

# SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based only on the provisions contained in the legislation as of the latest date listed below.)

BILL: CS/SB 2628

SPONSOR: Senator Myers

SUBJECT: Rulemaking Authority of the Department of Health

DATE: April 12, 2000 REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Munroe</u>	<u>Wilson</u>	<u>HC</u>	<u>Favorable/CS</u>
2.	_____	_____	<u>RC</u>	_____
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____

**I. Summary:**

The Department of Health (DOH) reported 203 rules, or portions thereof, to the Joint Administrative Procedures Committee (JAPC), pursuant to section 120.536(2)(b), Florida Statutes, as exceeding DOH’s statutory rulemaking authority. This section requires the Legislature to determine whether specific legislation should be enacted to authorize the rules, or portions thereof, identified by the agency. This bill provides specific statutory authority to authorize the rules reported by DOH.

This bill substantively amends the following ss. 154.011, 154.06, 381.003, 381.004, 381.0051, 381.0056, 381.0057, 381.006, 381.0062, 381.0065, 381.0072, 381.0086, 381.0098, 381.0101, 381.89, 381.0203, 383.011, 383.14, 383.19, 383.216, 384.33, 385.207, 391.026, 392.66, 395.401, 395.402, 401.35, 403.862, 404.056, 404.22, 489.553, 491.006, 491.0145, 499.003, 499.005, 499.0054, 499.01, 499.1021, 499.0122, 499.013, 499.015, 499.05, 499.701, 501.122, 513.05, 514.021, 766.1115, F.S.

This bill amends ss. 499.024 and 499.03, F.S., to incorporate statutory cross-references.

**II. Present Situation:**

**Administrative Procedure Act**

The Administrative Procedure Act (APA), contained in chapter 120, F.S., sets forth the general standards and procedures that all agencies must follow when adopting administrative rules. Agencies do not have inherent rulemaking authority.<sup>1</sup> Shaping public policy through lawmaking is the exclusive power of the Legislature.<sup>2</sup> The Legislature, however, may delegate to agencies the

<sup>1</sup>*Grove Isle, Ltd. v. State Dept. of Env'tl. Reg.*, 454 So.2d 571, 573 (Fla. 1st DCA 1984).

<sup>2</sup>*Jones v. Department of Rev.*, 523 So.2d 1211, 1214 (Fla. 1st DCA 1988).

authority to adopt rules<sup>3</sup> that implement, enforce, and interpret a statute.<sup>4</sup> An enabling statute that delegates rulemaking authority to an agency cannot provide unbridled authority to an agency to decide what the law is,<sup>5</sup> but must be complete,<sup>6</sup> must declare the legislative policy or standard,<sup>7</sup> and must operate to limit the delegated power.<sup>8</sup>

Agencies are not authorized to determine whether or not they want to adopt rules.<sup>9</sup> They are required by law to adopt as a rule each agency statement that meets the definition of a rule as soon as feasible and practicable. Rulemaking is presumed to be feasible and practicable unless the agency proves certain statutory standards. Whenever an act of the Legislature requires implementation by rule, an agency has 180 days after the effective date of the act to do so, unless the act provides otherwise.<sup>10</sup>

While agencies are required to adopt as a rule each agency statement that implements, interprets, or prescribes law or policy, there are limitations on the content and scope of these rules. When the Legislature adopted changes to the APA in 1996, it overturned case law that had permitted broader bases for rulemaking, and significantly narrowed the standard for rulemaking.<sup>11</sup> In 1996, ss. 120.52(8) and 120.536(1), F.S., provided in relevant part that, “A grant of rulemaking authority is necessary but not sufficient to allow an agency to adopt a rule; a specific law to be

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<sup>3</sup> A rule is defined by s. 120.52(15), F.S., to mean, “. . . each agency statement of general applicability that implements, interprets, or prescribes law or policy or describes the procedure or practice requirements of an agency and includes any form which imposes any requirement or solicits any information not specifically required by statute or by an existing rule. The term also includes the amendment or repeal of a rule. . . .”

<sup>4</sup>*State v. Atlantic C.L.R. Co.*, 47 So. 969 (1909).

<sup>5</sup>*State ex rel. Davis v. Fowler*, 114 So. 435, 437 (Fla. 1927).

<sup>6</sup>*Spencer v. Hunt*, 147 So. 282, 286 (Fla. 1933); accord *Florida Beverage Corp. v. Wynne*, 306 So.2d 200, 202 (Fla. 1st DCA 1975).

<sup>7</sup>*Chiles v. Children A, B, C, D, E, & F*, 589 So.2d 260, 268 (Fla. 1991).

<sup>8</sup>*Palm Beach Jockey Club, Inc. v. Florida State Racing Comm’n.*, 28 So.2d 330 (Fla. 1946).

<sup>9</sup>Section 120.54(1)(a), F.S.

<sup>10</sup>Section 120.54(1)(b), F.S.

<sup>11</sup>Before the 1996 revision to the APA, the courts had held that a rule is a valid exercise of delegated legislative authority if it is “reasonably related” to the enabling statute and not arbitrary and capricious. See, *General Tel. Co. of Fla. v. Florida Pub. Serv. Comm’n*, 446 So.2d 1063 (Fla. 1984); *Department of Labor and Employment Sec., Div. of Workers’ Compensation v. Bradley*, 636 So.2d 802 (Fla. 1st DCA 1994); *Florida Waterworks Ass’n v. Florida Pub. Serv. Comm’n*, 473 So.2d 237 (Fla. 1st DCA 1985); *Department of Prof’l Regulation, Bd. of Med. Exam’rs v. Durrani*, 455 So.2d 515 (Fla. 1st DCA 1984); *Agrico Chem. Co. v. State, Dept. of Env’tl. Regulation*, 365 So.2d 759 (Fla. 1st DCA 1978); *Florida Beverage Corp., Inc. v. Wynne*, 306 So.2d 200 (Fla. 1st DCA 1975).

implemented is also required. An agency may adopt only rules that implement, interpret, or make specific the *particular powers and duties* granted by the enabling statute. [*emphasis added*].”

When this new provision was challenged, the courts had difficulty construing the “particular powers and duties” language. In an administrative proceeding, a judge ruled that the phrase meant an enabling statute must detail the powers and duties that would be the subject of the rule.<sup>12</sup> On appeal, however, the First District Court of Appeals held that a broader interpretation was proper, and stated that the test to determine whether a rule is a valid exercise of delegated authority is whether:

the rule falls within the *range of powers* the Legislature has granted to the agency for the purpose of enforcing or implementing the statutes within its jurisdiction. A rule is a valid exercise of delegated legislative authority if it regulates a matter *directly within the class of powers and duties identified in the statute* to be implemented. This approach meets the legislative goal of restricting the agencies’ authority to promulgate rules, and, at the same time, ensures that the agencies will have the authority to perform the essential functions assigned to them by the Legislature [*emphasis added*].<sup>13</sup>

In 1999, the Legislature rejected the First District’s broad “class of powers and duties” test when it enacted 99-379, Laws of Florida (L.O.F.). The APA now provides:

A grant of rulemaking authority is necessary but not sufficient to allow an agency to adopt a rule; a specific law to be implemented is also required. An agency may adopt only rules that implement or interpret the *specific powers and duties* granted by the enabling statute. No agency shall have authority to adopt a rule only because it is reasonably related to the purpose of the enabling legislation and is not arbitrary and capricious or is within the agency's class of powers and duties, nor shall an agency have the authority to implement statutory provisions setting forth general legislative intent or policy. Statutory language granting rulemaking authority or generally describing the powers and functions of an agency shall be construed to extend no further than implementing or interpreting the specific powers and duties conferred by the same statute (*emphasis added*).<sup>14</sup>

The Legislature recognized that as a result of this amendment some existing rules might no longer be authorized, and consequently, also provided that agencies could temporarily shield unauthorized rules from rule challenges based on the amendment until July 1, 2001.<sup>15</sup> In order to have shielded a rule, agencies were required to have submitted to JAPC by October 1, 1999, a list

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<sup>12</sup> *St. Johns River Water Management District v. Consolidated-Tomoka Land Co., et al*, 717 So.2d 72 (Fla. 1st DCA 1998).

<sup>13</sup> *Id.*

<sup>14</sup> Sections 120.52(8) and 120.536(1), F.S.

<sup>15</sup> Section 120.536(2)(b), F.S.

of rules, or portions thereof, adopted prior to June 18, 1999, which exceeded the newly amended rulemaking authority standard.

The statutory directive further provided that the Legislature is required to consider at the 2000 Regular Session whether specific legislation authorizing the shielded rules, or portions thereof, should be enacted. Thereafter, agencies must begin repeal proceedings by January 1, 2001, for shielded rules for which authorizing legislation does not exist. On or after July 1, 2001, the JAPC or any substantially affected person may petition an agency to repeal any rule because it exceeds the rulemaking authority permitted by the new standard.

### **Department of Health**

The Department of Health (DOH) shielded 203 rules. The rules which are addressed by the bill, along with the related statutes relate to the following subject matters under the regulatory jurisdiction of DOH:

- 64B-25-28, Florida Administrative Code (F.A.C.), specifies requirements for the certification of master social workers under DOH. Section 491.0145, F.S., provides requirements for the certification of master social workers by DOH.
- 64C-1, F.A.C., provides for rules relating to definitions; program organization; and responsibilities of applicants and patients for the Division of Children's Medical Services (CMS). Section 391.026, F.S., gives DOH powers, duties and responsibilities over CMS which include, but are not limited to: providing or contracting for the provision of health services to eligible individuals; determining the medical and financial eligibility of individuals seeking health services from the program; coordinating a comprehensive delivery system; promoting, establishing, and coordinating programs relating to CMS in cooperation with other public and private agencies and coordinating the funding of health care programs with federal, state, or local indigent health care funding mechanisms; and overseeing and operating the CMS network, but does not give DOH specific rulemaking authority to adopt definitions and other requirements for its responsibilities relating to CMS.
- 64C-2, F.A.C., provides for rules relating to application for services; eligibility for treatment; and determination of continuing eligibility for CMS. (s. 391.026, F.S.)
- 64C-3, F.A.C., provides for rules relating to methods of resource development and allocation for CMS; reimbursement of services rendered to clients by physicians and other medically necessary expenses, billing, and payment requirements of CMS providers. (s. 391.026, F.S.)
- 64C-4, F.A.C., provides for rules relating to personnel and facility standards for CMS. (s. 391.026, F.S.)
- 64C-5, F.A.C., provides for rules relating to methods of service delivery by CMS providers. (s. 391.026, F.S.)
- 64C-6, F.A.C., provides for rules relating to the CMS Regional Perinatal Intensive Care Centers program. Section 383.19, F.S., requires DOH to adopt rules that specify standards for development and operation of regional perinatal intensive care centers and requirements

for the population to be served, but does not give DOH specific rulemaking authority to adopt definitions.

- 64C-7, F.A.C., provides for rules relating prenatal and postnatal risk screening and infant screening for metabolic, hereditary, and congenital disorders. Section 383.14, F.S., requires DOH to promote the screening of all infants born in Florida for phenylketonuria and other metabolic, hereditary, and congenital disorders known to result in significant impairment of health or intellect, as screening programs accepted by current medical practice become available and practical in the judgment of the department.
- 64D-1, F.A.C., specifies rules relating to DOH's enforcement of the Florida Clean Indoor Air Act. Part II, ch. 386, F.S., provides for the Florida Clean Indoor Air Act, and requires DOH to investigate complaints of alleged violators, but does not give DOH specific rulemaking authority to adopt definitions relating to its enforcement of the Act.
- 64D-2, F.A.C., specifies rules relating to DOH's adoption of definitions relating to HIV/AIDS; requirements for confidentiality with HIV/AIDS; and HIV testing requirements. Section 381.004, provides requirements for HIV/AIDS testing, including confidentiality requirements but does not give DOH specific rulemaking authority to provide definitions, procedures for providing access to confidential information, and requirements for testing and registered testing sites.
- 64D-3, F.A.C., provides for DOH's authority to control communicable diseases and conditions which may affect public health, including blood testing of pregnant women for syphilis; patient treatment and follow-up for tuberculosis; and the execution of certificates for involuntary commitments for tuberculosis patients. Chapter 384, F.S., provides for DOH's authority to control sexually transmissible diseases, but does not give DOH specific rulemaking authority for reporting, investigation, quarantine, and procedures for the management of such diseases. Chapter 392, F.S., provides for DOH's authority to take measures to control and treat patients with tuberculosis, but does not give DOH specific rulemaking authority for reporting, investigation, quarantine, and procedures for the management of such diseases.
- 64E-2, F.A.C., provides for DOH's authority over emergency medical services (EMS), including but not limited to: definitions; EMS basic life support service (ground) licensure; EMS advanced life support service (ground) licensure; requirements for EMS medical directors; EMS air ambulance licensure; emergency medical technician (EMT) certification; paramedics; examinations; records and reports; prehospital requirements for trauma care; trauma transport protocols; adult trauma scorecard methodology; pediatric trauma scorecard methodology; trauma registry; trauma agency formation requirements; trauma agency plan approval and denial process; trauma agency implementation and operation requirements; apportionment of state-approved trauma centers or state-approved pediatric trauma referral centers within a trauma service area; recognition of certificates of public necessity and convenience issued by local governments; and convicted felons applying for EMT or paramedic certification or recertification, but does not give DOH specific rulemaking authority to recognize the issuance of certificates of public convenience and necessity by local governments; to specify EMS medical director's standing orders and protocols; to require

medical director to participate in EMS service's quality assurance system; to authorize an EMS medical director to substitute equipment, supplies and medications or personnel; to perform advanced life support functions; to require EMS medical director to meet minimum qualifications to serve as an EMS crew member; and minimum qualifications for education and experience requirements for medical directors; regrading, examination review, passing scores, scheduling of examinations; safeguarding of records; to require licensees to display licenses; to require EMS ambulance service to maintain personnel records; to maintain a copy of trauma transport protocols; or requirements for determining whether a convicted felon is eligible for certification or recertification. Part III, chapter 401, F.S., provides for the regulation of emergency medical transportation services. Section 401.25 (2)(d), F.S., authorizes the governing body of each county to adopt ordinances that provide reasonable standards for certificates of public convenience and necessity for basic or advanced life support services and air ambulances. Under s. 401.35, F.S., DOH has rulemaking authority to enforce provisions relating to the regulation of emergency medical services. Section 401.27, F.S., establishes standards and certification and recertification requirements for emergency medical technicians and paramedics. Section 395.401, F.S., requires DOH to establish a state trauma system plan and a trauma agency may not operate unless the department has approved the local or regional trauma services plan of the agency.

- 64E-4, F.A.C., prescribes requirements for DOH's control of nonionizing radiation hazards including but not limited to: radiation protection surveys, but does not authorize DOH to require measurements. Section 501.122, F.S., authorizes DOH to adopt rules as necessary to protect the health and safety of persons exposed to laser devices and other nonionizing radiation, except electrical transmission and distribution lines and substation facilities subject to regulation by the Department of Environmental Protection.
- 64E-5, F.A.C., prescribes requirements for DOH's control of radon hazards including but not limited to: definitions; general provisions; certification requirements for radon measurement specialists and technicians; certification requirements for radon mitigation specialists and technicians; certification requirements for radon measurement businesses; and certification requirements for radon mitigation businesses; therapeutic x-ray systems of less than 1MeV; x-ray and electron therapy systems with energies of 1 Me V and above; surveys for area requirements relating to radiation safety for analytical x-ray equipment; personnel requirements relating to radiation safety for analytical x-ray equipment; registration requirements for particle accelerators; particle accelerators for therapeutic use on humans; limitations imposed for radiation safety requirements for the use of particle accelerators; shielding and safety design requirements for the use of particle accelerators; particle accelerators controls and interlock systems; and operating procedures for particle accelerators; and radiation monitoring requirements. Section 404.051, F.S., authorizes DOH to adopt rules and standards which may provide for licensure, registration, or regulation relating to the manufacture, production, transportation, use, possession, handling, treatment, storage, disposal, sale, lease, or other disposition of radioactive material, including naturally occurring radioactive material and low-level radioactive waste, and radiation machines.
- 64E-6, F.A.C., specifies requirements for DOH's regulation of onsite sewage treatment and disposal systems including but not limited to: definitions; system size determinations; disposal of septage; standards for the construction, operation, and maintenance of aerobic treatment

units; construction standards for drain fields, systems; registration requirements for the onsite sewage treatment and disposal industry regulated by DOH; master septic tank contractors registration requirements; and location and installation requirements for performance-based treatment systems. Part III, ch. 489, F.S., provides requirements for the regulation of septic tank contracting by DOH.

- 64E-8, F.A.C., provides requirements for drinking water systems enforced by DOH including but not limited to: definitions; operation and maintenance of drinking water systems; and water quality standards and monitoring. Section 381.0062, F.S., requires DOH to have general supervision and control over all private water systems, multifamily water systems, and public water systems not included in the Florida Safe Drinking Water Act, and over those aspects of the public water supply program for which it has duties and responsibilities.
- 64E-9, F.A.C., specifies requirements for public swimming pools and bathing places enforced by DOH including but not limited to definitions. Section 514.021, F.S., requires DOH to adopt and enforce administrative rules to protect the health, safety, or welfare of persons using public swimming pools and bathing places.
- 64E-11, F.A.C., specifies requirements for food hygiene enforced by DOH including but not limited to: definitions; food supplies; food equipment and utensils; personnel requirements; operations; and food protection. Section 381.0072, F.S., requires DOH to adopt rules consistent with law to ensure the protection of the public from food-borne illness and such rules must provide standards and requirements for the storage, preparation, serving, or display of food in food service establishments.
- 64E-12, F.A.C., prescribes sanitary practices relating to construction, operation, and maintenance of community-based-residential facilities including but not limited to definitions. Section 381.006, F.S., requires DOH to conduct an environmental health program as a part of its public health mission to detect and prevent disease caused by natural and manmade factors in the environment. The environmental health program includes but is not limited to: a drinking water function; an environmental health surveillance function; a toxicology and hazard assessment function; a sanitary nuisance function; a migrant labor function; a public facilities function; an onsite sewage treatment and disposal function; a function to control diseases transmitted from animals to humans; an environmental epidemiology function; mosquito and pest control function; a radiation control function; a public swimming and bathing facilities function; a mobile home park, lodging park, recreational park, and recreational camp function; a sanitary facilities function; and a group- care-facilities function.
- 64E-14, F.A.C., prescribes minimum sanitary requirements to protect the health and safety of person residing in migrant labor housing including but not limited to: definitions; sites; building and structures; field sanitation facilities; food service facilities; and fire protection. Section 381.0086, F.S., requires DOH to adopt rules to protect the health and safety of migrant farm workers and other migrant labor camp or resident migrant housing occupants. (see also, section 381.006, F.S.)
- 64E-15, F.A.C., specifies requirements for mobile home, lodging, and recreational vehicle parks and camps regulated by DOH including but not limited to definitions. Chapter 513,

F.S., requires DOH and its representative county health departments to administer and enforce regulations relating to sanitation, control of communicable diseases, illnesses, and hazards to health among humans in mobile home parks, lodging parks, recreational vehicle parks, and recreational camps. (see also, section 381.006, F.S.)

- 64E-16, F.A.C., prescribes minimum sanitary practices relating to the management of biomedical waste including but not limited to: definitions; and the procedures for the issuance of permits to biomedical waste facilities; and enforcement and penalties. Section 381.0098, F.S., requires DOH, except, as otherwise provided in the section to regulate the packaging, transport, storage, and treatment of biomedical waste. Under that section, the Department of Environmental Protection regulates onsite incineration and disposal of biomedical waste. Both agencies must enter into an interagency agreement to ensure maximum efficiency in coordinating, administrating, and regulating biomedical waste.
- 64E-17, F.A.C., specifies minimum safety requirements for tanning facilities including but not limited to: definitions; and inspection, enforcement, and penalties. Section 381.89, F.S., requires DOH to regulate tanning facilities and to adopt rules specifying 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.
- 64E-18, F.A.C., provides standards for the certification of environmental health professionals by DOH including but not limited to definitions. Section 381.0101, F.S., provides for the regulation of environmental health professionals by DOH.
- 64F-2, F.A.C., provides requirements for the Healthy Start Coalitions including but not limited to: definitions; coalition requirements; establishment of coalitions; and approval of coalitions; and operation of coalitions. Chapter 383, F.S., requires DOH to administer or provide maternal and child health services to residents of Florida. Section 383.216, F.S., requires DOH to cooperate with localities which wish to establish prenatal and infant health care coalitions.
- 64F-3, F.A.C., provides requirements for the coordination of Healthy Start Coalitions including but not limited to: county health department responsibilities; Healthy Start Coalition responsibilities; Healthy Start coordination system; care coordination services; and enhanced services. Section 383.011, F.S., requires DOH to administer or provide maternal and child health services to residents of Florida.
- 64F-4, F.A.C., provides requirements for physically drug dependent newborns, substance exposed children, children adversely affected by alcohol, and the families of these children including but not limited to: definitions; reducing the impact of prenatal drug abuse; reporting requirements for physically drug dependent newborns, substance exposed children, children adversely affected by alcohol abuse; and district responsibilities for interprogram coordination of the investigation and other services provided to substance exposed children and their families. (Section 383.011, F.S.)
- 64F-5, F.A.C., specifies requirements for sudden infant death syndrome recognition and response by DOH including but not limited to: definitions; and state health office

responsibilities. Section 383.3362, F.S., specifies responsibilities for DOH to collaborate with other agencies in the development and presentation of training programs for sudden infant death syndrome (SIDS), to maintain a database of statistics on reported SIDS deaths, to serve as liaison and coordinate activities with the Florida SIDS Alliance, to maintain a library of SIDS material for public dissemination, and to coordinate the activities and promote a link between the fetal and infant mortality review committees of local healthy start coalitions, the local SIDS alliance, and other related support groups.

- 64F-6, F.A.C., specifies requirements for the school health services implemented by DOH including but not limited to: definitions; school health services plan; screening; meeting emergency health needs; maintenance of records; exceptional student education program; and supplemental school health services. Section 381.0056, F.S., requires DOH, in cooperation with the Department of Education, to supervise the administration of the school health services program and perform periodic program reviews.
- 64F-7, F.A.C., specifies requirements for family planning services implemented by DOH including but not limited to: definitions; eligibility; informed consent; services; revisits; temporary contraceptive methods; voluntary sterilization; and infertility services. Section 381.0051, F.S., requires DOH to implement a comprehensive family planning program which must include education and counseling programs, prescription for and provision of all medically recognized methods of contraception, medical evaluation, and an emphasis on service to post partum mothers.
- 64F-8, F.A.C., specifies requirements for comprehensive health improvement projects including definitions, and minimum requirements. Section 385.103, F.S., requires DOH to assist county health departments in developing and operating comprehensive health improvement projects throughout Florida and at a minimum the projects must address the chronic diseases of cancer, diabetes, heart disease, hypertension, renal disease, and chronic obstructive lung disease.
- 64F-9, F.A.C., specifies requirements for the epilepsy services program implemented by DOH including but not limited to: definitions; eligibility for epilepsy services; individual action plan; prevention program activities; and reporting requirements. Section 385.207, F.S., establishes the Epilepsy Services Program within the Department of Health for the care and assistance of persons with epilepsy. Under the program the department must promote and assist in the continued development and expansion of programs for the case management, diagnosis, care and treatment of persons with epilepsy, including required pharmaceuticals, medical procedures, and techniques which will have a positive effect in the care and treatment of such persons. The department's responsibilities include the development of standards for determining eligibility for care and treatment of persons with epilepsy; the establishment of screening programs for epilepsy; and the provision of assistance in developing programs which target prevention of and early intervention in epilepsy.
- 64F-10, F.A.C., specifies requirements for primary care projects including but not limited to: definitions; eligibility criteria; eligibility determination process; fees; primary care project services; intake and registration procedures; twenty-four hour telephone access and evening and weekend clinic services; health records; and quality control and utilization review.

Section 154.011, F.S., requires DOH to monitor and administer certain primary care programs within county health departments.

- 64F-11, F.A.C., provides for requirements for the Volunteer Health Care Provider program. Section 766.1115, F.S., requires DOH to adopt rules to implement the Access to Health Care Act which extends sovereign immunity to the acts of certain health care providers who execute a contract with DOH, county health departments, a special taxing district with health care responsibilities, or a hospital owned and operated by a governmental entity when the provider delivers health care services as a governmental agent.
- 64F-12, F.A.C., specifies requirements for DOH's regulation of drugs, devices, and cosmetics including but not limited to: definitions; false and misleading advertising; prohibited acts; requirements for intrastate investigational drug program; suspension and revocation; labeling requirements for drugs and devices; cosmetic labeling requirements; wholesale distribution of prescription drugs - exceptions and specific distributions authorized; records of drugs, cosmetics, and devices; receipt, storage and security of prescription drugs; licensing, application, and permitting; product registration; certificates of free sale; fees; inspections, investigations, and monitoring; trade secrets; and ether applications, licensing, permitting, records, security, distributing, and disposal. Part I, ch. 499, F.S., provides requirements for the Florida Drug and Cosmetic Act to administered by DOH.
- 64F-15, F.A.C., relating to DOH's administration of the statewide pharmaceutical contract. Part I, ch. 499, F.S., provides requirements for the Florida Drug and Cosmetic Act to administered by DOH.
- 64F-16, F.A.C., specifies eligibility and fee assessments for services offered by county public health units including but not limited to definitions; income eligibility determination; income verification; vaccine charges and fees; fee exemption; sliding fee scales; waiver of charges; limitation of income eligibility; continuity of care for pregnant women; county health department responsibilities; and disenrollment. (Section 154.011, F.S.)

### III. Effect of Proposed Changes:

**Section 1.** Amends s. 154.011, F.S., to authorize rules for the operation of primary care programs which may include income eligibility, income verification, continuity of care, client services, client enrollment and disenrollment, eligibility, intake, recordkeeping, coverage, and quality control under ch. 64F-16, F.A.C.

**Section 2.** Amends s. 154.06, F.S., to authorize rules for establishing fee schedules for public health services rendered through the county health departments to include provisions for fee assessments, copayments, sliding fee scales, fee waivers, and fee exemptions under ch. 64F-16, F.A.C.

**Section 3.** Amends s. 381.003, F.S., to authorize Rule 64D-3.013, F.A.C., relating to the prevention and control of communicable diseases to include definitions and procedures for the management of specific diseases under ch. 64D-3, F.A.C.

**Section 4.** Amends s. 381.004, F.S., to authorize Rules 64D-2002, 64D-2.003, and 64D-2.004 (7), F.A.C., relating to definitions, confidentiality for the testing of human immunodeficiency virus, and requirements for registered testing sites.

**Section 5.** Amends s. 381.0051, F.S., to authorize rules for definitions and requirements for eligibility, informed-consent services, revisits, temporary contraceptive methods, voluntary sterilization, and infertility services under ch. 64F-7, F.A.C., relating to family planning services.

**Section 6.** Amends s. 381.0056, F.S., to authorize rules for school health services plans; screening; meeting emergency health needs; maintenance of records; and coordinating exceptional student education programs under ch. 64F-6, F.A.C., relating to the school health services program.

**Section 7.** Amends s. 381.0057, F.S., to authorize Rule 64F-6.008, F.A.C., for supplemental school health services under ch. 64F-6, F.A.C., relating to the school health services program.

**Section 8.** Amends s. 381.006, F.S., to authorize rules under ch. 64E-12, F.A.C., for definitions and food service relating to group-care facilities.

**Section 9.** Amends s. 381.0062, F.S., to authorize Rule 64E-8.004 (6)(e), F.A.C., relating to installation requirements for certain public water systems.

**Section 10.** Amends s. 381.0065, F.S., to authorize Rules 64E-6.005(8), 64E-6.002, 64E-6.001(2), and 64E-6.010, F.A.C., under ch. 64E-6, F.A.C., relating to DOH's regulation of onsite sewage treatment and disposal systems.

**Section 11.** Amends s. 381.0072, F.S., to authorize rules under ch. 64E-11, F.A.C., which specifies requirements for definitions; food supplies; food equipment and utensils; personnel requirements; operations; and food protection relating to food hygiene regulations enforced by DOH.

**Section 12.** Amends s. 381.0086, F.S., to authorize rules for definitions; sites; building and structures; field sanitation facilities; and food service facilities; under ch. 64E-14, F.A.C., relating to minimum sanitary requirements to protect the health and safety of persons residing in migrant labor housing.

**Section 13.** Amends s. 381.0098, F.S., to authorize rules for definitions relating to the management of biomedical waste, the procedures for the issuance of permits to biomedical waste facilities, and enforcement and penalties under ch. 64E-16, F.A.C.

**Section 14.** Amends s. 381.0101, F.S., to authorize rules for definitions relating to certification of environmental health professionals under ch. 64E-18, F.A.C.

**Section 15.** Amends s. 381.0203, F.S., to authorize Rules 64F-15.001, 64F-15.002, under ch. 64F-15, F.A.C., relating to DOH's administration of the statewide pharmaceutical contract.

**Section 16.** Amends s. 381.89, F.S., to authorize rules for definitions, and inspection, enforcement, and penalties relating to minimum safety requirements for tanning facilities under ch. 64E-17, F.A.C.

**Section 17.** Amends s. 383.011, F.S., to authorize rules for the requirements of the coordination of Healthy Start Coalitions under ch. 64F-3, F.A.C., and to authorize rules for physically drug dependent newborns, substance exposed children, children adversely affected by alcohol, and the families of these children under ch. 64F-4, F.A.C.

**Section 18.** Amends s. 383.14, F.S., to authorize rules for definitions relating to prenatal and postnatal risk screening and infant screening for metabolic, hereditary, and congenital disorders under ch. 64C-7, F.A.C.

**Section 19.** Amends s. 383.19, F.S., to authorize rules for definitions relating to standards for development and operation of regional perinatal intensive care centers and requirements for the population to be served under ch. 64C-6, F.A.C.

**Section 20.** Amends s. 383.216, F.S., to authorize rules for definitions, coalition requirements, establishment of coalitions, and approval of coalitions, and operation of coalitions relating to Healthy Start Coalitions under ch. 64F-2, F.A.C.

**Section 21.** Amends s. 384.33, F.S., to authorize rules for blood testing of pregnant women for syphilis and other sexually transmissible diseases to control communicable diseases and conditions which may affect the public health under ch. 64D-3, F.A.C.

**Section 22.** Amends s. 385.207, F.S., to authorize rules for eligibility for epilepsy services, requirements for records and forms, and the scope of service, relating to the epilepsy services program implemented by DOH under ch. 64F-9, F.A.C.

**Section 23.** Amends s. 391.026, F.S., to authorize rules for the Children's Medical Services program under chs. 64FC-1, 64C-2, 64C-3, 64C-4, and 64C-5, F.A.C.

**Section 24.** Amends s. 392.66, F.S., to authorize Rules 64D 3.024(1), (2), and (6), F.A.C. and 64D-3.026, F.A.C., relating to tuberculosis control under ch. 64D-3, F.A.C.

**Section 25.** Amends s. 395.401, F.S., to authorize Rules 64E-2.019 and 64E-2.022, F.A.C., for trauma agencies relating to DOH's authority over emergency medical services under ch. 64E-2, F.A.C.

**Section 26.** Amends s. 395.402, F.S., to authorize Rule 64E-2.022, F.A.C., for trauma agencies relating to DOH's authority over emergency medical services under ch. 64E-2, F.A.C.

**Section 27.** Amends s. 401.35, F.S., to authorize rules for medical transportation services to include definitions and requirements relating to staffing for air ambulance services, and licensure and certification relating to DOH's authority over emergency medical services under ch. 64E-2, F.A.C.

**Section 28.** Amends s. 403.862, F.S., to authorize Rule 64E-8.001, F.A.C., relating to definitions for the regulation of drinking water systems, under ch. 64E-8, F.A.C.

**Section 29.** Amends s. 404.056, F.S., to authorize rules for enforcement procedures, certification, and reporting requirements for DOH's control of radon hazards under ch. 64E-5, F.A.C.

**Section 30.** Amends s. 404.22, F.S., to authorize rules relating to inspection of and standards for radiation machines and their operation under ch. 64E-5, F.A.C.

**Section 31.** Amends s. 489.553, F.S., to authorize Rule 64E-6.019, F.A.C., for registration requirements of septic tank contractors under ch. 64E-6, F.A.C., relating to the regulation of onsite sewage treatment and disposal systems.

**Sections 32-33.** Amend ss. 491.006 and 491.0145, F.S., to authorize rules for nonrefundable application fees relating to the certification of master social workers under ch. 64B-25-28, F.A.C.

**Section 34.** Amends s. 499.003, F.S., to authorize Rule 64F-12.001, F.A.C., relating to definition of "distribute" for DOH's regulation of drugs, devices, and cosmetics under the Florida Drug and Cosmetic Act.

**Sections 35.** Amends s. 499.005, F.S., to authorize Rule 64F-12.004, F.A.C., for prohibited acts under the Florida Drug and Cosmetic Act, relating to DOH's regulation of drugs, devices, and cosmetics under ch. 64F-12, F.A.C.

**Section 36.** Amends s. 499.0054, F.S., to authorize Rule 64F-12.002, F.A.C., for false and misleading labeling or advertising relating to DOH's regulation of drugs, devices, and cosmetics under ch. 64F-12, F.A.C.

**Section 37.** Amends s. 499.01, F.S., to authorize Rule 64F-12.012, F.A.C., for records of drugs, cosmetics and devices relating to DOH's regulation of drugs, devices, and cosmetics under ch. 64F-12, F.A.C.

**Section 38.** Amends s. 499.0121, F.S., to authorize Rules 64F-12.013, 64F-12.012, and 64F-12.015, F.A.C., for requirements for the receipt, storage, and security of prescription drugs; records of drugs, cosmetics and devices, and procedures for licensing, applications, and permits relating to DOH's regulation of drugs, devices, and cosmetics under ch. 64F-12, F.A.C.

**Section 39.** Amends s. 499.0122, F.S., to authorize Rule 64F-12.012, F.A.C., for records of drugs, cosmetics and devices relating to DOH's regulation of drugs, devices, and cosmetics under ch. 64F-12, F.A.C.

**Section 40.** Amends s. 499.013, F.S., to authorize Rules 64F-12.015 and 64F-12.012, F.A.C., for procedures for licensing, applications, and permits; and records of drugs, cosmetics and devices relating to DOH's regulation of drugs, devices, and cosmetics under ch. 64F-12, F.A.C.

**Section 41.** Amends 499.015, F.S., to authorize Rules 64F-12.016, F.A.C., for the registration of products not in compliance with the Federal Food, Drug, and Cosmetic Act and related federal regulations relating to DOH's regulation of drugs, devices, and cosmetics under ch. 64F-12, F.A.C.

**Sections 42-43.** Amend ss. 499.024 and 499.03, F.S., to revise statutory cross-references.

**Section 44.** Amends s. 499.05, F.S., to authorize Rules 64F-12.016, 64F-12.017, 64F-12.018, and 64F-12.021, F.A.C., for definitions; false and misleading advertising; prohibited acts; requirements for intrastate investigational drug program; suspension and revocation; labeling requirements for drugs and devices; cosmetic labeling requirements; wholesale distribution of prescription drugs - exceptions and specific distributions authorized; records of drugs, cosmetics, and devices; receipt, storage and security of prescription drugs; licensing, application, and permitting; product registration; certificates of free sale; fees; inspections, investigations, and monitoring; trade secrets; and other applications, licensing, permitting, records, security, distributing, and disposal relating to DOH's regulation of drugs, devices, and cosmetics under ch. 64F-12, F.A.C.

**Section 45.** Amends s. 499.701, F.S., to authorize Rule 64F-12.022, F.A.C., for recordkeeping and security requirements for the regulation of ether pursuant to DOH's regulation of drugs, devices, and cosmetics under ch. 64F-12, F.A.C.

**Section 46.** Amends s. 501.122, F.S., to authorize rules for radiation surveys and measurements and the methods and instruments used to perform surveys relating DOH's control of nonionizing radiation hazards under ch. 64E-4, F.A.C.

**Section 47.** Amends s. 513.05, F.S., to authorize rules for definitions relating to mobile home, lodging, and recreational vehicle parks and camps regulated by DOH under ch. 64E-15, F.A.C.

**Section 48.** Amends s. 514.021, F.S., to authorize rules for definitions relating to public swimming and bathing places under ch. 64E-9, F.A.C.

**Section 49.** Amends s. 766.1115, F.S., to authorize rules for definitions relating to the Volunteer Health Care Provider program under ch. 64F-11, F.A.C.

**Section 50.** Provides an effective date of upon becoming law.

**IV. Constitutional Issues:**

**A. Municipality/County Mandates Restrictions:**

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

**B. Public Records/Open Meetings Issues:**

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Subsections 24(a) and (b) of the Florida Constitution.

**C. Trust Funds Restrictions:**

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

**V. Economic Impact and Fiscal Note:****A. Tax/Fee Issues:**

None.

**B. Private Sector Impact:**

None.

**C. Government Sector Impact:**

None.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Amendments:**

None.