CHAPTER 98-151

Committee Substitute for Senate Bill No. 1716

An act relating to the rulemaking authority of the Department of Health with respect to laws that protect the public health, safety, and welfare (RAB); amending s. 232.032, F.S.; authorizing the department to adopt rules governing the immunization of children; amending s. 381.0011, F.S.; authorizing the department to adopt rules specifying conditions and procedures for imposing quarantines; amending s. 381.003, F.S.; providing requirements for the department in adopting rules governing the prevention and control program for communicable diseases; amending s. 381.0031, F.S.; requiring that certain hospitals and laboratories report to the department the occurrence of diseases that are a threat to public health; authorizing the department to adopt rules governing the reporting of such diseases; amending s. 381.006, F.S.; providing that the department's public health mission includes the regulation of sanitary facilities; amending s. 381.0062, F.S.; providing additional requirements for the department in regulating suppliers of water; authorizing fees to cover inspection costs; amending s. 381.0065, F.S.; requiring that the department inspect and regulate certain commercial sewage systems and temporary facilities; providing inspection requirements for establishments that use an aerobic treatment unit or that generate commercial waste; requiring approval by the department before a municipality or political subdivision issues certain building or plumbing permits or authorizes occupancy; amending s. 381.0072, F.S.; redefining the term "food service establishment"; requiring that the department adopt rules governing sanitation standards; amending s. 381.008, F.S.; clarifying the definition of terms with respect to the department's regulation of migrant labor camps; amending s. 381.0083, F.S.; requiring that a person notify the department before constructing or renovating a migrant labor camp; requiring that a new owner of any such camp apply to the department for a permit; amending s. 381.0086, F.S.; authorizing the department to issue rules for maintaining the roads of a migrant labor camp; amending s. 381.0087, F.S.; specifying a time period for correcting a violation of a department rule; amending s. 381.0098, F.S.; providing for a funeral home that performs embalming procedures to be regulated as a biomedical waste generator; requiring that the department adopt rules for operating plans for managing biomedical waste; exempting certain generators of biomedical waste from permit requirements; authorizing the department to prorate fees; providing for enforcement; amending s. 381.0101, F.S.; revising terms with respect to the regulation of environmental health professionals; providing additional duties of the Environmental Health Professionals Advisory Board; providing requirements for the department in adopting rules; amending s. 381.89, F.S., relating to the regulation of tanning facilities; providing requirements for inspection reports and the training of operators; amending s. 383.011, F.S.; revising duties of the department

with respect to administering the federal Child and Adult Care Food Program; authorizing the department to adopt rules for administering certain other federal programs; amending s. 384.33, F.S.; authorizing the department to adopt rules with respect to procedures for notifying a physician or person's partner of a sexually transmissible disease; amending s. 384.34, F.S.; authorizing the department to adopt rules for administering penalty provisions; amending s. 401.26, F.S.; requiring a vehicle permit for an aircraft used to provide life-support services; providing certain exceptions; requiring the department to adopt certain criteria and rules; amending ss. 401.265, 401.30, F.S.; authorizing the department to adopt rules governing the provision of life-support services; amending ss. 403.0625, 403.863, F.S.; authorizing the department to adopt rules governing the certification of environmental laboratories and public water supply laboratories; specifying acts for which the department may impose disciplinary sanctions; amending s. 404.056, F.S.; authorizing the department to establish criteria for certifying persons and businesses that conduct radon gas or radon progeny measurements; providing additional requirements for reporting the results of such measurements; amending s. 404.22, F.S.; providing requirements for the department in inspecting radiation machines and components; requiring persons who install such machines to register with the department; amending s. 468.306, F.S.; providing requirements for examinations; amending s. 489.553, F.S.; providing for out-of-state work experience and examinations to fulfill certain requirements for registration as a septic tank contractor; amending s. 489.555, F.S.; providing additional requirements for the certification of partnerships and corporations that offer septic tank contracting services; amending s. 499.005, F.S.; prohibiting misrepresentation or fraud in obtaining or distributing a prescription drug or device; amending s. 499.01, F.S.; authorizing the department to issue a permit for the distribution of drugs to a health care entity; providing for changing the type of permit issued; amending s. 499.012, F.S.; redefining the term "wholesale distribution" for purposes of the regulation of the sale of prescription drugs; authorizing the department to adopt rules for issuing permits and handling prescription drugs; amending s. 499.0121, F.S.; providing for the exemption of certain establishments from requirements governing the storage and handling of prescription drugs; amending s. 499.0122, F.S.; authorizing the department to adopt rules governing the sale of veterinary legend drugs; amending s. 499.013, F.S.; authorizing the department to adopt rules governing manufacturers of drugs or devices; amending s. 499.014, F.S.; requiring persons who process returned drugs to obtain a permit from the department; amending s. 499.015, F.S.; providing requirements for registering product names with the department; amending ss. 499.03, 499.65, F.S.; authorizing the department to adopt rules to allow researchers to possess prescription drugs or ether; amending s. 499.05, F.S.; requiring the department to adopt rules governing recordkeeping and the storage, handling, and distribution of medical devices and over-the-counter drugs; amending s. 499.66, F.S.; revising the recordkeeping requirements

for sales of ether; amending s. 499.67, F.S.; specifying unlawful acts with respect to the purchase, storage, or use of ether; amending s. 501.122, F.S.; authorizing the department to establish additional standards for the use of lasers; amending s. 513.045, F.S.; revising the permit fees charged to operators of mobile home parks and recreational camps; amending s. 513.05, F.S.; providing additional rulemaking authority for the department with respect to such parks and camps; amending s. 514.011, F.S.; defining the term "portable pool"; amending s. 514.0115, F.S.; authorizing the department to grant variances with respect to regulations governing the operation of swimming pools; amending s. 514.03, F.S.; revising requirements for construction plans for a public swimming pool or bathing place; amending s. 514.031, F.S.; requiring the posting of an operating permit for a pool; prohibiting the use of a portable pool as a public pool; amending s. 514.033, F.S.; providing for the department to prorate certain fees for an operating permit; amending s. 514.05, F.S.; authorizing the department to adopt rules specifying conditions for closing a pool; providing an effective date.

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

Section 1. Subsection (1) of section 232.032, Florida Statutes, is amended to read:

232.032 Immunization against communicable diseases; school attendance requirements; exemptions.—

(1) The Department of Health may adopt rules necessary to administer and enforce this section. The Department of Health, after consultation with the Department of Education, shall adopt ~~promulgate~~ rules governing the immunization of children against, the testing for, and the control of preventable communicable diseases. The rules must include procedures for exempting a child from immunization requirements. Immunizations shall be required for poliomyelitis, diphtheria, rubeola, rubella, pertussis, mumps, tetanus, and other communicable diseases as determined by rules of the Department of Health. The manner and frequency of administration of the immunization or testing shall conform to recognized standards of medical practice. The Department of Health shall supervise and secure the enforcement of the required immunization. Immunizations required by this section ~~act~~ shall be available at no cost from the county health departments.

Section 2. Subsection (6) of section 381.0011, Florida Statutes, is amended to read:

381.0011 Duties and powers of the Department of Health.—It is the duty of the Department of Health to:

(6) Declare, enforce, modify, and abolish quarantine of persons, animals, and premises as the circumstances indicate for controlling communicable diseases or providing protection from unsafe conditions that pose a threat to public health, except as provided in s. 384.28 and ss. 392.545-392.60.

(a) The department shall adopt rules to specify the conditions and procedures for imposing and releasing a quarantine. The rules must include provisions related to:

1. The closure of premises.

2. The movement of persons or animals exposed to or infected with a communicable disease.

3. The tests or prophylactic treatment for communicable disease required prior to employment or admission to the premises.

4. Testing or destruction of animals with or suspected of having a disease transmissible to humans.

5. Access by the department to quarantined premises.

6. The disinfection of quarantined animals, persons, or premises.

(b) Any health regulation that restricts travel or trade within the state may not be adopted or enforced in this state except by authority of the department.

Section 3. Section 381.003, Florida Statutes, is amended to read:

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

(1) The department shall conduct a communicable disease prevention and control program as part of fulfilling its public health mission. A communicable disease is any disease caused by transmission of a specific infectious agent, or its toxic products, from an infected person, an infected animal, or the environment to a susceptible host, either directly or indirectly. The communicable disease ~~This~~ program must ~~shall~~ include, but need ~~is~~ not be limited to:

(a) Programs for the prevention and control of tuberculosis in accordance with chapter 392.

(b) Programs for the prevention and control of human immunodeficiency virus infection and acquired immune deficiency syndrome in accordance with chapter 384 and this chapter.

(c) Programs for the prevention and control of sexually transmissible diseases in accordance with chapter 384.

(d) Programs for the prevention, control, and reporting of diseases of public health significance as provided for in this chapter.

(e) Programs for the prevention and control of vaccine-preventable diseases, including programs to immunize school children as required by s. 232.032.

(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, requirements for followup reports of known or suspected exposure to disease, and procedures for providing access to confidential information necessary for disease investigations ~~the programs discussed in this section~~.

Section 4. Section 381.0031, Florida Statutes, is amended to read:

381.0031 Report of diseases of public health significance to department.—

(1) Any practitioner~~,~~ licensed in this state ~~Florida~~ to practice medicine, osteopathic medicine, chiropractic, naturopathy, or veterinary medicine; any hospital licensed under part I of chapter 395; or any laboratory licensed under chapter 483 that~~, who~~ diagnoses or suspects the existence of a disease of public health significance shall immediately report the fact to the Department of Health.

(2) Periodically the department shall issue a list of infectious or noninfectious diseases determined by it to be a threat to public health and therefore of ~~public health~~ significance to public health ~~within the meaning of this chapter~~ and shall furnish a copy of the list to the practitioners listed in subsection (1).

(3) Reports required by this section must be in accordance with methods ~~made on forms furnished, or by electronic means~~ specified~~,~~ by rule of the department.

(4) Information submitted in reports required by this section is confidential, exempt from the provisions of s. 119.07(1), and is to be made public only when necessary to public health. A report so submitted is not a violation of the confidential relationship between practitioner and patient.

(5) The department may adopt rules related to reporting diseases of significance to public health, which must specify the information to be included in the report, who is required to report, the method and time period for reporting, requirements for enforcement, and required followup activities by the department which are necessary to protect public health.

This section does not affect s. 384.25.

Section 5. Subsection (15) is added to section 381.006, Florida Statutes, 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:

(15) A sanitary facilities function, which shall include minimum standards for the maintenance and sanitation of sanitary facilities; public access to sanitary facilities; the number, operation, design, and maintenance of

plumbing fixtures in places serving the public and places of employment; and fixture ratios for special or temporary events and for homeless shelters.

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

Section 6. Paragraphs (j) and (k) are added to subsection (3) of section 381.0062, Florida Statutes, to read:

381.0062 Supervision; private and certain public water systems.—

(3) SUPERVISION.—The department and its agents shall have general supervision and control over all private water systems, and public water systems not covered or included in the Florida Safe Drinking Water Act (part VI of chapter 403), and over those aspects of the public water supply program for which it has the duties and responsibilities provided for in part VI of chapter 403. The department shall:

(j) Require suppliers of water to give public notice of water problems and corrective measures under the conditions specified by rule of the department.

(k) Require a fee to cover the cost of reinspection of any system regulated under this section, which may not be less than $25 or more than $40.

Section 7. Paragraphs (b) and (m) of subsection (3) and subsection (4) of section 381.0065, Florida Statutes, are amended to read:

381.0065 Onsite sewage treatment and disposal systems; regulation.—

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

(b) Perform application reviews and site evaluations, issue permits, and conduct inspections and complaint investigations associated with the construction, installation, maintenance, modification, abandonment, 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.

(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. 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 ~~An~~ 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. Seventy-five feet from surface waters.

5. Fifty feet from any nonpotable well.

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

7. 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) 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.

(g)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 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 a variance review and advisory committee, which shall meet monthly to recommend agency action on variance requests. The board 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.

d. A representative from the septic tank industry.

e. A representative from the Department of Environmental Protection.

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 are entitled to reimbursement ~~may be reimbursed~~ for per diem and travel expenses as provided in s. 112.061.

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

(i) 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 sys-

tem 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.

(j) 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.

(k) 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. The department shall require effluent from onsite sewage treatment and disposal systems to meet advanced waste treatment concentrations, as defined in s. 403.086.

(l) 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.

(m) 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. The department shall accept evaluations submitted by professional engineers and such other persons as meet the expertise established by rule unless the department has a reasonable scientific basis for questioning the accuracy or completeness of the evaluation.

(n) 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 <u>are entitled to reimbursement</u> ~~may be reimbursed~~ for per diem and travel expenses as provided in s. 112.061.

(o) 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.

(p) 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.

(q) 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.

Section 8. Paragraph (b) of subsection (1) and paragraph (a) of subsection (2) of section 381.0072, Florida Statutes, are 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.

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

(b) "Food service establishment" means any facility, as described in this paragraph, where food is prepared and intended for individual portion service, and includes the site at which individual portions are provided. The term includes any such facility regardless of whether consumption is on or off the premises and regardless of whether there is a charge for the food. The term includes detention facilities, child care facilities, schools, institutions, civic or fraternal organizations, ~~and~~ bars and lounges and facilities used at temporary food events, mobile food units, and vending machines at any facility regulated under this section. The term does not include private homes where food is prepared or served for individual family consumption; nor does the term include churches, synagogues, or other not-for-profit religious organizations as long as these organizations serve only their members and guests and do not advertise food or drink for public consumption, or any facility or establishment permitted or licensed under chapter 500 or chapter 509; nor does the term include any theater, if the primary use is as a theater and if patron service is limited to food items customarily served to the admittees of theaters; nor does the term include a research and development test kitchen limited to the use of employees and which is not open to the general public.

(2) DUTIES.—

(a) The department shall adopt rules consistent with law prescribing minimum sanitation standards and manager certification requirements as prescribed in s. 509.039, 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; plan review; design, construction, installation, maintenance, sanitation, and storage of food equipment; employee training, health, hygiene, and work practices; food supplies, preparation, storage, transportation, and service; 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 9. Subsections (5) and (8) of section 381.008, Florida Statutes, are amended to read:

381.008 Definitions of terms used in ss. 381.008-381.00897.—As used in ss. 381.008-381.00897, the following words and phrases mean:

(5) "Migrant labor camp"—One or more buildings, structures, barracks, or dormitories, and the land appertaining thereto, constructed, established, operated, or furnished as an incident of employment as living quarters for seasonal or migrant farmworkers whether or not rent is paid or reserved in connection with the use or occupancy of such premises. The term does not include a single family residence that is occupied by a single family.

(8) "Residential migrant housing"—A building, structure, mobile home, barracks, or dormitory, and any combination thereof on adjacent property which is under the same ownership, management, or control, and the land appertaining thereto, that is rented or reserved for occupancy by five or more migrant farmworkers, except:

(a) Housing furnished as an incident of employment.;

(b) A single-family residence or mobile home dwelling unit that is not under the same ownership, management, or control as other farmworker housing to which it is adjacent or contiguous.;

(c) A hotel, motel, or resort condominium, as defined in chapter 509, that is furnished for transient occupancy.

(d) Any housing owned or operated by a public housing authority except for housing which is specifically provided for persons whose principal income is derived from agriculture.

Section 10. Section 381.0083, Florida Statutes, is amended to read:

381.0083 Issuance of permit to operate migrant labor camp or residential migrant housing.—Any person who is planning to construct, enlarge, remodel, use, or occupy a migrant labor camp or residential migrant housing or convert property for use as a migrant labor camp or residential migrant housing must give written notice to the department of the intent to do so at least 45 days before beginning such construction, enlargement, or renovation. If the department is satisfied, after causing an inspection to be made, that the camp or the residential migrant housing meets the minimum standards of construction, sanitation, equipment, and operation required by rules issued under s. 381.0086 and that the applicant has paid the application fees

required by s. 381.0084, it shall issue in the name of the department the necessary permit in writing on a form to be prescribed by the department. The permit, unless sooner revoked, shall expire on September 30 next after the date of issuance, and it shall not be transferable. An application for a permit shall be filed with the department 30 days prior to operation. When there is a change in ownership of a currently permitted migrant labor camp or residential migrant housing, the new owner must file an application with the department at least 15 days before the change. In the case of a facility owned or operated by a public housing authority, an annual satisfactory sanitation inspection of the living units by the Farmers Home Administration or the Department of Housing and Urban Development shall substitute for the pre-permitting inspection required by the department.

Section 11. 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. These rules must include provisions relating to plan review of the construction of new, expanded, or remodeled camps, personal hygiene facilities, lighting, sewage disposal, safety, minimum living space per occupant, bedding, food storage and preparation, insect and rodent control, garbage, heating equipment, water supply, maintenance and operation of the camp, ~~or~~ 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 12. Subsections (1) and (2) of section 381.0087, Florida Statutes, are amended to read:

381.0087 Enforcement; citations.—

(1) Department personnel or crew chief compliance officers employed by the Bureau of Compliance of the Florida Department of Labor and Employment Security may issue citations that contain an order of correction or an order to pay a fine, or both, for violations of ss. 381.008-381.00895 or the field sanitation facility rules adopted by the department when a violation of those sections or rules is enforceable by an administrative or civil remedy, or when a violation of those sections or rules is a misdemeanor of the second degree. A citation issued under this section constitutes a notice of proposed agency action. The recipient of a citation for a major deficiency, as defined by rule of the department, will be given a maximum of 48 hours to make satisfactory correction or demonstrate that provisions for correction are satisfactory.

(2) Citations must be in writing and must describe the particular nature of the violation, including specific reference to the provision of statute or rule allegedly violated. Continual or repeat violations of the same requirement will result in the issuance of a citation.

Section 13. Paragraph (b) of subsection (2), subsection (3), paragraphs (a), (d), and (f) of subsection (4), and subsection (7) of section 381.0098, Florida Statutes, are amended to read:

381.0098 Biomedical waste.—

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

(b) "Biomedical waste generator" means a facility or person that produces or generates biomedical waste. The term includes, but is not limited to, hospitals, skilled nursing or convalescent hospitals, intermediate care facilities, clinics, dialysis clinics, dental offices, health maintenance organizations, surgical clinics, medical buildings, physicians' offices, laboratories, veterinary clinics, and funeral homes where embalming procedures are performed.

(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, 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.

(d) The permit for a biomedical waste generator shall not be transferred from one owner to another. When the ownership or name of a biomedical waste 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.

(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 promulgated by rule of the department. Facilities owned and operated by the state shall be exempt from the payment of any fees.

(7) ENFORCEMENT AND PENALTIES.—Any person or public body in violation of this section or rules adopted under this section is subject to penalties provided in ss. 381.0012, 381.0025, and 381.0061. However, an administrative fine not to exceed $2,500 may be imposed for each day such person or public body is in violation of this section. The department may deny, suspend, or revoke any biomedical waste permit or registration if the permittee violates this section, any rule adopted under this section, or any lawful order of the department.

Section 14. Paragraphs (d), (f), and (g) of subsection (2), paragraph (b) of subsection (4), and subsections (5) and (7) of section 381.0101, Florida Statutes, are amended to read:

381.0101 Environmental health professionals.—

(2) DEFINITIONS.—As used in this section:

(d) "Environmental health professional" means a person who is employed or assigned the responsibility for assessing the environmental health or sanitary conditions, as defined by the department, within a building, on an individual's property, or within the community at large, and who has the knowledge, skills, and abilities to carry out these tasks. Environmental health professionals may be either field, supervisory, or administrative staff members.

(f) "Registered sanitarian," ~~or~~ "R.S.," "Registered Environmental Health Specialist," or "R.E.H.S." means a person who has been certified by either the National Environmental Health Association or the Florida Environmental Health Association as knowledgeable in the environmental health profession.

(g) "Primary environmental health program" means those programs determined by the department to be essential for providing basic environmental and sanitary protection to the public. At a minimum, these programs shall include food protection program work ~~hygiene evaluations~~, and onsite sewage treatment and disposal system evaluations.

(4) ENVIRONMENTAL HEALTH PROFESSIONALS ADVISORY BOARD.—The State Health Officer shall appoint an advisory board to assist the department in the promulgation of rules for certification, testing, establishing standards, and seeking enforcement actions against certified professionals.

(b) The board shall advise the department as to the minimum disciplinary guidelines and standards of competency and proficiency necessary to obtain certification in a primary area of environmental health practice.

1. The board shall recommend primary areas of environmental health practice in which environmental health professionals should be required to obtain certification.

2. The board shall recommend minimum standards of practice which the department shall incorporate into rule.

3. The board shall evaluate and recommend to the department existing registrations and certifications which meet or exceed minimum department standards and should, therefore, exempt holders of such certificates or registrations from compliance with this section.

4. The board shall hear appeals of certificate denials, revocation, or suspension and shall advise the department as to the disposition of such an appeal.

5. The board shall meet as often as necessary, but no less than semiannually, handle appeals to the department, and conduct other duties of the board.

6. Members of the board shall receive no compensation but are entitled to reimbursement ~~shall be reimbursed~~ for per diem and travel expenses in accordance with s. 112.061.

(5) STANDARDS FOR CERTIFICATION.—The department shall adopt rules that establish minimum standards of education, training, or experience for those persons subject to this section. The rules 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 ~~No~~ person may not ~~shall~~ 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.

(7) FEES.—The department shall charge fees in amounts necessary to meet the cost of providing certification. Fees for certification shall be not ~~no~~ less than $10 or ~~$25 nor~~ more than $300 and shall be set by rule. Application, examination, and certification costs shall be included in this fee. Fees for renewal of a certificate shall be no less than $25 nor more than $150 per biennium.

Section 15. Paragraph (b) of subsection (4), paragraph (a) of subsection (6), and subsection (13) of section 381.89, Florida Statutes, are amended to read:

381.89 Regulation of tanning facilities.—

(4)

(b) A tanning facility must have a copy of the facility's most recent inspection report available to the public and must post a warning sign in any area where a tanning device is used. Posting this sign does not absolve the facility of any liability. The sign must state:

DANGER, ULTRAVIOLET RADIATION
Follow these instructions:

1. Avoid frequent or lengthy exposure. As with natural sunlight, exposure can cause eye and skin injury or allergic reactions. Repeated exposure can cause chronic sun damage characterized by wrinkling, dryness, fragility and bruising of the skin or skin cancer.

2. Wear protective eyewear. FAILURE TO USE PROTECTIVE EYEWEAR CAN RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYES.

3. Ultraviolet radiation from sunlamps will aggravate the effects of the sun. Therefore, do not sunbathe before or after exposure to ultraviolet radiation.

4. Using medications or cosmetics can increase your sensitivity to ultraviolet radiation. Consult a physician before using a sunlamp if you are using medications, have a history of skin problems, or believe you are especially sensitive to sunlight. Women who are pregnant or on birth control who use this product can develop discolored skin. IF YOU DO NOT TAN IN THE SUN YOU WILL NOT TAN BY USING THIS DEVICE.

(6) A tanning facility must:

(a) During operating hours, have an operator present who is sufficiently knowledgeable and trained in accordance with rules of the department in the correct operation of the tanning devices to inform and assist each customer in the proper use of the devices.

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

Section 16. Paragraph (g) of subsection (1) and subsection (2) of section 383.011, Florida Statutes, are amended, and paragraph (i) is added to subsection (1) of that section, to read:

383.011 Administration of maternal and child health programs.—

(1) The Department of Health is designated as the state agency for:

(g) Receiving the federal funds for the "Special Supplemental Nutrition ~~Food~~ Program for Women, Infants, and Children," or WIC, authorized by the Child Nutrition Act of 1966, as amended, and for administering the statewide WIC program. ~~(The WIC program provides nutrition education and supplemental foods, by means of food instruments called checks that are redeemed by authorized food vendors, to participants certified by the department as pregnant, breastfeeding, or postpartum women; infants; or children.)~~

(h) Designating facilities that provide maternity services or newborn infant care as "baby-friendly" when the facility has established a breastfeeding policy under s. 383.016.

(i) Receiving federal funds for children eligible for assistance through the portion of the federal Child and Adult Care Food Program for children, which is referred to as the Child Care Food Program, and for administering the program.

(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, ~~or~~ 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, quality assurance, and provider selection.

(b) The department may adopt rules that are necessary to administer the statewide WIC program. The rules may include, but need not be limited to, criteria for grocers' participation, client eligibility, contracts with local agencies for service delivery, and food purchases and penalties for program abuse.

Section 17. Section 384.33, Florida Statutes, is amended to read:

384.33 Rules.—The department may adopt rules to carry out the provisions of this chapter. The rules may include requirements for methods of contacting a physician to determine the need for follow-up services related to sexually transmissible diseases and for maintaining the security of confidential information.

Section 18. Subsection (4) of section 384.34, Florida Statutes, is amended to read:

384.34 Penalties.—

(4) Any person who violates the provisions of the department's rules pertaining to sexually transmissible diseases may be punished by a fine not to exceed $500 for each violation. Any penalties enforced under this subsection shall be in addition to other penalties provided by this chapter ~~act~~. The department may enforce this section and adopt rules necessary to administer this section.

Section 19. Section 401.26, Florida Statutes, is amended to read:

401.26 Vehicle permits for basic life support and advanced life support services.—

(1) Every licensee shall possess a valid permit for each transport vehicle, ~~and~~ advanced life support nontransport vehicle, and aircraft in use. Applications for such permits shall be made upon forms prescribed by the department. The licensee shall provide documentation that each vehicle for which a permit is sought meets the appropriate requirements for a basic life support or advanced life support service vehicle, whichever is applicable, as specified by rule of the department. A permit is not required for an advanced life support nontransport vehicle that is intended to be used for scene supervision, incident command, or the augmentation of supplies.

(2) To receive a valid ~~vehicle~~ permit, the applicant must submit a completed application form for each vehicle or aircraft for which a permit is desired, pay the appropriate fees established as provided in s. 401.34, and provide documentation that each vehicle or aircraft meets the following requirements as established by rule of the department; the vehicle or aircraft must:

(a) Be furnished with essential medical supplies and equipment which is in good working order.

(b) Meet appropriate standards for design and construction.

(c) Be equipped with an appropriate communication system.

(d) Meet appropriate safety standards.

(e) Meet sanitation and maintenance standards.

(f) Be insured for an appropriate sum against injuries to or the death of any person arising out of an accident.

(3) The department may deny, suspend, or revoke a permit if it determines that the vehicle, aircraft, or ~~its~~ equipment fails to meet the requirements specified in this part or in the rules of the department.

(4) A permit issued in accordance with this section will expire automatically concurrent with the service license.

(5) In order to renew a vehicle or aircraft permit issued pursuant to this part, the applicant must:

(a) Submit a renewal application. Such application must be received by the department not more than 90 days or less than 30 days prior to the expiration of the permit.

(b) Submit the appropriate fee or fees, established as provided in s. 401.34.

(c) Provide documentation that current standards for issuance of a permit are met.

(6) The department shall establish criteria and time limits for substitution of permitted vehicles that are out of service for maintenance purposes.

(7) The department shall adopt and enforce rules necessary to administer this section.

Section 20. Subsection (4) is added to section 401.265, Florida Statutes, to read:

401.265 Medical directors.—

(4) The department shall adopt and enforce all rules necessary to administer this section.

Section 21. Subsection (4) is added to section 401.30, Florida Statutes, to read:

401.30 Records.—

(4) The department shall adopt and enforce all rules necessary to administer this section.

Section 22. Section 403.0625, Florida Statutes, is amended to read:

403.0625 Environmental laboratory certification; water quality tests conducted by a certified laboratory.—

(1) To assure the acceptable quality, reliability, and validity of testing results, the department and the Department of Health ~~and Rehabilitative Services~~ shall jointly establish criteria for certification of laboratories that perform analyses of environmental ~~water quality~~ samples that ~~which~~ are not covered by the provisions in s. 403.863 ~~and that wish to be certified~~. The Department of Health ~~and Rehabilitative Services~~ shall have the responsibility for the operation and implementation of such laboratory certification. The Department of Health ~~and Rehabilitative Services~~ may charge and collect fees for the certification of such laboratories. The fee schedule shall be based on the number of analytical functions for which certification is sought. Such fees shall be sufficient to meet the costs incurred by the Department of Health ~~and Rehabilitative Services~~ in administering this program in coordination with the department. All fees collected pursuant to this section shall be deposited in a trust fund to be administered by the Department of Health ~~and Rehabilitative Services~~ and shall be used only for the purposes of this section.

(2) An environmental water quality test to determine the quality of the effluent of a domestic wastewater facility must be conducted by a laboratory certified under this section if such test results are to be submitted to the department or a local pollution control program pursuant to s. 403.182.

(3) The Department of Health may adopt and enforce rules to administer this section, including, but not limited to, definitions of terms, certified laboratory personnel requirements, sample collection methodology and proficiency testing, the format and frequency of reports, onsite inspections of laboratories, and quality assurance.

(4) The following acts constitute grounds for which the disciplinary actions specified in subsection (5) may be taken:

(a) Making false statements on an application or on any document associated with certification.

(b) Making consistent errors in analyses or erroneous reporting.

(c) Permitting personnel who are not qualified, as required by rules of the Department of Health, to perform analyses.

(d) Falsifying the results of analyses.

(e) Failing to employ approved laboratory methods in performing analyses as outlined in rules of the Department of Health.

(f) Failing to properly maintain facilities and equipment according to the laboratory's quality assurance plan.

(g) Failing to report analytical test results or maintain required records of test results as outlined in rules of the Department of Health.

(h) Failing to participate successfully in a performance-evaluation program approved by the Department of Health.

(i) Violating any provision of this section or of the rules adopted under this section.

(j) Falsely advertising services or credentials.

(k) Failing to pay fees for initial certification or renewal certification or to pay inspection expenses incurred by the Department of Health.

(l) Failing to report any change of an item included in the initial or renewal certification application.

(m) Refusing to allow representatives of the department or the Department of Health to inspect a laboratory and its records during normal business hours.

(5) When the Department of Health finds any applicant or certificate-holder guilty of any of the grounds set forth in subsection (4), it may enter an order imposing one or more of the following penalties:

(a) Denial of an application for certification.

(b) Revocation or suspension of certification.

(c) Imposition of an administrative fine not to exceed $1,000 for each count or separate offense.

(d) Issuance of a reprimand.

(e) Placement of the certification on probation for a period of time and subject to such conditions as the Department of Health specifies.

(f) Restricting the authorized scope of the certification.

(6) The certification program shall be governed by chapter 120.

Section 23. Section 403.863, Florida Statutes, is amended to read:

403.863 State public water supply laboratory certification program.—

(1) ~~Within 120 days of the effective date of this act,~~ The department and the Department of Health ~~and Rehabilitative Services~~ shall jointly develop a state program, and the Department of Health ~~and Rehabilitative Services~~ shall adopt rules for the evaluation and certification of all laboratories ~~in the state~~, other than the principal state laboratory, which perform or make application to perform analyses pursuant to the Florida Safe Drinking Water Act or which conduct a water-analysis business. Such joint development shall be funded in part through the use of a portion of the State Public Water Systems Supervision Program grants received by the department from the Federal Government in order to implement the federal act.

(2) The Department of Health may adopt and enforce rules to administer this section, including, but not limited to, definitions of terms, certified

laboratory personnel requirements, methodologies for the collection of samples, the handling and analysis of samples, methodology and proficiency testing, the format and frequency of reports, onsite inspections of laboratories, and quality assurance.

(3)~~(2)~~ The Department of Health ~~and Rehabilitative Services~~ shall have the responsibility for the operation and implementation of the state laboratory certification program, except that, upon completion of the evaluation and review of the laboratory certification application, the evaluation shall be forwarded, along with recommendations, to the department for review and comment, prior to final approval or disapproval.

(4) The following acts constitute grounds for which the disciplinary actions specified in subsection (5) may be taken:

(a) Making false statements on an application or on any document associated with certification.

(b) Making consistent errors in analyses or erroneous reporting.

(c) Permitting personnel who are not qualified, as required by rules of the Department of Health, to perform analyses.

(d) Falsifying the results of analyses.

(e) Failing to employ approved laboratory methods in performing analyses as outlined in rules of the Department of Health.

(f) Failing to properly maintain facilities and equipment according to the laboratory's quality assurance plan.

(g) Failing to report analytical test results or maintain required records of test results as outlined in rules of the Department of Health.

(h) Failing to participate successfully in a performance-evaluation program approved by the Department of Health.

(i) Violating any provision of this section or of the rules adopted under this section.

(j) Falsely advertising services or credentials.

(k) Failing to pay fees for initial certification or renewal certification or to pay inspection expenses incurred by the Department of Health.

(l) Failing to report any change of an item included in the initial or renewal certification application.

(m) Refusing to allow representatives of the department or the Department of Health to inspect a laboratory and its records during normal business hours.

(5) When the Department of Health finds any applicant or certificate-holder guilty of any of the grounds set forth in subsection (4), it may enter an order imposing one or more of the following penalties:

(a) Denial of an application for certification.

(b) Revocation or suspension of certification.

(c) Imposition of an administrative fine not to exceed $1,000 for each count or separate offense.

(d) Issuance of a reprimand.

(e) Placement of the certification on probation for a period of time and subject to such conditions as the Department of Health specifies.

(f) Restricting the authorized scope of the certification.

(6)~~(3)~~ Any federal grant funds received by the department for the operation and implementation of the state laboratory certification program shall be transferred to the Department of Health ~~and Rehabilitative Services~~ by interagency agreement between the two departments. Such agreement shall require the Department of Health ~~and Rehabilitative Services~~ to provide the department with a quarterly accounting of the funds transferred.

(7)~~(4)~~ A ~~Within 60 days of the effective date of the rules adopted pursuant to this section, no~~ laboratory that conducts a water-analysis business ~~in the state~~, except the principal state laboratory, may not ~~shall~~ perform analyses pursuant to the Florida Safe Drinking Water Act without having applied for and received certification under the state certification program to perform such analyses.

(8)~~(5)~~ For the purposes of this section, the term "principal state laboratory" means the central laboratory of the Department of Health ~~and Rehabilitative Services~~.

(9)~~(6)~~ For the purposes of this section, the term "certification" means regulatory recognition given to a laboratory that performs analyses pursuant to the Florida Safe Drinking Water Act, that it meets minimum analytical performance standards.

(10) The certification program shall be governed by chapter 120.

Section 24. 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 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 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 ~~After January 1, 1989, no~~ person may not ~~shall~~ 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 ~~shall~~ include the radon levels detected; ~~and~~ 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 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 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 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 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 mitigation measurements.

(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 25. Subsections (1) and (2) of section 404.22, Florida Statutes, are amended to read:

404.22 Radiation machines and components; inspection.—

(1) The department and its duly authorized agents may ~~have the power to~~ 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 thereto. If, in the opinion of the department, a radiation machine 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 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 utilization of the radiation machine.

(2) Any person who enters the state with a radiation machine or component owned by him or her for the purpose of installing and utilizing the radiation machine shall register the radiation machine with the department. The department shall inspect the radiation machine to determine its compliance with the standards and shall approve or disapprove the radiation machine or shall order adjustments to the radiation machine in accord-

ance with the provisions of subsection (1). Each person who installs or offers to install or service radiation machines must register with the department and must apply to the department, on forms furnished by the department, before furnishing or offering to furnish any such service.

Section 26. Subsection (2) of section 468.306, Florida Statutes, is amended to read:

468.306 Examinations.—All applicants, except those certified pursuant to s. 468.3065, shall be required to pass an examination. The department is authorized to develop or use examinations for each type of certificate.

(2) Examinations shall be given for each type of certificate at least twice a year at such times and places as the department may determine to be advantageous for applicants. If an applicant applies less than 75 days before an examination, the department may schedule the applicant for a later examination.

Section 27. Paragraph (d) of subsection (4) of section 489.553, Florida Statutes, is amended to read:

489.553 Administration of part; registration qualifications; examination.—

(4) To be eligible for registration by the department as a septic tank contractor, the applicant must:

(d) Have a total of at least 3 years of active experience serving an apprenticeship as a skilled workman under the supervision and control of a registered septic tank contractor or a plumbing contractor as defined in s. 489.105 who has provided septic tank contracting services. Related work experience or educational experience may be substituted for no more than 2 years of active contracting experience. Each 30 hours of coursework approved by the department will substitute for 6 months of work experience. Out-of-state work experience shall be accepted on a year-for-year basis for any applicant who demonstrates that he or she holds a current license issued by another state for septic tank contracting which was issued upon satisfactory completion of an examination and continuing education courses that are equivalent to the requirements in this state. For purposes of this section, an equivalent examination must include the topics of system location and installation, site evaluation, system size determinations, disposal of septage, construction standards for drainfield systems, and the soil-texture classification system of the United States Department of Agriculture. A person employed by and under the supervision of a licensed contractor shall be granted up to 2 years of related work experience.

Section 28. Subsection (1) of section 489.555, Florida Statutes, is amended to read:

489.555 Certification of partnerships and corporations.—

(1) The practice of or the offer to practice septic tank contracting services by registrants through a parent corporation, corporation, subsidiary of a

corporation, or partnership offering septic tank contracting services to the public through registrants under this chapter as agents, employers, officers, or partners is permitted, provided that one or more of the principal officers of the corporation or one or more partners of the partnership and all personnel of the corporation or partnership who act in its behalf as septic tank contractors or master septic tank contractors in this state are registered as provided by this part, and further provided that the corporation or partnership has been issued a certificate of authorization by the department as provided in this section. A registered contractor may not be the sole qualifying contractor for more than one business that requests a certificate of authorization. A business organization that loses its qualifying contractor has 60 days following the date the qualifier terminates his or her affiliation within which to obtain another qualifying contractor. During this period, the business organization may complete any existing contract or continuing contract, but may not undertake any new contract. This period may be extended once by the department for an additional 60 days upon a showing of good cause. Nothing in this section shall be construed to mean that a certificate of registration to practice septic tank contracting shall be held by a corporation. No corporation or partnership shall be relieved of responsibility for the conduct or acts of its agents, employees, or officers by reason of its compliance with this section, nor shall any individual practicing septic tank contracting be relieved of responsibility for professional services performed by reason of his or her employment or relationship with a corporation or partnership.

Section 29. Subsection (6) of section 499.005, Florida Statutes, is amended, and subsection (23) is added to that section, to read:

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

(6) The refusal or constructive refusal:

(a) To allow the department to enter or inspect an establishment in which drugs, devices, or cosmetics are manufactured, processed, repackaged, sold, brokered, or held;

(b) To allow inspection of any record of that establishment;

(c) To allow the department to enter and inspect any vehicle that is being used to transport drugs, devices, or cosmetics; or

(d) To allow the department to take samples of any drug, device, or cosmetic.

(23) Obtaining or attempting to obtain a prescription drug or device by fraud, deceit, misrepresentation or subterfuge, or engaging in misrepresentation or fraud in the distribution of a drug or device.

Section 30. Subsection (1) of section 499.01, Florida Statutes, is amended to read:

499.01 Permits; applications; renewal; general requirements.—

(1) Any person that is required under ss. 499.001-499.081 to have a permit must apply to the department on forms furnished by the department.

(a) A permit issued pursuant to ss. 499.001-499.081 may be issued only to an individual who is at least 18 years of age or to a corporation that is registered pursuant to chapter 607 or chapter 617 and each officer of which is at least 18 years of age.

(b) An establishment that is a place of residence may not receive a permit and may not operate under ss. 499.001-499.081.

(c) A person that applies for or renews a permit to manufacture or distribute legend drugs may not use a name identical to the name used by any other establishment or licensed person authorized to purchase prescription drugs in this state, except that a restricted drug-distributor permit issued to a health care entity will be issued in the name in which the institutional pharmacy permit is issued and a retail pharmacy drug wholesaler will be issued a permit in the name of its retail pharmacy permit.

(d) A permit is required for each establishment that operates as a:

1. Prescription drug manufacturer;

2. Over-the-counter drug manufacturer;

3. Compressed medical gas manufacturer;

4. Device manufacturer;

5. Cosmetic manufacturer;

6. Prescription drug wholesaler;

7. Compressed medical gas wholesaler;

8. Out-of-state prescription drug wholesaler;

9. Retail pharmacy drug wholesaler;

10. Veterinary legend drug retail establishment;

11. Medical oxygen retail establishment; ~~or~~

12. Complimentary drug distributor; or~~.~~

13. Restricted prescription drug distributor.

(e) A permit for a prescription drug manufacturer, prescription drug wholesaler, or retail pharmacy wholesaler may not be issued to the address of a health care entity.

(f) Notwithstanding subsection (4), a permitted person in good standing may change the type of permit issued to that person by completing a new application for the requested permit, paying the amount of the difference in the permit fees if the fee for the new permit is more than the fee for the

original permit, and meeting the applicable permitting conditions for the new permit type. The new permit expires on the expiration date of the original permit being changed. A refund may not be issued if the biennial fee for the new permit is less than the original permit for which a fee was paid.

Section 31. Paragraph (a) of subsection (1) and paragraph (a) of subsection (2) of section 499.012, Florida Statutes, are amended, and subsection (5) is added to that section, to read:

499.012 Wholesale distribution; definitions; permits; general requirements.—

(1) As used in this section, the term:

(a) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

1. Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with s. 499.014:

a.~~1.~~ The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of that organization.~~;~~

b.~~2.~~ The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended and revised, to a nonprofit affiliate of the organization to the extent otherwise permitted by law.~~;~~

c.~~3.~~ The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control. For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise.

2. Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with rules established by the department:

a.~~4.~~ The sale, purchase, or trade of a prescription drug among federal, state, or local government health care entities that are under common control and are authorized to purchase such prescription drug.

b.~~5.~~ The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug for emergency medical reasons; for purposes of this subparagraph, the term "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.~~;~~

c.~~6.~~ The purchase or acquisition of a prescription drug by an emergency medical services medical director for use by emergency medical services providers acting within the scope of their professional practice pursuant to chapter 401.

d. The revocation of a sale or the return of a prescription drug to the person's prescription drug wholesale supplier.

e. The donation of a prescription drug by a health care entity to a charitable organization that has been granted an exemption under s. 501(c)(3) of the Internal Revenue Code of 1986, as amended, and that is authorized to possess prescription drugs.

f. The transfer of a prescription drug by a person authorized to purchase or receive prescription drugs to a person licensed or permitted to handle reverse distributions or destruction under the laws of the jurisdiction in which the person handling the reverse distribution or destruction receives the drug.

3.~~7.~~ The dispensing of a prescription drug pursuant to a prescription;

4.~~8.~~ The distribution of prescription drug samples by manufacturers' representatives or distributors' representatives; or

5.~~9.~~ The sale, purchase, or trade of blood and blood components intended for transfusion. As used in this section, the term "blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing, and the term "blood components" means that part of the blood separated by physical or mechanical means.

(2) The following types of wholesaler permits are established:

(a) A prescription drug wholesaler's permit. A prescription drug wholesaler is a wholesale distributor that may engage in the wholesale distribution of prescription drugs. A prescription drug wholesaler that applies to the department after January 1, 1993, must submit a bond of $200, payable to the Florida Drug, Device, and Cosmetic Trust Fund. This bond will be refunded to the permittee when the permit is returned to the department and the permittee ceases to function as a business. A permittee that fails to notify the department before changing the address of the business, fails to notify the department before closing the business, or fails to notify the department before a change of ownership forfeits its bond. The department may adopt rules for issuing a prescription drug wholesaler-broker permit to a person who engages in the wholesale distribution of prescription drugs and does not take physical possession of any prescription drugs.

(5) The department may adopt rules governing the recordkeeping, storage, and handling with respect to each of the distributions of prescription drugs specified in subparagraphs (1)(a)1., 2., 4., and 5.

Section 32. Section 499.0121, Florida Statutes, is amended to read:

499.0121 Storage and handling of prescription drugs.—The department shall adopt ~~such~~ rules to implement this section ~~relating to wholesale drug~~

~~distribution~~ as ~~are~~ 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.

(1) ESTABLISHMENTS.—An establishment at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed must:

(a) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(b) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(c) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

(d) Be maintained in a clean and orderly condition; and

(e) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(2) SECURITY.—

(a) An establishment that is used for wholesale drug distribution must be secure from unauthorized entry.

1. Access from outside the premises must be kept to a minimum and be well-controlled.

2. The outside perimeter of the premises must be well-lighted.

3. Entry into areas where prescription drugs are held must be limited to authorized personnel.

(b) An establishment that is used for wholesale drug distribution must be equipped with:

1. An alarm system to detect entry after hours; however, the department may exempt by rule establishments that only hold a permit as prescription drug wholesaler-brokers and establishments that only handle medical oxygen; and

2. A security system that will provide suitable protection against theft and diversion. When appropriate, the security system must provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(3) STORAGE.—All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the official compendium.

(a) If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in the official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(b) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs must be used to document proper storage of prescription drugs.

(c) The recordkeeping requirements in subsection (6) must be followed for all stored prescription drugs.

(4) EXAMINATION OF MATERIALS.—

(a) Upon receipt, each outside shipping container must be visually examined for identity and to prevent the acceptance of contaminated prescription drugs that are otherwise unfit for distribution. This examination must be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(b) Each outgoing shipment must be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have expired or been damaged in storage or held under improper conditions.

(c) The recordkeeping requirements in subsection (6) must be followed for all incoming and outgoing prescription drugs.

(5) RETURNED, DAMAGED, OR OUTDATED PRESCRIPTION DRUGS.—

(a)1. Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier. A quarantine section must be separate and apart from other sections where prescription drugs are stored so that prescription drugs in this section are not confused with usable prescription drugs.

2. Prescription drugs must be examined at least every 12 months, and drugs for which the expiration date has passed must be removed and quarantined.

(b) Any prescription drugs of which the immediate or sealed outer containers or sealed secondary containers have been opened or used must be identified as such and must be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(c) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug must be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining

whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor must consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the conditions of the drug and its container, carton, or labeling, as a result of storage or shipping.

(d) The recordkeeping requirements in subsection (6) must be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(6) RECORDKEEPING.—The department shall adopt rules that require keeping such records of prescription drugs as are necessary for the protection of the public health.

(a) Wholesale drug distributors must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records must provide a complete audit trail from receipt to sale or other disposition, be readily retrievable for inspection, and include, at a minimum, the following information:

1. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

2. The name, principal address, and state license permit or registration number of the person authorized to purchase prescription drugs;

3. The name, strength, dosage form, and quantity of the drugs received and distributed or disposed of; and

4. The dates of receipt and distribution or other disposition of the drugs.

(b) Inventories and records must be made available for inspection and photocopying by authorized federal, state, or local officials for a period of 2 years following disposition of the drugs.

(c) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means must be readily available for authorized inspection during the retention period. Records that are kept at a central location outside of this state and that are not electronically retrievable must be made available for inspection within 2 working days after a request by an authorized official of a federal, state, or local law enforcement agency. Records that are maintained at a central location within this state must be maintained at an establishment that is permitted pursuant to ss. 499.001-499.081 and must be readily available.

(d)1. Each person who is engaged in the wholesale distribution of a prescription drug, and who is not an authorized distributor of record of such drug, must provide to each wholesale distributor of such drug, before the sale is made to such wholesale distributor, a written statement identifying each previous sale of the drug. The written statement identifying all sales

of such drug must accompany the drug for each subsequent wholesale distribution of the drug to a wholesale distributor. The department shall adopt rules relating to the requirements of this written statement.

2. Each wholesale distributor of prescription drugs must maintain separate and distinct from other required records all statements that are required under subparagraph 1.

3. Each manufacturer of a prescription drug sold in this state must maintain at its corporate offices a current list of authorized distributors and must make such list available to the department upon request.

For the purposes of this subsection, the term "authorized distributors of record" means those distributors with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products.

(7) WRITTEN POLICIES AND PROCEDURES.—Wholesale drug distributors must establish, maintain, and adhere to written policies and procedures, which must be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors must include in their written policies and procedures:

(a) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if the deviation is temporary and appropriate.

(b) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure must be adequate to deal with recalls and withdrawals due to:

1. Any action initiated at the request of the Food and Drug Administration or any other federal, state, or local law enforcement or other government agency, including the department.

2. Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

3. Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

(c) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility if a strike, fire, flood, or other natural disaster, or a local, state, or national emergency, occurs.

(d) A procedure to ensure that any outdated prescription drugs are segregated from other drugs and either returned to the manufacturer or destroyed. This procedure must provide for written documentation of the disposition of outdated prescription drugs. This documentation must be maintained for 2 years after disposition of the outdated drugs.

(8) RESPONSIBLE PERSONS.—Wholesale drug distributors must establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(9) COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAW.—A wholesale drug distributor must operate in compliance with applicable federal, state, and local laws and regulations.

(a) A wholesale drug distributor must allow the department and authorized federal, state, and local officials to enter and inspect its premises and delivery vehicles, and to audit its records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(b) A wholesale drug distributor that deals in controlled substances must register with the Drug Enforcement Administration and must comply with all applicable state, local, and federal laws. A wholesale drug distributor that distributes any substance controlled under chapter 893 must notify the department when registering with the Drug Enforcement Administration pursuant to that chapter and must provide the department with its DEA number.

(10) SALVAGING AND REPROCESSING.—A wholesale drug distributor is subject to any applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing.

Section 33. Paragraphs (a) and (d) of subsection (1) of section 499.0122, Florida Statutes, are amended to read:

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

(1) As used in this section, the term:

(a) "Medical oxygen retail establishment" means a person licensed to sell medical oxygen to patients only. The sale must be based on an order from a practitioner authorized by law to prescribe. The term does not include a pharmacy licensed under chapter 465.

1. A medical oxygen retail establishment may not possess, purchase, sell, or trade any legend drug other than medical oxygen.

2. A medical oxygen retail establishment may refill medical oxygen for an individual patient based on an order from a practitioner authorized by law to prescribe. A medical oxygen retail establishment that refills medical oxygen must comply with all appropriate state and federal good manufacturing practices.

(d) "Veterinary legend drug retail establishment" means a person permitted to sell veterinary legend drugs to the public or to veterinarians, but does not include a pharmacy licensed under chapter 465.

1. The sale to the public must be based on a valid written order from a veterinarian licensed in this state who has a valid client-veterinarian relationship with the purchaser's animal.

2. Veterinary legend drugs may not be sold in excess of the amount clearly indicated on the order or beyond the date indicated on the order.

3. An order may not be valid for more than 1 year.

4. A veterinary legend drug retail establishment may not purchase, sell, trade, or possess human prescription drugs or any controlled substance as defined in chapter 893.

5. A veterinary legend drug retail establishment must sell a veterinary legend drug ~~drugs~~ in the original, sealed manufacturer's container ~~containers~~ with all labeling intact and legible. The department may adopt by rule additional labeling requirements for the sale of a veterinary legend drug.

Section 34. Paragraph (e) of subsection (2) of section 499.013, Florida Statutes, is amended 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:

(e) A cosmetic manufacturer's permit is required for any person that manufactures cosmetics in this state.

~~1.~~ A person that only labels or changes the labeling of a cosmetic but does not open the container sealed by the manufacturer of the product is exempt from obtaining a permit under this paragraph.

(3)~~2.~~ The department may adopt such rules as are necessary for the protection of the public health, safety, and welfare regarding good manufacturing practices that ~~cosmetic~~ manufacturers must follow to ensure the safety of the products.

Section 35. Section 499.014, Florida Statutes, is amended to read:

499.014 Distribution of legend drugs by hospitals, health care entities, ~~and~~ charitable organizations and return or destruction companies; permits, general requirements.—

(1) A restricted prescription drug distributor permit is required for any person that engages in the distribution of a legend drug, which distribution ~~is made in accordance with and~~ is not considered "wholesale distribution" under subparagraph (1)(a)1.~~, subparagraph (1)(a)2., or subparagraph (1)(a)3.~~ of s. 499.012.

(2) A person who engages in the receipt or distribution of a legend drug in this state for the purpose of processing its return or its destruction must

obtain a permit as a restricted prescription drug distributor if such person is not the person initiating the return, the prescription drug wholesale supplier of the person initiating the return, or the manufacturer of the drug.

(3)~~(2)~~ Storage and handling, and recordkeeping of these distributions must comply with the requirements for wholesale distributors under s. 499.0121.

(4) A person who applies for a permit as a restricted prescription drug distributor, or for the renewal of such a permit, must provide to the department the information required under s. 499.01.

(5)~~(3)~~ The department may issue permits to restricted prescription drug distributors and may adopt rules regarding the distribution of prescription drugs by hospitals, health care entities, charitable organizations, or other persons not involved in wholesale distribution, which rules are necessary for the protection of the public health, safety, and welfare.

Section 36. Subsection (7) is added to section 499.015, Florida Statutes, to read:

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

(7) A product registration is valid only for the company named on the registration and located at the address on the registration. A person whose product is registered by the department under this section must notify the department before any change in the name or address of the establishment to which the product is registered. If a person whose product is registered ceases conducting business, the person must notify the department before closing the business.

Section 37. Subsection (4) is added to section 499.03, Florida Statutes, to read:

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

(4) The department may adopt rules regarding persons engaged in lawful teaching, research, or testing who possess prescription drugs and may issue letters of exemption to facilitate the lawful possession of prescription drugs under this section.

Section 38. Subsection (3) is added to section 499.05, Florida Statutes, to read:

499.05 Rules.—

(3) The department shall adopt rules regulating recordkeeping for and the storage, handling, and distribution of medical devices and over-the-counter drugs to protect the public from adulterated products.

Section 39. Subsection (5) is added to section 499.65, Florida Statutes, to read:

499.65 Possession of ether without license or permit prohibited; confiscation and disposal; exceptions.—

(5) The department may adopt rules regarding persons engaged in lawful teaching, research, or testing who possess ether and may issue letters of exemption to facilitate the lawful possession of ether under this section.

Section 40. Subsection (2) of section 499.66, Florida Statutes, is amended to read:

499.66 Maintenance of records and sales of ether by manufacturers, distributors, and dealers; inspections.—

(2) Each sale or transfer ~~of 2.5 gallons, or equivalent by weight, or more~~ of ether shall be evidenced by an invoice, receipt, sales ticket, or sales slip which shall bear the name, address, and license or permit number of the manufacturer, distributor, or dealer and the purchaser or transferee, the date of sale or transfer, and the quantity sold or transferred. All original invoices, receipts, sales tickets, and sales slips shall be retained by the manufacturer, distributor, or dealer, and a copy thereof provided to the purchaser or transferee.

Section 41. Subsection (1) of section 499.67, Florida Statutes, is amended to read:

499.67 Maintenance of records by purchasers; inspections.—

(1) It is unlawful for any person ~~permittee~~ to purchase, receive, store, or use ether without maintaining an accurate and current written inventory of all ether purchased, received, stored, and used.

Section 42. Paragraph (e) of subsection (1) and subsection (2) of section 501.122, Florida Statutes, are amended to read:

501.122 Control of nonionizing radiations; laser; penalties.—

(1) DEFINITIONS.—For the purposes of this section:

(e) "Department" means the Department of Health ~~and Rehabilitative Services~~.

(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 ~~and Rehabilitative Services~~ shall adopt ~~promulgate such~~ rules ~~and regulations~~ as ~~it may determine to be~~ 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 ~~and Rehabilitative Services is further authorized~~:

(a) ~~To~~ Develop a program for registration of laser devices and uses and of identifying and controlling sources and uses of other nonionizing radiations.

(b) ~~To~~ Maintain liaison with, and receive information from, industry, industry associations, and other organizations or individuals relating to present or future radiation-producing products or devices.

(c) ~~To~~ Study and evaluate the degree of hazard associated with the use of laser devices or other sources of radiation.

(d) ~~To~~ Establish and prescribe performance standards for lasers ~~laser~~ and other radiation control, including requirements for 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.

(e) ~~To~~ Amend or revoke any performance standard established under the provisions of this section.

Section 43. Paragraph (b) of subsection (1) of section 513.045, Florida Statutes, is amended to read:

513.045 Permit fees.—

(1)

(b) Fees established pursuant to this subsection must be based on the actual costs incurred by the department in carrying out its responsibilities under this chapter. The fee for a permit may not be set at a rate that is more than $6.50 per space or less than $3.50 per space. Until rules setting these fees are adopted by the department, the permit fee per space is $3.50. The permit fee for a nonexempt recreational camp shall be based on an equivalency rate for which two camp occupants equal one space. ~~However, in no case may~~ The total fee assessed to an applicant may not be more than $600 or less than $50, except that a fee may be prorated on a quarterly basis.

Section 44. Section 513.05, Florida Statutes, is amended to read:

513.05 Rules.—The department may adopt ~~such~~ 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 ~~may be~~ necessary to implement this chapter. Such rules may include 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 45. Subsection (5) is added to section 514.011, Florida Statutes, to read:

514.011 Definitions.—As used in this chapter:

(5) "Portable pool" means a pool or spa, and related equipment systems of any kind, which is designed or intended to be movable from location to location.

Section 46. Section 514.0115, Florida Statutes, is amended to read:

514.0115 Exemptions from supervision or regulation; variances.—

(1) Private pools and water therapy facilities connected with facilities connected with hospitals, medical doctors' offices, and licensed physical therapy establishments shall be exempt from supervision under this chapter.

(2)(a) Pools serving no more than 32 condominium or cooperative units which are not operated as a public lodging establishment shall be exempt from supervision under this chapter, except for water quality.

(b) Pools serving condominium or cooperative associations of more than 32 units and whose recorded documents prohibit the rental or sublease of the units for periods of less than 60 days are exempt from supervision under this chapter, except that the condominium or cooperative owner or association must file applications with the department and obtain construction plans approval and receive an initial operating permit. The department shall inspect the swimming pools at such places annually, at the fee set forth in s. 514.033(3), or upon request by a unit owner, to determine compliance with department rules relating to water quality and lifesaving equipment. The department may not require compliance with rules relating to swimming pool lifeguard standards.

(3) A private pool used for instructional purposes in swimming shall not be regulated as a public pool.

(4) The department may grant variances from any rule adopted under this chapter pursuant to procedures adopted by department rule.

Section 47. Subsection (4) is added to section 514.03, Florida Statutes, to read:

514.03 Construction plans approval necessary to construct, develop, or modify public swimming pools or bathing places.—It is unlawful for any person or public body to construct, develop, or modify any public swimming pool or bathing place without a valid construction plans approval from the department.

(4) An approval of construction plans issued by the department under this section becomes void 1 year after the date the approval was issued if the construction is not commenced within 1 year after the date of issuance.

Section 48. Subsections (5) and (6) of section 514.031, Florida Statutes, are amended to read:

514.031 Permit necessary to operate public swimming pool or bathing place.—It is unlawful for any person or public body to operate or continue to operate any public swimming pool or bathing place without a valid permit from the department, such permit to be obtained in the following manner:

(5) Each such operating permit shall be renewed annually and the permit must be posted in a conspicuous place.

(6) An owner or operator of a public swimming pool, including, but not limited to, a spa, wading, or special purpose pool, to which admittance is obtained by membership for a fee shall post in a prominent location within the facility the most recent pool inspection report issued by the department pertaining to the health and safety conditions of such facility. The report shall be legible and readily accessible to members or potential members. The department shall adopt ~~promulgate~~ rules to enforce this subsection provision. A portable pool may not be used as a public pool.

Section 49. Subsections (4) and (5) of section 514.033, Florida Statutes, are amended to read:

514.033 Creation of fee schedules authorized.—

(4) Fees collected by the department in accordance with ~~the provisions of~~ this chapter shall be deposited into the Public Swimming Pool and Bathing Place Trust Fund for the payment of costs incurred in the administration of this chapter. Fees collected by county health departments performing functions pursuant to s. 514.025 shall be deposited into the County Health Department Trust Fund. Any fee collected under this chapter is nonrefundable.

(5) The department may not charge any ~~No other~~ fees ~~shall be charged~~ for services provided under ~~the provisions of~~ this chapter other than those fees authorized in this section. However, the department shall prorate the initial annual fee for an operating permit on a half-year basis.

Section 50. Subsection (5) is added to section 514.05, Florida Statutes, to read:

514.05 Denial, suspension, or revocation of permit; administrative fines.—

(5) Under conditions specified by rule, the department may close a public pool that is not in compliance with this chapter or the rules adopted under this chapter.

Section 51. This act shall take effect July 1, 1998.

Became a law without the Governor's approval May 22, 1998.

Filed in Office Secretary of State May 21, 1998.