

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

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

9 3. Has passed a substantially equivalent licensing  
10 examination in another state or has passed the licensure  
11 examination in this state in the profession for which the  
12 applicant seeks licensure.

13 4. Holds a license in good standing, is not under  
14 investigation for an act that ~~which~~ would constitute a  
15 violation of this chapter, and has not been found to have  
16 committed any act that ~~which~~ would constitute a violation of  
17 this chapter.

18 Section 33. Subsections (1) and (5) of section  
19 491.0145, Florida Statutes, are amended to read:

20 491.0145 Certified master social worker.--The  
21 department may certify an applicant for a designation as a  
22 certified master social worker upon the following conditions:

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

29 (5) The applicant has passed an examination required  
30 by the department for this purpose. The nonrefundable fee for  
31

1 such examination may ~~shall~~ not exceed \$250 as set by  
2 department rule.

3 Section 34. Present subsections (11) through (29) of  
4 section 499.003, Florida Statutes, are redesignated as  
5 subsections (12) through (30), respectively, and a new  
6 subsection (11) is added to that section, to read:

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

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

15 499.005 Prohibited acts.--It is unlawful to perform or  
16 cause the performance of any of the following acts in this  
17 state:

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

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

23 Section 36. Subsection (8) is added to section  
24 499.0054, Florida Statutes, to read:

25 499.0054 Advertising and labeling of drugs, devices,  
26 and cosmetics.--It is a violation of the Florida Drug and  
27 Cosmetic Act to perform or cause the performance of any of the  
28 following acts:

29 (8) The representation or suggestion in labeling or  
30 advertising that an article is approved under ss.  
31 499.001-499.081, when such is not the case.



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

4           499.01 Permits; applications; renewal; general  
5 requirements.--

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

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

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

31

1 e. Any other relevant information that the department  
2 requires.

3 (b) Upon approval of the application by the department  
4 and payment of the required fee, the department shall issue a  
5 permit to the applicant, if the applicant meets the  
6 requirements of ss. 499.001-499.081 and rules adopted under  
7 those sections.

8 (c) Any change in information required under paragraph  
9 (a) must be submitted to the department before the change  
10 occurs.

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

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

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

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

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

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

30 6. Suspension or revocation by a federal, state, or  
31 local government of any permit currently or previously held by

1 the applicant for the manufacture or distribution of any  
2 drugs, devices, or cosmetics;

3 7. Compliance with permitting requirements under any  
4 previously granted permits;

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

9 9. Any other factors or qualifications the department  
10 considers relevant to and consistent with the public health  
11 and safety.

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

19 (d) If an establishment permitted under ss.  
20 499.001-499.081 closes, the owner must notify the department  
21 in writing before the effective date of closure and must:

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

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

1           499.0121 Storage and handling of prescription  
2 drugs.--The department shall adopt rules to implement this  
3 section as necessary to protect the public health, safety, and  
4 welfare. Such rules shall include, but not be limited to,  
5 requirements for the storage and handling of prescription  
6 drugs and for the establishment and maintenance of  
7 prescription drug distribution records.

8           (2) SECURITY.--

9           (c) Any vehicle that contains prescription drugs must  
10 be secure from unauthorized access to the prescription drugs  
11 in the vehicle.

12           Section 39. Paragraph (b) of subsection (2) of section  
13 499.0122, Florida Statutes, is amended to read:

14           499.0122 Medical oxygen and veterinary legend drug  
15 retail establishments; definitions, permits, general  
16 requirements.--

17           (2)

18           (b) The department shall adopt rules relating to  
19 information required from each retail establishment pursuant  
20 to s. 499.01(2), including requirements for prescriptions or  
21 orders.

22           Section 40. Paragraph (d) of subsection (2) of section  
23 499.013, Florida Statutes, is amended, and subsection (4) is  
24 added to that section, to read:

25           499.013 Manufacturers of drugs, devices, and  
26 cosmetics; definitions, permits, and general requirements.--

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

31

1 (d) A device manufacturer's permit is required for any  
2 person that engages in the manufacture or assembly of medical  
3 devices for human use in this state, except that a permit is  
4 not required if the person is engaged only in manufacturing or  
5 assembling a medical device pursuant to a practitioner's order  
6 for a specific patient.

7 1. A manufacturer of medical devices in this state  
8 must comply with all appropriate state and federal good  
9 manufacturing practices.

10 2. The department shall adopt rules related to  
11 storage, handling, and recordkeeping requirements for  
12 manufacturers of medical devices for human use.

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

20 Section 41. Subsections (1) and (3) of section  
21 499.015, Florida Statutes, are amended to read:

22 499.015 Registration of drugs, devices, and cosmetics;  
23 issuance of certificates of free sale.--

24 (1)(a) Except for those persons exempted from the  
25 definition in s. 499.003(22)~~s. 499.003(21)~~, any person who  
26 manufactures, packages, repackages, labels, or relabels a  
27 drug, device, or cosmetic in this state must register such  
28 drug, device, or cosmetic biennially with the department; pay  
29 a fee in accordance with the fee schedule provided by s.  
30 499.041; and comply with this section. The registrant must  
31

1 list each separate and distinct drug, device, or cosmetic at  
2 the time of registration.

3 (b) The department may not register any product that  
4 does not comply with the Federal Food, Drug, and Cosmetic Act,  
5 as amended, or Title 21 C.F.R., or that is not an approved  
6 investigational drug as provided for in s. 499.018.

7 Registration of a product by the department does not mean that  
8 the product does in fact comply with all provisions of the  
9 Federal Food, Drug, and Cosmetic Act, as amended.

10 (3) Except for those persons exempted from the  
11 definition in s. 499.003(22)~~s. 499.003(21)~~, a person may not  
12 sell any product that he or she has failed to register in  
13 conformity with this section. Such failure to register  
14 subjects such drug, device, or cosmetic product to seizure and  
15 condemnation as provided in ss. 499.062-499.064, and subjects  
16 such person to the penalties and remedies provided in ss.  
17 499.001-499.081.

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

20 499.024 Drug product classification.--The secretary  
21 shall adopt rules to classify drug products intended for use  
22 by humans which the United States Food and Drug Administration  
23 has not classified in the federal act or the Code of Federal  
24 Regulations.

25 (4) Any product that falls under the drug definition,  
26 s. 499.003(12)~~s. 499.003(11)~~, may be classified under the  
27 authority of this section. This section does not subject  
28 portable emergency oxygen inhalators to classification;  
29 however, this section does not exempt any person from ss.  
30 499.01 and 499.015.

31

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

3           499.03 Possession of new drugs or legend drugs without  
4 prescriptions unlawful; exemptions and exceptions.--

5           (1) A person may not possess, or possess with intent  
6 to sell, dispense, or deliver, any habit-forming, toxic,  
7 harmful, or new drug subject to s. 499.003(23)~~s. 499.003(22)~~,  
8 or legend drug as defined in s. 499.003, unless the possession  
9 of the drug has been obtained by a valid prescription of a  
10 practitioner licensed by law to prescribe the drug. However,  
11 this section does not apply to the delivery of such drugs to  
12 persons included in any of the classes named in this  
13 subsection, or to the agents or employees of such persons, for  
14 use in the usual course of their businesses or practices or in  
15 the performance of their official duties, as the case may be;  
16 nor does this section apply to the possession of such drugs by  
17 those persons or their agents or employees for such use:

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

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

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

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

30           (e) An officer or employee of a federal, state, or  
31 local government; or

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

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

6 499.05 Rules.--

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

9 (a) The definition of terms used in ss.  
10 499.001-499.081, and used in the rules adopted under ss.  
11 499.001-499.081, when the use of the term is not its usual and  
12 ordinary meaning.

13 (b) Labeling requirements for drugs, devices, and  
14 cosmetics.

15 (c) Application requirements, protocols, reporting  
16 requirements, and requirements for submitting other  
17 information to the department and the Florida Drug Technical  
18 Review Panel, as required under the investigational drug  
19 program.

20 (d) The establishment of fees authorized in ss.  
21 499.001-499.081.

22 (e) The identification of permits that require an  
23 initial application and onsite inspection or other  
24 prerequisites for permitting which demonstrate that the  
25 establishment and person are in compliance with the  
26 requirements of ss. 499.001-499.081.

27 (f) The application processes and forms for product  
28 registration.

29 (g) Procedures for requesting and issuing certificates  
30 of free sale.

31



1           (h) Inspections and investigations conducted under s.  
2 499.051, and the identification of information claimed to be a  
3 trade secret and exempt from the public records law as  
4 provided in s. 499.051(5).

5           (i) The establishment of a range of penalties, as  
6 provided in s. 499.006; requirements for notifying persons of  
7 the potential impact of a violation of ss. 499.001-499.081;  
8 and a process for the uncontested settlement of alleged  
9 violations.

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

12           Section 45. Section 499.701, Florida Statutes, is  
13 amended to read:

14           499.701 Adoption of rules by the department.--

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

25           (2) The department may adopt rules regarding  
26 recordkeeping and security for methyl ethyl ketone (MEK) or  
27 butyl acetate as needed. These products and records are open  
28 to inspection in the same manner as are ether products and  
29 records.

30           Section 46. Paragraph (d) of subsection (2) of section  
31 501.122, Florida Statutes, is amended to read:

1           501.122 Control of nonionizing radiations; laser;  
2 penalties.--

3           (2) AUTHORITY TO ISSUE REGULATIONS.--Except for  
4 electrical transmission and distribution lines and substation  
5 facilities subject to regulation by the Department of  
6 Environmental Protection pursuant to chapter 403, the  
7 Department of Health shall adopt rules as necessary to protect  
8 the health and safety of persons exposed to laser devices and  
9 other nonionizing radiation, including the user or any others  
10 who might come in contact with such radiation. The Department  
11 of Health may:

12           (d) Establish and prescribe performance standards for  
13 lasers and other radiation control, including requirements for  
14 radiation surveys and measurements and the methods and  
15 instruments used to perform surveys;the qualifications,  
16 duties, and training of users; the posting of warning signs  
17 and labels for facilities and devices; recordkeeping; and  
18 reports to the department, if it determines that such  
19 standards are necessary for the protection of the public  
20 health.

21           Section 47. Section 513.05, Florida Statutes, is  
22 amended to read:

23           513.05 Rules.--The department may adopt rules  
24 pertaining to the location, construction, modification,  
25 equipment, and operation of mobile home parks, lodging parks,  
26 recreational vehicle parks, and recreational camps, except as  
27 provided in s. 633.022, as necessary to administer ~~implement~~  
28 this chapter. Such rules may include definitions of terms;  
29 requirements for plan reviews of proposed and existing parks  
30 and camps; plan reviews of parks that consolidate space or  
31 change space size; water supply; sewage collection and

1 disposal; plumbing and backflow prevention; garbage and refuse  
2 storage, collection, and disposal; insect and rodent control;  
3 space requirements; heating facilities; food service;  
4 lighting; sanitary facilities; bedding; an occupancy  
5 equivalency to spaces for permits for recreational camps;  
6 sanitary facilities in recreational vehicle parks; and the  
7 owners' responsibilities at recreational vehicle parks and  
8 recreational camps.

9           Section 48. Section 514.021, Florida Statutes, is  
10 amended to read:

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

24           Section 49. Section 766.1115, Florida Statutes, is  
25 amended to read:

26           766.1115 Health care providers; creation of agency  
27 relationship with governmental contractors.--

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

30           (2) FINDINGS AND INTENT.--The Legislature finds that a  
31 significant proportion of the residents of this state who are

1 uninsured or Medicaid recipients are unable to access needed  
2 health care because health care providers fear the increased  
3 risk of medical malpractice liability. It is the intent of  
4 the Legislature that access to medical care for indigent  
5 residents be improved by providing governmental protection to  
6 health care providers who offer free quality medical services  
7 to underserved populations of the state. Therefore, it is the  
8 intent of the Legislature to ensure that health care  
9 professionals who contract to provide such services as agents  
10 of the state are provided sovereign immunity.

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

12 (a) "Contract" means an agreement executed in  
13 compliance with this section between a health care provider  
14 and a governmental contractor. This contract shall allow the  
15 health care provider to deliver health care services to  
16 low-income recipients as an agent of the governmental  
17 contractor. The contract must be for volunteer, uncompensated  
18 services.

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

20 (c) "Governmental contractor" means the department,  
21 county health departments, a special taxing district with  
22 health care responsibilities, or a hospital owned and operated  
23 by a governmental entity.

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

25 1. A birth center licensed under chapter 383.

26 2. An ambulatory surgical center licensed under  
27 chapter 395.

28 3. A hospital licensed under chapter 395.

29 4. A physician or physician assistant licensed under  
30 chapter 458.

31

1           5. An osteopathic physician or osteopathic physician  
2 assistant licensed under chapter 459.

3           6. A chiropractic physician licensed under chapter  
4 460.

5           7. A podiatric physician licensed under chapter 461.

6           8. A registered nurse, nurse midwife, licensed  
7 practical nurse, or advanced registered nurse practitioner  
8 licensed or registered under chapter 464 or any facility which  
9 employs nurses licensed or registered under chapter 464 to  
10 supply all or part of the care delivered under this section.

11          9. A midwife licensed under chapter 467.

12          10. A health maintenance organization certificated  
13 under part I of chapter 641.

14          11. A health care professional association and its  
15 employees or a corporate medical group and its employees.

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

20          13. A dentist or dental hygienist licensed under  
21 chapter 466.

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

27  
28 The term includes any nonprofit corporation qualified as  
29 exempt from federal income taxation under s. 501(c) of the  
30 Internal Revenue Code which delivers health care services  
31 provided by licensed professionals listed in this paragraph,

1 any federally funded community health center, and any  
2 volunteer corporation or volunteer health care provider that  
3 delivers health care services.

4 (e) "Low-income" means:

5 1. A person who is Medicaid-eligible under Florida  
6 law;

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

11 3. Any client of the department who voluntarily  
12 chooses to participate in a program offered or approved by the  
13 department and meets the program eligibility guidelines of the  
14 department.

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

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

31

1           (b) The governmental contractor has access to the  
2 patient records of any health care provider delivering  
3 services pursuant to the contract.

4           (c) Adverse incidents and information on treatment  
5 outcomes must be reported by any health care provider to the  
6 governmental contractor if such incidents and information  
7 pertain to a patient treated pursuant to the contract. The  
8 health care provider shall annually submit an adverse incident  
9 report that includes all information required by s.

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

25           (d) Patient selection and initial referral must be  
26 made solely by the governmental contractor, and the provider  
27 must accept all referred patients. However, the number of  
28 patients that must be accepted may be limited by the contract,  
29 and patients may not be transferred to the provider based on a  
30 violation of the antidumping provisions of the Omnibus Budget  
31

1 Reconciliation Act of 1989, the Omnibus Budget Reconciliation  
2 Act of 1990, or chapter 395.

3 (e) If emergency care is required, the patient need  
4 not be referred before receiving treatment, but must be  
5 referred within 48 hours after treatment is commenced or  
6 within 48 hours after the patient has the mental capacity to  
7 consent to treatment, whichever occurs later.

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

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

12

13 A governmental contractor that is also a health care provider  
14 is not required to enter into a contract under this section  
15 with respect to the health care services delivered by its  
16 employees.

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



1 or of any employee or agent thereof acting within the scope of  
2 duties pursuant to the contract is by commencement of an  
3 action pursuant to the provisions of s. 768.28.

4 (6) QUALITY ASSURANCE PROGRAM REQUIRED.--The  
5 governmental contractor shall establish a quality assurance  
6 program to monitor services delivered under any contract  
7 between an agency and a health care provider pursuant to this  
8 section.

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

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

26 (9) MALPRACTICE LITIGATION COSTS.--Governmental  
27 contractors other than the department are responsible for  
28 their own costs and attorney's fees for malpractice litigation  
29 arising out of health care services delivered pursuant to this  
30 section.

31

