# CHAPTER 2000-242

## Committee Substitute for Senate Bill No. 2628

An act relating to rulemaking authority of the Department of Health (RAB); amending s. 154.011, F.S., relating to primary care services; requiring the department to adopt certain rules developed by the State Health Officer; amending s. 154.06, F.S.; requiring the adoption of rules with respect to fees for services rendered through county health departments; amending s. 381.003, F.S., relating to prevention and control of communicable diseases and acquired immune deficiency syndrome; authorizing rules governing procedures for managing diseases; amending s. 381.004, F.S., relating to testing for human immunodeficiency virus; providing additional rulemaking authority; amending s. 381.0051, F.S., relating to family planning services; providing for rules administering the provision of such services; amending s. 381.0056, F.S., relating to the school health services program; authorizing the department to adopt rules in cooperation with the Department of Education; amending s. 381.0057, F.S.; providing requirements for the services provided by school health programs; amending s. 381.006, F.S., relating to public health; providing additional rulemaking authority; amending s. 381.0062, F.S., relating to the regulation of water systems; providing additional requirements for obtaining an exemption from the department; amending s. 381.0065, F.S.; redefining the term "onsite sewage treatment and disposal system"; providing additional rulemaking authority; revising requirements for sewage treatment and disposal systems; amending s. 381.0072, F.S.; requiring the department to adopt additional rules with respect to food service protection; amending s. 381.0086, F.S.; requiring the department to adopt additional rules with respect to the health and safety of migrant farm workers; amending s. 381.0098, F.S.; prohibiting the transfer of a permit for a biomedical waste facility or a biomedical waste transporter; providing requirements for a permit application; amending s. 381.0101, F.S., relating to environmental health professionals; providing additional rulemaking authority with respect to standards for certification; amending s. 381.0203, F.S.; authorizing the department to adopt rules governing pharmacy services; amending s. 381.89, F.S.; authorizing the department to issue a stop-use order against a tanning facility; amending s. 383.011, F.S., relating to maternal and child health programs; providing additional rulemaking authority; amending s. 383.14, F.S.; providing for rules governing screening for metabolic disorders, hereditary disorders, and environmental risk factors; amending s. 383.19, F.S.; providing for rules governing perinatal intensive care centers; amending s. 383.216, F.S.; revising requirements for prenatal and infant health care coalitions; providing additional rulemaking authority; amending s. 384.33, F.S.; authorizing rules governing screenings and investigations to control the spread of sexually transmitted diseases; amending s. 385.207, F.S., relating to care and assistance of persons with epilepsy; providing additional rulemaking authority; amending s. 391.026, F.S., relating to the Children's Medical Services Act;

requiring the department to adopt rules to administer the act; amending s. 392.66, F.S.; requiring the department to adopt rules to administer the Tuberculosis Control Act; amending ss. 395.401, 395.402, F.S.; requiring the department to adopt rules governing the procedures for establishing a trauma agency and for performance evaluations; requiring the department to establish the number of trauma centers within each service area; amending s. 401.35, F.S.; requiring the department to adopt rules governing medical transportation services; amending s. 403.862, F.S.; authorizing the department to adopt rules governing water systems; amending s. 404.056, F.S., relating to environmental radiation standards and programs; providing additional rulemaking authority; amending s. 404.22, F.S.; authorizing the department to adopt rules governing the operation of radiation machines and components; amending s. 489.553, F.S., relating to septic tank contracting; providing additional rulemaking authority; amending ss. 491.006, 491.0145, F.S., relating to clinical, counseling, and psychotherapy services; providing for nonrefundable application fees; amending s. 499.003, F.S.; defining the terms "distribute or distribution" for purposes of ch. 499, F.S., relating to the Florida Drug and Cosmetic Act; amending s. 499.005, F.S.; prohibiting charging certain fees or dispensing certain drugs; amending s. 499.0054, F.S.; prohibiting certain labels or advertisements; amending s. 499.01, F.S.; providing additional requirements for closing an establishment permitted under the Florida Drug and Cosmetic Act; amending s. 499.0121, F.S.; providing additional requirements for a vehicle that contains prescription drugs; amending s. 499.0122, F.S., relating to medical oxygen and veterinary legend drugs; providing additional rulemaking authority; amending s. 499.013, F.S., relating to manufacturers of drugs, devices, and cosmetics; exempting manufacturers of a device for a specific patient from certain requirements; requiring that manufacturers maintain certain records; amending ss. 499.015, 499.024, 499.03, F.S.; providing certain limitations on the registration of products or drugs; conforming cross-references to changes made by the act; amending s. 499.05, F.S.; requiring the department to adopt additional rules to administer the Florida Drug and Cosmetic Act; amending s. 499.701, F.S., relating to the regulation of ether; providing additional rulemaking authority; amending s. 501.122, F.S.; requiring the department to adopt rules governing radiation surveys; amending s. 513.05, F.S., relating to mobile home and recreational vehicle parks; providing additional rulemaking authority; amending s. 514.021, F.S.; authorizing the department to adopt rules governing public swimming and bathing facilities; amending s. 766.1115, F.S., relating to the Access to Health Care Act; providing for rules governing services and procedures; providing an effective date.

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

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

154.011 Primary care services.—

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

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

154.06 Fees and services rendered; authority.—

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

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

381.003 Communicable disease and acquired immune deficiency syndrome prevention and control.—

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

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

381.004 Testing for human immunodeficiency virus.—

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

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

381.0051 Family planning.—

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

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

381.0056 School health services program.—

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

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

381.0057 Funding for school health services.—

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

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

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

(16) A group-care-facilities function, where a group-care facility means any public or private school, housing, building or buildings, section of a building, or distinct part of a building or other place, whether operated for profit or not, which undertakes, through its ownership or management, to provide one or more personal services, care, protection, and supervision to persons who require such services and who are not related to the owner or administrator. The department may adopt rules necessary to protect the health and safety of residents, staff, and patrons of group-care facilities, such as child care facilities, family day-care homes, assisted-living facilities, adult day-care centers, adult family-care homes, hospices, residential treatment facilities, crisis-stabilization units, pediatric extended-care centers,

intermediate-care facilities for the developmentally disabled, group-care homes, and, jointly with the Department of Education, private and public schools. These rules may include definitions of terms; provisions relating to operation and maintenance of facilities, buildings, grounds, equipment, furnishings, and occupant-space requirements; lighting; heating, cooling, and ventilation; food service; water supply and, plumbing; sewage; sanitary facilities; insect and rodent control; garbage; safety; personnel health, hygiene, and work practices; and other matters the department finds are appropriate or necessary to protect the safety and health of the residents, staff, or patrons. The department may not adopt rules that conflict with rules adopted by the licensing or certifying agency. The department may enter and inspect at reasonable hours to determine compliance with applicable statutes or rules. In addition to any sanctions that the department may impose for violations of rules adopted under this section, the department shall also report such violations to any agency responsible for licensing or certifying the group-care facility. The licensing or certifying agency may also impose any sanction based solely on the findings of the department.

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

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

381.0062 Supervision; private and certain public water systems.—

(6) VARIANCES AND EXEMPTIONS.—

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

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

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

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

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

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

381.0065 Onsite sewage treatment and disposal systems; regulation.—

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

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

1. For a residential subdivision lot, a single-family residence, or an establishment, any of which has an estimated sewage flow of 1,000 gallons per day or less, a gravity sewer line to maintain gravity flow from the property's drain to the sewer line, or a low pressure or vacuum sewage collection line in those areas approved for low pressure or vacuum sewage collection, exists in a public easement or right-of-way that abuts the property line of the lot, residence, or establishment.

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

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

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

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

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

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

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

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

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

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

(i) "Mean annual flood line" means the elevation determined by calculating the arithmetic mean of the elevations of the highest yearly flood stage or discharge for the period of record, to include at least the most recent 10-year period. If at least 10 years of data is not available, the mean annual flood line shall be as determined based upon the data available and field verification conducted by a certified professional surveyor and mapper with experience in the determination of flood water elevation lines or, at the option of the applicant, by department personnel. Field verification of the mean annual flood line shall be performed using a combination of those indicators listed in subparagraphs 1. through 7. that are present on the site, and that reflect flooding that recurs on an annual basis. In those situations where any one or more of these indicators reflect a rare or aberrant event, such indicator or indicators shall not be utilized in determining the mean annual flood line. The indicators that may be considered are:

1. Water stains on the ground surface, trees, and other fixed objects;

2. Hydric adventitious roots;

3. Drift lines;

4. Rafted debris;

5. Aquatic mosses and liverworts;

6. Moss collars; and

7. Lichen lines.

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

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

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

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

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

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

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

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

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

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

(3) DUTIES AND POWERS OF THE DEPARTMENT OF HEALTH.—The department shall:

(a) Adopt rules to administer ss. 381.0065-381.0067, including definitions that are consistent with the definitions in this section, decreases to setback requirements where no health hazard exists, increases for the lot-flow allowance for performance-based systems, requirements for separation

from water table elevation during the wettest season, requirements for the design and construction of any component part of an onsite sewage treatment and disposal system, application and permit requirements for persons who maintain an onsite sewage treatment and disposal system, requirements for maintenance and service agreements for aerobic treatment units and performance-based treatment systems, and recommended standards, including disclosure requirements, for voluntary system inspections to be performed by individuals who are authorized by law to perform such inspections and who shall inform a person having ownership, control, or use of an onsite sewage treatment and disposal system of the inspection standards and of that person's authority to request an inspection based on all or part of the standards.

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

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

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

(e) Permit the use of a limited number of innovative systems for a specific period of time, when there is compelling evidence that the system will function properly and reliably to meet the requirements of this section and rules adopted under this section.

(f) Issue annual operating permits under this section.

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

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

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

(j) Supervise research on, demonstration of, and training on the performance, environmental impact, and public health impact of onsite sewage treatment and disposal systems within this state. Research fees collected under s. 381.0066(2)(k) must be used to develop and fund hands-on training centers designed to provide practical information about onsite sewage treatment and disposal systems to septic tank contractors, master septic tank contractors, contractors, inspectors, engineers, and the public and must also be used to fund research projects which focus on improvements of onsite sewage treatment and disposal systems, including use of performance-based standards and reduction of environmental impact. Research projects shall be initially approved by the technical advisory panel and shall be applicable to and reflect the soil conditions specific to Florida. Such projects shall be awarded through competitive negotiation, using the procedures provided in s. 287.055, to public or private entities that have experience in onsite sewage treatment and disposal systems in Florida and that are principally located in Florida. Research projects shall not be awarded to firms or entities that employ or are associated with persons who serve on either the technical advisory panel or the research review and advisory committee.

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

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

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

(4) PERMITS; INSTALLATION; AND CONDITIONS.—A person may not construct, repair, modify, abandon, or operate an onsite sewage treatment and disposal system without first obtaining a permit approved by the department. The department may issue permits to carry out this section, but shall not make the issuance of such permits contingent upon prior approval by the Department of Environmental Protection. A construction permit is valid for 18 months from the issuance date and may be extended by the department for one 90-day period under rules adopted by the department. A repair permit is valid for 90 days from the date of issuance. An operating permit must be obtained prior to the use of any aerobic treatment unit or if the establishment generates commercial waste. Buildings or establishments that use an aerobic treatment unit or generate commercial waste

shall be inspected by the department at least annually to assure compliance with the terms of the operating permit. The operating permit is valid for 1 year from the date of issuance and must be renewed annually. If all information pertaining to the siting, location, and installation conditions or repair of an onsite sewage treatment and disposal system remains the same, a construction or repair permit for the onsite sewage treatment and disposal system may be transferred to another person, if the transferee files, within 60 days after the transfer of ownership, an amended application providing all corrected information and proof of ownership of the property. There is no fee associated with the processing of this supplemental information. A person may not contract to construct, modify, alter, repair, service, abandon, or maintain any portion of an onsite sewage treatment and disposal system without being registered under part III of chapter 489. A property owner who personally performs construction, maintenance, or repairs to a system serving his or her own owner-occupied single-family residence is exempt from registration requirements for performing such construction, maintenance, or repairs on that residence, but is subject to all permitting requirements. A municipality or political subdivision of the state may not issue a building or plumbing permit for any building that requires the use of an onsite sewage treatment and disposal system unless the owner or builder has received a construction permit for such system from the department. A building or structure may not be occupied and a municipality, political subdivision, or any state or federal agency may not authorize occupancy until the department approves the final installation of the onsite sewage treatment and disposal system. A municipality or political subdivision of the state may not approve any change in occupancy or tenancy of a building that uses an onsite sewage treatment and disposal system until the department has reviewed the use of the system with the proposed change, approved the change, and amended the operating permit.

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

(b) Subdivisions and lots using a public water system as defined in s. 403.852 may use onsite sewage treatment and disposal systems, provided there are no more than four lots per acre, provided the projected daily ~~domestic~~ sewage flow does not exceed an average of 2,500 gallons per acre per day, and provided that all distance and setback, soil condition, water table elevation, and other related requirements that are generally applicable to the use of onsite sewage treatment and disposal systems are met.

(c) Notwithstanding the provisions of paragraphs (a) and (b), for subdivisions platted of record on or before October 1, 1991, when a developer or

other appropriate entity has previously made or makes provisions, including financial assurances or other commitments, acceptable to the Department of Health, that a central water system will be installed by a regulated public utility based on a density formula, private potable wells may be used with onsite sewage treatment and disposal systems until the agreed-upon densities are reached. The department may consider assurances filed with the Department of Business and Professional Regulation under chapter 498 in determining the adequacy of the financial assurance required by this paragraph. In a subdivision regulated by this paragraph, the average daily ~~domestic~~ sewage flow may not exceed 2,500 gallons per acre per day. This section does not affect the validity of existing prior agreements. After October 1, 1991, the exception provided under this paragraph is not available to a developer or other appropriate entity.

(d) Paragraphs (a) and (b) do not apply to any proposed residential subdivision with more than 50 lots or to any proposed commercial subdivision with more than 5 lots where a publicly owned or investor-owned sewerage system is available. It is the intent of this paragraph not to allow development of additional proposed subdivisions in order to evade the requirements of this paragraph. The department shall report to the Legislature by February 1 of each odd-numbered year concerning the success in meeting this intent.

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

1. Seventy-five feet from a private potable well.

2. Two hundred feet from a public potable well serving a residential or nonresidential establishment having a total sewage flow of greater than 2,000 gallons per day.

3. One hundred feet from a public potable well serving a residential or nonresidential establishment having a total sewage flow of less than or equal to 2,000 gallons per day.

4. Fifty feet from any nonpotable well.

5. Ten feet from any storm sewer pipe, to the maximum extent possible, but in no instance shall the setback be less than 5 feet.

6. Seventy-five feet from the mean high-water line of a tidally influenced surface water body;

7. Seventy-five feet from the normal annual flood line of a permanent nontidal surface water body;

8. Fifteen feet from the design high-water line of retention areas, detention areas, or swales designed to contain standing or flowing water for less than 72 hours after a rainfall or the design high-water level of normally dry drainage ditches or normally dry individual lot stormwater retention areas.

(f) Except as provided under paragraphs (e) and (t), no limitations shall be imposed by rule, relating to the distance between an onsite disposal

system and any area that either permanently or temporarily has visible surface water.

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

1. Any residential lot that was platted and recorded on or after January 1, 1972, or that is part of a residential subdivision that was approved by the appropriate permitting agency on or after January 1, 1972, and that was eligible for an onsite sewage treatment and disposal system construction permit on the date of such platting and recording or approval shall be eligible for an onsite sewage treatment and disposal system construction permit, regardless of when the application for a permit is made. If rules in effect at the time the permit application is filed cannot be met, residential lots platted and recorded or approved on or after January 1, 1972, shall, to the maximum extent possible, comply with the rules in effect at the time the permit application is filed. At a minimum, however, those residential lots platted and recorded or approved on or after January 1, 1972, but before January 1, 1983, shall comply with those rules in effect on January 1, 1983, and those residential lots platted and recorded or approved on or after January 1, 1983, shall comply with those rules in effect at the time of such platting and recording or approval. In determining the maximum extent of compliance with current rules that is possible, the department shall allow structures and appurtenances thereto which were authorized at the time such lots were platted and recorded or approved.

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

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

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

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

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

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

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

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

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

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

b. A representative from the county health departments.

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

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

e. A representative from the Department of Environmental Protection.

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

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

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

(i) A construction permit may not be issued for an onsite sewage treatment and disposal system in any area zoned or used for industrial or manu-

facturing purposes, or its equivalent, where a publicly owned or investor-owned sewage treatment system is available, or where a likelihood exists that the system will receive toxic, hazardous, or industrial waste. An existing onsite sewage treatment and disposal system may be repaired if a publicly owned or investor-owned sewerage system is not available within 500 feet of the building sewer stub-out and if system construction and operation standards can be met. This paragraph does not require publicly owned or investor-owned sewerage treatment systems to accept anything other than domestic wastewater.

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

2. Each person who owns or operates a business or facility in an area zoned or used for industrial or manufacturing purposes, or its equivalent, or who owns or operates a business that has the potential to generate toxic, hazardous, or industrial wastewater or toxic or hazardous chemicals, and uses an onsite sewage treatment and disposal system that is installed on or after July 5, 1989, must obtain an annual system operating permit from the department. A person who owns or operates a business that uses an onsite sewage treatment and disposal system that was installed and approved before July 5, 1989, need not obtain a system operating permit. However, upon change of ownership or tenancy, the new owner or operator must notify the department of the change, and the new owner or operator must obtain an annual system operating permit, regardless of the date that the system was installed or approved.

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

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

1. The performance criteria applicable to engineer-designed systems must be limited to those necessary to ensure that such systems do not adversely affect the public health or significantly degrade the groundwater or surface water. Such performance criteria shall include consideration of

the quality of system effluent, the proposed total sewage flow per acre, wastewater treatment capabilities of the natural or replaced soil, water quality classification of the potential surface-water-receiving body, and the structural and maintenance viability of the system for the treatment of domestic wastewater. However, performance criteria shall address only the performance of a system and not a system's design.

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

3. A person electing to utilize an engineer-designed system shall, upon completion of the system design, submit such design, certified by a registered professional engineer, to the county health department. The county health department may utilize an outside consultant to review the engineer-designed system, with the actual cost of such review to be borne by the applicant. Within 5 working days after receiving an engineer-designed system permit application, the county health department shall request additional information if the application is not complete. Within 15 working days after receiving a complete application for an engineer-designed system, the county health department either shall issue the permit or, if it determines that the system does not comply with the performance criteria, shall notify the applicant of that determination and refer the application to the department for a determination as to whether the system should be approved, disapproved, or approved with modification. The department engineer's determination shall prevail over the action of the county health department. The applicant shall be notified in writing of the department's determination and of the applicant's rights to pursue a variance or seek review under the provisions of chapter 120.

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

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

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

(l) For the Florida Keys, the department shall adopt a special rule for the construction, installation, modification, operation, repair, maintenance, and performance of onsite sewage treatment and disposal systems which considers the unique soil conditions and which considers water table elevations, densities, and setback requirements. On lots where a setback distance of 75

feet from surface waters, saltmarsh, and buttonwood association habitat areas cannot be met, an injection well, approved and permitted by the department, may be used for disposal of effluent from onsite sewage treatment and disposal systems.

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

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

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

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

2. A representative from the septic tank industry.

3. A representative from the home building industry.

4. A representative from an environmental interest group.

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

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

7. A representative from the real estate profession.

8. A representative from the restaurant industry.

9. A consumer.

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

(p) An application for an onsite sewage treatment and disposal system permit shall be completed in full, signed by the owner or the owner's authorized representative, or by a contractor licensed under chapter 489, and shall be accompanied by all required exhibits and fees. No specific documentation of property ownership shall be required as a prerequisite to the review of an application or the issuance of a permit. The issuance of a permit does not constitute determination by the department of property ownership.

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

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

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

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

1. The absorption surface of the drainfield shall not be subject to flooding based on 10-year flood elevations. Provided, however, for lots or parcels created by the subdivision of land in accordance with applicable local government regulations prior to January 17, 1990, if an applicant cannot construct a drainfield system with the absorption surface of the drainfield at an elevation equal to or above 10-year flood elevation, the department shall issue a permit for an onsite sewage treatment and disposal system within the 10-year floodplain of rivers, streams, and other bodies of flowing water if all of the following criteria are met:

a. The lot is at least one-half acre in size;

b. The bottom of the drainfield is at least 36 inches above the 2-year flood elevation; and

c. The applicant installs either: a waterless, incinerating, or organic waste composting toilet and a graywater system and drainfield in accordance with department rules; an aerobic treatment unit and drainfield in accordance with department rules; a system approved by the State Health Office that is capable of reducing effluent nitrate by at least 50 percent; or a system approved by the county health department pursuant to department rule other than a system using alternative drainfield materials. The United States Department of Agriculture Soil Conservation Service soil

maps, State of Florida Water Management District data, and Federal Emergency Management Agency Flood Insurance maps are resources that shall be used to identify flood-prone areas.

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

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

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

(2) DUTIES.—

(a) The department shall adopt rules, including definitions of terms which are consistent with law prescribing minimum sanitation standards and manager certification requirements as prescribed in s. 509.039, and which shall be enforced in food service establishments as defined in this section. The sanitation standards must address the construction, operation, and maintenance of the establishment; lighting, ventilation, laundry rooms, lockers, use and storage of toxic materials and cleaning compounds, and first-aid supplies; plan review; design, construction, installation, location, maintenance, sanitation, and storage of food equipment and utensils; employee training, health, hygiene, and work practices; food supplies, preparation, storage, transportation, and service, including access to the areas where food is stored or prepared; and sanitary facilities and controls, including water supply and sewage disposal; plumbing and toilet facilities; garbage and refuse collection, storage, and disposal; and vermin control. Public and private schools, hospitals licensed under chapter 395, nursing homes licensed under part II of chapter 400, child care facilities as defined in s. 402.301, and residential facilities colocated with a nursing home or hospital if all food is prepared in a central kitchen that complies with nursing or hospital regulations shall be exempt from the rules developed for manager certification. The department shall administer a comprehensive inspection, monitoring, and sampling program to ensure such standards are maintained. With respect to food service establishments permitted or licensed under chapter 500 or chapter 509, the department shall assist the Division of Hotels and Restaurants of the Department of Business and Professional Regulation and the Department of Agriculture and Consumer Services with rulemaking by providing technical information.

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

381.0086 Rules; variances; penalties.—

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

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

381.0098 Biomedical waste.—

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

(4) PERMITS AND FEES.—

(a) All persons who generate, store, or treat biomedical waste shall obtain a permit from the department prior to commencing operation, except that a biomedical waste generator generating less than 25 pounds of biomedical waste in each 30-day period shall be exempt from the registration and fee requirements of this subsection. A biomedical waste generator need not obtain a separate permit if such generator works less than 6 hours in a 7-day period at a location different than the location specified on the permit. The department may issue combined permits for generation, storage, and treatment as appropriate to streamline permitting procedures. Application for such permit shall be made on an application form provided by the department and within the timeframes and in the manner prescribed by department rule.

(b) Once the department determines that the person generating, storing, or treating biomedical waste is capable of constructing a facility or operating

in compliance with this section and the rules adopted under this section, the department shall grant the permit.

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

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

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

~~1. Within 30 days after the sale or legal transfer of a permitted facility, the permittee shall file with the department an application for transfer of a permit on such form as the department shall establish by rule. The form must be completed with the notarized signatures of both the transferring permittee and the proposed permittee.~~

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

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

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

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

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

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

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

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

(5) TRANSPORTERS.—Any person who transports biomedical waste within the state must register with the department prior to engaging in the transport of biomedical waste in accordance with rules adopted ~~promulgated~~ by the department. A registration may not be transferred from one biomedical waste transporter to another. If the ownership or name of a biomedical waste transporter is changed and the owner intends to continue operation of the transporter, the owner must apply to the department on departmental forms within the timeframes and in the manner prescribed by department rule. The department may charge registration fees in the same manner as is provided in paragraphs (4)(e) and (f) ~~(4)(f) and (g)~~. The department may exempt from this requirement any person who, or facility that, transports less than 25 pounds of such waste on any single occasion.

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

381.0101 Environmental health professionals.—

(5) STANDARDS FOR CERTIFICATION.—The department shall adopt rules that establish definitions of terms and minimum standards of education, training, or experience for those persons subject to this section. The rules must ~~shall~~ also address the process for application, examination, issuance, expiration, and renewal of certification and ethical standards of practice for the profession.

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

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

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

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

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

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

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

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

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

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

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

381.0203 Pharmacy services.—

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

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

381.89 Regulation of tanning facilities.—

(12) The department may institute legal action for injunctive or other relief to enforce this section. If a tanning facility or other person violates this section or any rule adopted under this section, the department may issue a stop-use order, as prescribed by rule, to remove a tanning device from service.

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

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

383.011 Administration of maternal and child health programs.—

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

(a) The department may adopt rules that are necessary to administer the maternal and child health care program. The rules may include, but need not be limited to, requirements for client eligibility, program standards, service delivery, system responsibilities of county health departments and system assurance for healthy start coalitions, care coordination, enhanced services, quality assurance, and provider selection. The rules may also include provisions for the identification, screening, and intervention efforts by health care providers prior to and following the birth of a child and responsibilities for the interprogram coordination of prenatal and infant care coalitions.

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

383.14 Screening for metabolic disorders, other hereditary and congenital disorders, and environmental risk factors.—

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

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

383.19 Standards; funding; ineligibility.—

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

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

(b) Equipment.

(c) Facilities.

(d) Staffing and qualifications of personnel.

(e) Transportation services.

(f) Data collection.

(g) Definitions of terms.

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

383.216 Community-based prenatal and infant health care.—

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

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

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

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

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

385.207 Care and assistance of persons with epilepsy; establishment of programs in epilepsy control.—

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

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

391.026 Powers and duties of the department.—The department shall have the following powers, duties, and responsibilities:

(18) To adopt rules pursuant to ss. 120.536(1) and 120.54 to administer ~~implement~~ the Children's Medical Services ~~provisions of this~~ Act. The rules may include requirements for definitions of terms, program organization, and program description; a process for selecting an area medical director; responsibilities of applicants and clients; requirements for service applications, including required medical and financial information; eligibility requirements for initial treatment and for continued eligibility, including financial and custody issues; methodologies for resource development and allocation, including medical and financial considerations; requirements for reimbursement services rendered to a client; billing and payment requirements for providers; requirements for qualification, appointments, verification, and emergency exceptions for health-professional consultants; general and diagnostic-specific standards for diagnostic and treatment facilities; and standards for the method of service delivery, including consultant services, respect-for-privacy considerations, examination requirements, family support plans, and clinic design.

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

392.66 Rules.—The department shall adopt rules pursuant to ss. 120.536(1) and 120.54 to administer ~~implement the provisions of~~ this chap-

ter. The rules must include requirements for tuberculosis treatment and provide consequences if a person who has active tuberculosis fails to comply with treatment requirements.

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

395.401 Trauma services system plans; verification of trauma centers and pediatric trauma referral centers; procedures; renewal.—

(2)(a) The local and regional trauma agencies shall plan, implement, and evaluate trauma services systems, in accordance with this section and ss. 395.4015, 395.404, and 395.4045, which consist of organized patterns of readiness and response services based on public and private agreements and operational procedures. The department shall establish, by rule, processes and procedures for establishing a trauma agency and obtaining its approval from the department.

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

1. The organizational structure of the trauma system.

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

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

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

5. Data collection regarding system operation and patient outcome.

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

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

8. Public information and education about the trauma system.

9. Emergency medical services communication system usage and dispatching.

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

11. Medical control and accountability.

12. Quality control and system evaluation.

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

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

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

(f) A local or regional trauma agency may implement a trauma care system only if the system meets the minimum standards set forth in the rules for implementation established by the department and if the plan has been submitted to, and approved by, the department. At least 60 days before the local or regional trauma agency submits the plan for the trauma care system to the department, the local or regional trauma agency shall hold a public hearing and give adequate notice of the public hearing to all hospitals and other interested parties in the area to be included in the proposed system.

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

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

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

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

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

(l) A county, upon the recommendations of the local or regional trauma agency, may adopt ordinances governing the transport of a patient who is receiving care in the field from prehospital emergency medical personnel when the patient meets specific criteria for trauma, burn, or pediatric centers adopted by the local or regional trauma agency. These ordinances must be consistent with s. 395.4045, ordinances adopted under s. 401.25(6), and the local or regional trauma system plan and, to the furthest possible extent, must ensure that individual patients receive appropriate medical care while protecting the interests of the community at large by making maximum use of available emergency medical care resources.

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

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

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

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

395.402 Trauma service areas; number and location of trauma centers.—

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

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

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

401.35 Rules.—The department shall adopt rules<u>, including definitions of terms,</u> necessary to carry out the purposes of this part.

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

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

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

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

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

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

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

(g) Advanced life support services equipment.

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

(i) Vehicles, equipment, communications, and <u>minimum</u> staffing <u>qualifications</u> for air ambulance services.

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

(k) Optional use of telemetry by licensees.

(l) Licensees' security and storage of controlled substances, medications, and fluids, not inconsistent with the provisions of chapter 499 or chapter 893.

(2) The rules must establish application requirements for licensure and certification. Pursuant thereto, the department must develop application forms for basic life support services and advanced life support services. An application for each respective service license must include, but is not limited to:

(a) The name and business address of the operator and owner of the service or proposed service.

(b) The name under which the applicant will operate.

(c) A list of the names and addresses of all officers, directors, and shareholders of the applicant.

(d) A description of each vehicle to be used, including the make, model, year of manufacture, mileage, and vehicle identification number (VIN); the state or federal aviation or marine registration number, when applicable; and the color scheme, insignia, name, monogram, or other distinguishing characteristics to be used to designate the applicant's vehicle or vehicles.

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

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

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

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

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

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

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

(5) The rules must establish requirements for licensees and certificateholders with respect to providing address information to the department; requirements for examinations, grading, and passing scores for certification; and requirements for determining whether a convicted felon whose civil rights have not been restored is eligible for certification or recertification.

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

403.862 Department of Health; public water supply duties and responsibilities; coordinated budget requests with department.—

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

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

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

404.056 Environmental radiation standards and programs; radon protection.—

(3) CERTIFICATION.—

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

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

(c) The results of measurements of radon gas or radon progeny performed by persons certified under the provisions of this subsection shall be reported to the department and persons contracting for the service. Upon request, the results of measurements of radon gas or radon progeny which are performed to evaluate the effectiveness of a radon mitigation system shall be reported to the certified business that installed the mitigation system. The report must include the radon levels detected; the location, age, and description of the building; the name and certification numbers of the certified radon measurement business and individual who performed the measurements; and other information determined by the department to meet the requirements of the protocols and procedures for the type of measurement performed. Each installation of a radon mitigation system performed by a person certified under this section must be reported to the department according to the schedule set by the department. The report must include

the premitigation and postmitigation radon levels; the type or types of systems installed; the location, age, and description of the building; and the name and certification number of the certified mitigation business that performed the mitigation.

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

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

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

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

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

(i) A certificateholder who is in good standing remains in good standing if he or she is absent from the state because of his or her spouse's active duty with the Armed Forces of the United States. The certificateholder remains in good standing without payment of renewal fees as long as his or her spouse is a member of the Armed Forces on active duty and for a period of 6 months after the spouse's discharge from active duty, if the certificateholder is not engaged in practicing radon measurement or radon mitigation

in the private sector for profit. The certificateholder must pay a renewal fee to renew the certificate.

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

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

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

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

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

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

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

7. Requirements for a worker health and safety program.

8. Requirements for maintaining radon records.

9. The operation of branch office locations.

10. Requirements for supervising subcontractors who install mitigation systems.

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

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

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

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

15. Requirements for reporting, including timeframes and content.

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

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

404.22 Radiation machines and components; inspection.—

(1) The department and its duly authorized agents may inspect in a lawful manner at all reasonable hours any hospital or other health care facility or other place in the state in which a radiation machine is installed for the purpose of determining whether the facility, the radiation machine and its components, the film and film processing equipment, the techniques and procedures, any mechanical holding devices, the warning labels and signs, the written safety procedures, and the resultant image produced meet the standards of the department as set forth in this chapter and rules adopted pursuant to this chapter ~~thereto~~. Such rules may include standards for radiation machine performance, surveys, calibrations, and spot checks; requirements for quality assurance programs and quality control programs; standards for facility electrical systems, safety alarms, radiation-monitoring equipment, and dosimetry systems; requirements for visual and aural communication with patients; procedures for establishing radiation-safety committees for a facility; and qualifications of persons who cause a radiation machine to be used, who operate a radiation machine, and who ensure that a radiation machine complies with the requirements of this chapter and with rules of the department. If, in the opinion of the department, a radiation machine that ~~which~~ fails to meet such standards can be made to meet the standards through an adjustment or limitation upon the stations or range of the radiation machine or through the purchase of a component meeting the standards, the department shall order the owner of the radiation machine to make the necessary adjustment or to purchase the necessary component within 90 days after ~~of~~ the date or receipt of the order. However, if the radiation machine cannot be made to meet the standards, the department shall order the owner to cease the use ~~utilization~~ of the radiation machine.

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

489.553 Administration of part; registration qualifications; examination.—

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

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

491.006 Licensure or certification by endorsement.—

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

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

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

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

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

4. Holds a license in good standing, is not under investigation for an act that ~~which~~ would constitute a violation of this chapter, and has not been found to have committed any act that ~~which~~ would constitute a violation of this chapter. The fees paid by any applicant for certification as a master social worker under this section are nonrefundable.

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

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

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

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

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

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

(11) "Distribute or distribution" means to sell; offer to sell; give away; transfer, whether by passage of title, physical movement, or both; deliver; or offer to deliver. The term does not mean to administer or dispense.

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

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

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

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

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

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

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

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

499.01 Permits; applications; renewal; general requirements.—

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

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

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

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

3. The address, telephone numbers, and the names of contact persons for each facility used by the applicant for the storage, handling, and distribution of prescription drugs;

4. The type of ownership or operation, such as a partnership, corporation, or sole proprietorship; and

5. The names of the owner and the operator of the establishment, including:

a. If an individual, the name of the individual;

b. If a partnership, the name of each partner and the name of the partnership;

c. If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation;

d. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity; and

e. Any other relevant information that the department requires.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. Return the permit to the department;

2. If the permittee is authorized to distribute legend drugs, indicate the disposition of such drugs, including the name, address, and inventory, and provide the name and address of a person to contact regarding access to records that are required to be maintained under ss. 499.001-499.081. Transfer of ownership of legend drugs may be made only to persons authorized to possess legend drugs under ss. 499.001-499.081.

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

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

(2) SECURITY.—

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

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

499.0122 Medical oxygen and veterinary legend drug retail establishments; definitions, permits, general requirements.—

(2)

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

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

499.013 Manufacturers of drugs, devices, and cosmetics; definitions, permits, and general requirements.—

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

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

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

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

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

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

499.015 Registration of drugs, devices, and cosmetics; issuance of certificates of free sale.—

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

(b) The department may not register any product that does not comply with the Federal Food, Drug, and Cosmetic Act, as amended, or Title 21 C.F.R., or that is not an approved investigational drug as provided for in s. 499.018. Registration of a product by the department does not mean that the product does in fact comply with all provisions of the Federal Food, Drug, and Cosmetic Act, as amended.

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

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

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

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

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

499.03 Possession of new drugs or legend drugs without prescriptions unlawful; exemptions and exceptions.—

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

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

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

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

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

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

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

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

499.05 Rules.—

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

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

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

(c) Application requirements, protocols, reporting requirements, and requirements for submitting other information to the department and the

Florida Drug Technical Review Panel, as required under the investigational drug program.

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

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

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

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

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

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

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

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

499.701 Adoption of rules by the department.—

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

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

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

501.122 Control of nonionizing radiations; laser; penalties.—

(2) AUTHORITY TO ISSUE REGULATIONS.—Except for electrical transmission and distribution lines and substation facilities subject to regulation by the Department of Environmental Protection pursuant to chapter 403, the Department of Health shall adopt rules as necessary to protect the health and safety of persons exposed to laser devices and other nonionizing

radiation, including the user or any others who might come in contact with such radiation. The Department of Health may:

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

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

513.05 Rules.—The department may adopt rules pertaining to the location, construction, modification, equipment, and operation of mobile home parks, lodging parks, recreational vehicle parks, and recreational camps, except as provided in s. 633.022, as necessary to administer ~~implement~~ this chapter. Such rules may include definitions of terms; requirements for plan reviews of proposed and existing parks and camps; plan reviews of parks that consolidate space or change space size; water supply; sewage collection and disposal; plumbing and backflow prevention; garbage and refuse storage, collection, and disposal; insect and rodent control; space requirements; heating facilities; food service; lighting; sanitary facilities; bedding; an occupancy equivalency to spaces for permits for recreational camps; sanitary facilities in recreational vehicle parks; and the owners' responsibilities at recreational vehicle parks and recreational camps.

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

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

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

766.1115 Health care providers; creation of agency relationship with governmental contractors.—

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

(2) FINDINGS AND INTENT.—The Legislature finds that a significant proportion of the residents of this state who are uninsured or Medicaid recipients are unable to access needed health care because health care providers fear the increased risk of medical malpractice liability. It is the intent of the Legislature that access to medical care for indigent residents be

improved by providing governmental protection to health care providers who offer free quality medical services to underserved populations of the state. Therefore, it is the intent of the Legislature to ensure that health care professionals who contract to provide such services as agents of the state are provided sovereign immunity.

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

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

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

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

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

1. A birth center licensed under chapter 383.

2. An ambulatory surgical center licensed under chapter 395.

3. A hospital licensed under chapter 395.

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

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

6. A chiropractic physician licensed under chapter 460.

7. A podiatric physician licensed under chapter 461.

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

9. A midwife licensed under chapter 467.

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

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

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

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

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

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

(e) "Low-income" means:

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

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

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

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

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

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

(c) Adverse incidents and information on treatment outcomes must be reported by any health care provider to the governmental contractor if such incidents and information pertain to a patient treated pursuant to the contract. The health care provider shall annually submit an adverse incident report that includes all information required by s. 395.0197(6)(a), unless the adverse incident involves a result described by s. 395.0197(8), in which case it shall be reported within 15 days after the occurrence of such incident. If an incident involves a professional licensed by the Department of Health or

a facility licensed by the Agency for Health Care Administration, the governmental contractor shall submit such incident reports to the appropriate department or agency, which shall review each incident and determine whether it involves conduct by the licensee that is subject to disciplinary action. All patient medical records and any identifying information contained in adverse incident reports and treatment outcomes which are obtained by governmental entities pursuant to this paragraph are confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

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

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

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

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

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

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

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

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

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

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

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

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

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

Approved by the Governor June 7, 2000.

Filed in Office Secretary of State June 7, 2000.