### 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.)

SPONSOR: Health, Aging and Long-Term Care Committee and Senator Clary

SUBJECT: Department of Health

DATE	April 16, 1999	REVISED: <u>4/20/99</u>		
1. 2. 3.	ANALYST Munroe Wilson	STAFF DIRECTOR Wilson Wilson	REFERENCE HC GO FP	ACTION Favorable/CS Fav/14 amendments
4. 5.				

#### I. Summary:

The Committee Substitute for Senate Bill 2220 makes revisions to address glitches in the statutes relating to the administration of the Department of Health. The bill gives the Department of Health specific authority for certain existing administrative rules, updates statutory references to the Department of Health and makes changes to comply with changes in federal law.

Significant provisions of the bill: modify the Department of Health's authority in the use of incentives and promotional items in disease prevention and health education; revise and rename divisions within the department; authorize the Department of Health to adopt rules for certain group-care facilities and to impose fines for violation of its rules; revise the requirements and the membership of the Diabetes Advisory Council; grant the Department of Health specific statutory authority to approve training programs for emergency medical technicians and paramedics and to impose minimum requirements on permitted emergency medical vehicles; allow the Department of Health to require documents to be submitted by emergency medical licensees and emergency medical certification applicants to the department under oath; update career service exemptions; impose additional requirements on co-payments made pursuant to primary care challenge grants; revise requirements for the Department of Health to hold formal hearings for disqualification reviews of certified nurse assistants; delay and revise the implementation of a plan to reimburse providers through the Children's Medical Services Program for services provided to Medicaid eligible children with special needs on a capitated basis; allow nursing homes to administer medical oxygen to their residents without getting a pharmacy license; authorize the Department of Health to contract with the Department of Children and Family Services to conduct administrative hearings for matters relating to the Special Supplemental Nutrition Program for Women, Infants and Children and the Children's Medical Services Program; permit the Department of Health to purchase automobiles for use by county health departments; eliminate the Department of Health's responsibility for monitoring the transportation of radioactive materials; revise the requirements for the release of preliminary results of an HIV test so that the results for a mother who has just delivered an infant may be released to the mother at the time of delivery to enhance treatment options for the mother's infant; revise requirements for the performance of an HIV test on

persons who die during treatment; authorize the Department of Health to adopt rules for family planning; revise the membership and responsibilities of the Health Information Systems Council; define multi-family water system; revise the Department of Health procedures for birth records in the Office of Vital Statistics and authorize the department to retain fees paid to that office for birth certificates in lieu of being transferred into the General Revenue Fund; eliminate requirements for the Department of Health to reimburse hospitals for costs of furnishing data for the cancer registry; revise penalties for certain violations of the Florida Drug and Cosmetic Act, and authorize federal, state, and local government employees to possess prescription drug samples when acting within the scope of their employment; prohibit the distribution of a legend device to a patient without a prescription or order from a licensed practitioner; revise the Department of Health's authority to issue a cease and desist order so that it has immediate effect and provide for an administrative hearing to abate or modify the department's order; authorize the Department of Health to use earned dollars to improve the A.G. Holley Hospital through a legislative budget request and to establish an advisory body for the facility; name the new Department of Health headquarters the "E. Charlton Prather, M.D., Building and the Division of Health's headquarters in honor of Dr. Wilson T. Sowder and facilities that will house the department's laboratory facilities in recognition of Senator Myers; authorizes the Department of Health to apply for and become a National Environmental Laboratory Accreditation program accrediting authority.

This bill substantially amends the following sections of the Florida Statutes: 20.43, 110.205, 120.80, 154.504, 287.155, 372.6672, 381.004, 381.0051, 381.006, 381.0061, 381.0062, 381.90, 382.003, 382.004, 382.008, 382.013, 382.015, 382.016, 382.019, 382.025, 382.0255, 383.14, 385.202, 385.203, 391.028, 391.0315, 392.69, 401.25, 401.27, 401.30, 401.35, 409.9126, 465.019, 499.005, 499.007, 499.028, 499.066, 499.069, 742.10, 39.303, 385.203, 391.021, 391.221, 391.222, 391.223, and 63.162.

The bill creates section 401.49, Florida Statutes.

This bill repeals the following sections of the Florida Statutes: 381.731(3), 383.307(5), 404.20(7), and 409.9125.

This bill creates four sections that have not been designated to a section within the Florida Statutes.

# II. Present Situation:

# **Department of Health**

Chapter 96-403, Laws of Florida, created the Department of Health (DOH) to promote and protect the health of all residents and visitors in the state. The department is composed of the State Health Office and Children's Medical Services Program of the former Department of Health and Rehabilitative Services (HRS). Examination and licensure of the health care professions were transferred from the Agency for Health Care Administration to the Department of Health on July 1, 1997. With the creation of the Department of Health, the Department of Health and Rehabilitative Services was renamed the Department of Children and Family Services. There are still several references to HRS in the statute that have not yet been changed to conform to the creation of the Department of Health and the Department of Children and Family Services.

The purpose and organizational structure for the Department of Health is provided in s. 20.43, F.S. This section establishes that the divisions of the Department of Health include: Division of Administration; Division of Environmental Health; Division of Disease Control; Division of Family Health Services; Division of Children's Medical Services; Division of Local Health Planning, Education, and Workforce Development, and Division of Medical Quality Assurance, which is responsible for medical boards and professions.

Section 20.43, F.S., also gives the Department of Health the authority to use state or federal funds to protect or improve the public health by providing incentives for encouraging disease prevention and patient compliance with medical treatment, and through health education campaigns and promotional campaigns to recruit health professionals to be employed by the department.

Section 120.80(15), F.S., 1998 Supplement, provides that notwithstanding s. 120.57(1)(a), F.S., a formal hearing may not be conducted by the Secretary of Health, the director of the Agency Health Care Administration, or a board or member of a board within the Department of Health or the Agency for Health Care Administration for matters relating to regulations of any activity, occupation, profession, or vocation regulated by the department in the Division of Medical Quality Assurance.

When the Department of Health was still part of the Department of Health and Rehabilitative Services, a procedure was established that allowed the Department of Health to conduct its own administrative hearings in matters concerning the Special Supplemental Food Program for Women, Infants, and Children (WIC), Children's Medical Services (CMS) program, and exemption from disqualification review for certified nurse assistants. The Department of Health no longer has authority to continue this process.

# **Private and Public Water Systems**

Section 381.0062, F.S., provides legislative intent to protect the public's health by establishing standards for the construction, modification, and operation of public and private water systems to assure consumers that the water provided to those systems is potable. Subsection (2) of s. 381.0062, F.S., defines "private water system" to mean a water system that provides piped water for no more than four nonrental residences. No definition is provided for a water system that serves only one rental residence, and therefore, a single rental residence would now be included within the definitions of a private water system and a multi-family water system.

Chapter 64E-8, Florida Administrative Code, requires that any owner of water systems connecting one or two residences only meet well setback requirements to protect the well from potential sources of contamination. Owners of water systems connecting three or four residences must meet the setback requirement, and also obtain a construction permit and provide satisfactory bacteria, nitrate and lead analytical results. There is no reference made to a single rental residence.

# Testing for Human Immunodeficiency Virus (HIV)

Section 381.004(3)(a), F.S., provides that a test designed to identify HIV may not be ordered without the informed consent of the person being tested, except under specified circumstances.

Additionally, s. 381.004(3)(d), F.S., provides that test results shall not be determined as positive or revealed to any person, without corroborating or confirmatory tests being conducted, except in certain situations. An exception to this requirement which was enacted in ch. 98-171, L.O.F., provides that preliminary test results may be released to health care providers and to the person tested when decisions about medical care or treatment of the person tested cannot await the results of confirmatory testing. It is unclear under the exception, whether the preliminary HIV test results of a mother who has just given birth may be released to the mother for purposes of immediate initiation of drug therapy for the newborn. Officials at the Department of Health have indicated that certain drug therapy may help prevent the newborn from contracting HIV from the mother. The earlier the drug therapy is initiated the more effective it is, and any delay in drug treatment could be detrimental to the infant. The Department of Health officials noted that this situation only occurs when a woman who has not received any prenatal care at all and therefore, has not been offered HIV tests as part of that prenatal care, arrives at a hospital emergency room for delivery.

Chapter 98-171, L.O.F., also provided for additional exceptions for when informed consent is not required in ordering an HIV test. Section 381.004(3)(h)12, F.S., provides that informed consent is not required for the performance of an HIV test by the medical examiner upon a deceased individual who was the source of a significant exposure to medical personnel or nonmedical personnel who provided emergency medical assistance and who expired or could not be resuscitated during treatment for the medical emergency. This exception to the informed consent requirements for ordering an HIV test allows medical personnel and "good Samaritans" to learn the test results of the potential source of exposure so that preventive treatment options could begin if the test results were positive. According to the Department of Health, not all deceased individuals who are the source of a significant exposure are sent to medical examiners so that a HIV test may be performed.

# **Health Information Systems Council**

The Health Information Systems Council was created by s. 381.90, F.S., within the Department of Health to facilitate the identification, collection, standardization, sharing, and coordination of health-related data, including fraud and abuse data, and professional and facility licensing data among federal, state, local, and private entities. Under s. 381.90, F.S., the membership of the council includes: the secretary of the Department of Health; the secretary of the Department of Business and Professional Regulation; the secretary of the Department of Children and Family Services; the director of the Agency of Health Care Administration; the secretary of the Department of Correctional Medical Authority; two members representing county health departments, one from a small county and one from a large county, appointed by the Governor; and a representative from the Florida Association of Counties.

# Vital Records

Section 382.013, F.S., requires a certificate for each live birth that occurs in this state to be filed within 5 days after such birth with the local registrar of the district in which the birth occurred. Section 382.013, F.S., sets out procedures for filing and requirements for the registration of paternity and the name of the child, undetermined parentage, and disclosure.

Section 382.025(1), F.S., provides that all Florida birth records are confidential and exempt from the provisions of s. 119.07(1), F.S., the Public Records Law. Subsection (2) of s. 382.025, F.S., authorizes the department to issue a certified copy of any marriage, dissolution of marriage, or death or fetal death certificate, excluding confidential portions, to the person requesting the information. Death and fetal death certificates which include the confidential portions will only be issued to the registrant's spouse or parent, child, grandchild, or sibling, of legal age, or to any family member who provides a will, insurance policy, or document demonstrating his or her interest in the registrant's estate. The confidential portions of records will also be provided to a state agency or local government or the United States for official purposes upon approval of the Department of Health or upon the order of any court of competent jurisdiction.

Section 382.0255, F.S., provides that the department is entitled to certain fees for the processing, filing, and retrieving of vital records and registrations. Previously, a portion of these fees was deposited in the Crimes Against Children Trust Fund administered by the Department of Law Enforcement. This trust fund, however, was eliminated on July 1, 1995, and the funds that were being deposited in this trust fund are now transferred to general revenue rather than to Vital Statistics within the Department of Health.

#### **Emergency Medical Services**

Part II, chapter 401, Florida Statutes, authorizes the Department of Health to make grants to local agencies and emergency medical services organizations to assist the agencies in providing emergency medical services. The Department of Health must certify advanced life support services, and basic life support services pursuant to s. 401.27, F.S. Section 401.27, F.S., establishes standards and certification requirements for emergency medical technicians and paramedics. Section 401.30, F.S., requires each permitted advanced life support service, basic life support service, or air ambulance (licensee) to maintain accurate records of emergency calls on forms that contain such information as is required by the department. The Department of Health has established by rule: requirements for staffing of permitted emergency medical service vehicles (64E-2.007, F.A.C.); requirements for the delivery of patient records by licensees (64E-2.013, F.A.C.); requirements for the department's approval of programs that educate emergency medical technicians and paramedics (64E-2.011, F.A.C.); and specific standards for the security and storage of controlled substances, medications, and fluids by licensees (64E-2.003, F.A.C.). Pursuant to s. 120.536, F.S., the Department of Health submitted administrative rules to the Joint Administrative Procedures Committee as rules that exceeded the rulemaking authority permitted in this section.

#### Florida Drug and Cosmetic Act

Chapter 499, Florida Statutes, provides for the regulation of drugs, cosmetics and household products by the Department of Health. Part I, ch. 499, F.S., (ss. 499.001-499.081, F.S.) sets forth the Florida Drug and Cosmetic Act. The purpose of this Act is to safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics. The part provides uniform legislation to be administered so far as practicable in conformity with the provisions of, and regulations issued under, the federal Food, Drug, and Cosmetic Act and the applicable portions of the federal Trade Commission Act which prohibits the false advertising of drugs, devices, and

cosmetics. The part specifies prohibited acts and requirements for the distribution and manufacture of legend drugs and legend devices by pharmacies, manufacturers, and other entities.

Section 499.05, F.S., establishes prohibited acts relating to drugs, devices, and cosmetics. Section 499.05, F.S., prohibits the sale or transfer of a legend drug or compressed medical gas if the person is not authorized to do so under the law of the state in which he or she resides. A person's residence, however, is irrelevant when determining whether that person is authorized to sell or receive prescription drugs.

Under s. 499.007, F.S., any drug that is habit forming or not safe for use unless under the supervision of a practitioner licensed by law to administer such drugs, is misbranded if it fails to bear on the label the statement" "Caution: Federal Law Prohibits Dispensing Without Prescription" or "Caution: State Law Prohibits Dispensing Without Prescription." In 1997, Congress passed the Food and Drug Administration Modernization Act, which provides that the label statement on such drugs is to appear as "Rx Only" or the prescription symbol followed by the word "Only." Federal regulations implementing this new prescription statement provide for a phase-in of labeling changes through February 2003. If ch. 499, F.S., is not revised to reflect this change in federal law, many prescription drug products entering Florida will be misbranded under Florida law.

Section 499.028, F.S., relating to drug samples and complimentary drugs, provides that individuals may not possess a prescription drug sample unless: the drug sample was prescribed to her or him, the individual is the employee of a complimentary drug distributor that holds a permit, or the individual is a person to whom prescription drug samples may be distributed pursuant to this section. No clear provision under state law allows federal, state, and local government employees, acting within the scope of their employment, to possess prescription drug samples.

# The Administrative Procedure Act and Agency Rulemaking Authority

Section 120.536(1), F.S., states that, "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 only adopt rules that implement, interpret, or make specific the particular powers and duties granted by the enabling statute." Section 120.536, F.S., further established that an agency may not adopt a rule merely because it is reasonably related to the purpose of the enabling legislation, nor may the agency have the authority to implement statutory provisions setting forth general legislative intent or policy.

Section 120.536(2), F.S., required each agency to provide the Administrative Procedures Committee a listing of rules adopted by the agency before October 1, 1996, which exceeded the rulemaking authority permitted in this section. These lists were to be provided by October 1, 1997, and subsequently combined and presented to the Speaker of the House of Representatives and the President of the Senate. This section further provided that the 1998 Legislature was to consider whether specific legislation authorizing these rules should be enacted. According to s. 120.536(2), F.S., each agency must have initiated appropriate proceedings to repeal rules exceeding rulemaking authority by January 1, 1999. By February 1, 1999, the Administrative Procedure Committee was required to submit to the President of the Senate and the Speaker of the House of Representatives, a report identifying rules that exceed rule authority for which repeal proceedings have not yet been initiated.

# III. Effect of Proposed Changes:

**Section 1**. Amends s. 20.43, F.S., 1998 Supplement, relating to the Department of Health, to add the Division of Children's Medical Services Network, Division of Emergency Medical Services and Community Health Resources, Division of Children's Medical Services Prevention and Intervention, Division of Information Resource Management, and the Division of Health Awareness and Tobacco to the list of divisions that are authorized to exist in the Department of Health. The Division of Children's Medical Services and the Division of Local Health Planning, Education, and Workforce Department are removed from the authorized list of divisions. The Department of Health's authority to improve the public health by its use of incentives and promotional items in disease prevention and health education activities is expanded.

**Section 2**. Amends s. 110.205, F.S., relating to career service exemptions, to update language regarding the establishment of exempt positions that now pertains to the Department of Health and Rehabilitative Services to conform to the creation of the Department of Health and the Department of Children and Family Services, and to include the positions of Assistant County Health Department Director and County Health Department Financial Administrator to the list of exempt positions.

**Section 3**. Amends s. 120.80., F.S., 1998 Supplement, relating to exceptions and special requirements of the Department of Health, to allow the Department of Health to contract with the Department of Children and Family Services to conduct administrative hearings in matters concerning the Special Supplemental Nutrition Program for Women, Infants and Children; Child Care Food Program; Children's Medical Services Program; and exemption from disqualification reviews for the certified nurse assistants program. The Department of Health is exempt from the requirements of a formal hearing under the Administrative Procedure Act for these programs.

**Section 4.** Amends s. 154.504, F.S., 1998 Supplement, relating to eligibility and benefits for the primary care challenge grant program, to permit providers to enter into contracts pursuant to s. 766.1115, F.S., relating to the provision of uncompensated care to low-income recipients by certain health care providers, if co-payments under the primary care challenge grants are not used as compensation for services to health care providers.

**Section 5**. Amends s. 287.155, F.S., relating to the purchase of motor vehicles by certain agencies, to authorize the Department of Health, to purchase automobiles, trucks, and other automotive equipment for use by county health departments, subject to the approval of the Department of Management Services.

**Section 6**. Amends s. 372.6672, F.S., 1998 Supplement, relating to alligator management and trapping program implementation, to delete obsolete references to the Department of Health and Rehabilitative Services.

**Section 7.** Amends s. 381.004, F.S., 1998 Supplement, relating to testing for human immunodeficiency virus, to revise requirements authorizing the use of preliminary HIV test results so that the information may be released to a mother at the time of delivery, for treatment and diagnosis of a newborn infant. Requirements for the performance of HIV tests on deceased persons are revised by authorizing the attending physician in addition to a medical examiner to perform an HIV test under limited circumstances to provide treatment options for medical personnel who were subject to a significant exposure when providing care or assistance to a person who expired or could not be resuscitated while receiving emergency care.

**Section 8**. Amends s. 381.0051, F.S., relating to family planning, to give the Department of Health the authority to adopt rules for family planning.

**Section 9.** Amends s. 381.006, F.S., 1998 Supplement, relating to environmental health, to provide the Department of Health with rulemaking authority relating to the health inspection of certain group-care facilities.

**Section 10.** Amends s. 381.0061, F.S., relating to administrative fines, to authorize the Department of Health to impose fines for violations relating to group care facilities.

**Section 11.** Amends s. 381.0062, F.S., 1998 Supplement, relating to water systems, to define "multi-family water system" to mean a water system that provides piped water for three to four residences, one of which may be a rental residence, and defines "private water system" to mean a water system that provides piped water for one to two residences, one of which may be a rental residence. Other minor and technical changes to conform to the new definition of "multi-family water system" are made.

**Section 12.** Amends s. 381.90, F.S., relating to the Health Information Systems Council, to revise the membership of the Health Information Systems Council by adding the State Treasurer/Insurance Commissioner; a representative from the Florida Healthy Kids Corporation; a representative from a school of public health chosen by the Board of Regents; the Commissioner of Education; the secretary of the Department of Elderly Affairs; and the secretary of the Department of Juvenile Justice. The duties of the Health Information Systems Council are revised so that it must develop a review process to ensure cooperative planning among agencies that collect or maintain health-related data and must submit a report on the implementation of this requirement to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 1, 2000.

**Section 13**. Amends s. 382.003, F.S., relating to powers and duties of the Department of Health, to remove the word "rescinding" in relation to the department's rule authority regarding vital records, and to authorize the department to adopt rules to require that forms, documents, and information submitted to the department to create or amend a vital record be under oath.

**Section 14.** Amends s. 382.004, F.S., relating to reproduction and destruction of records, to make minor and technical changes.

**Section 15.** Amends s. 382.008, F.S., 1998 Supplement, relating to death and fetal death registration, to delete obsolete language that limits the disclosure of social security numbers, which is in conflict with federal law.

**Section 16.** Amends s. 382.013, F.S., 1998 Supplement, relating to birth registration, to revise procedures to be followed when a birth occurs outside a health care facility, and to provide authority for the Department of Health to require documents and proof as it deems necessary to establish the fact of a birth when it occurred outside of a health care facility and was not attended by a Florida licensed physician, certified nurse midwife, Florida licensed midwife or a public health nurse employed by the department. Circumstances for listing the name of the husband of the mother on the birth certificate and procedures for the registration of a birth record of a child of undetermined parentage are revised. Other minor and technical changes to delete unnecessary language are made.

**Section 17.** Amends s. 382.015, F.S., relating to new certificates of live birth, to replace the term "court decree" with "court order," and to delete language addressing the administrative acknowledgment of paternity. Other minor and technical changes to delete unnecessary language are made.

**Section 18.** Amends s. 382.016, F.S., relating to amendment of birth records, to reinstate provisions outlining the amendment of a birth record in s. 382.015(2), F.S. relating to the administrative acknowledgment of paternity and subsequent amendment of the birth record.

**Section 19.** Amends s. 382.019, F.S., relating to delayed registration and administrative procedures for birth, death, or fetal death, to clarify that, after receipt of an application, the department may file a delayed registration and to authorize the Department of Health to dismiss an application not actively pursued within 1 year.

**Section 20.** Amends s. 382.025, F.S., relating to certified copies of vital records, to provide that birth records over 100 years old which are not sealed by a court order are available as a public record and to provide a method for indicating death on a commemorative birth certificate. The Department of Health is authorized to issue cause of death information to any person providing documented proof of need rather than restricting it to only a family member.

**Section 21.** Amends s. 382.0255, F.S., relating to fees for a certification of a birth record, to permit the Department of Health to retain fees collected by the Office of Vital Statistics for birth certificates rather than transferring the fees to the General Revenue Fund.

**Section 22.** Amends s. 383.14, F.S., relating to screening for metabolic disorders, other hereditary and congenital disorders, and environmental risk factors, to change the name of the WIC program from the Special Supplemental Food Program for Women, Infants, and Children, to the Special Supplemental Nutrition Program for Women, Infants, and Children to conform with federal law.

**Section 23.** Amends s. 385.202, F.S., relating to the statewide cancer registry, to no longer require the Department of Health to reimburse hospitals for the cost of furnishing data for the cancer registry.

**Section 24.** Amends s. 385.203, F.S., relating to the Diabetes Advisory Council, to revise the requirements and membership of the council. The council's membership is expanded from 18 to 25 members.

**Section 25.** Amends s. 391.028, F.S., 1998 Supplement, relating to administration of the Children's Medical Services program, to remove "the Division of" from the title of Children's Medical Services, and to provide that the director of Children's Medical Services may appoint division directors subject to the approval of the secretary.

**Section 26.** Amends s. 391.0315, F.S., 1998 Supplement, relating to benefits for children with special health needs, to clarify that benefits provided under the program shall be the same benefits provided to children in ss. 409.905 and 409.906, F.S., relating to Medicaid.

**Section 27.** Amends s. 392.69, FS, relating to appropriations, sinking, and maintenance trust funds, to allow the department to use excess money, notwithstanding ch. 216, F.S., for the improvement of health facilities at A. G. Holley State Hospital. The department is authorized to establish an advisory board to review and make recommendations relating to patient care at A. G. Holley State Hospital. Members of the advisory board shall be appointed by the Department of Health 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 are to serve without compensation, but per diem and travel expenses may be reimbursed by the Department of Health as provided in s. 112.061, F.S.

**Section 28.** Amends s. 401.25, F.S., relating to the licensure of a basic life support (BLS) or an advanced life support (ALS) service, to grant the Department of Health with specific authority for its administrative rule (64E-2003, F.A.C.) that imposes minimum staffing requirements. A BLS service must be occupied by at least two persons: a certified emergency medical technician, certified paramedic, or licensed physician and one ambulance driver. An ALS service must be occupied by at least two persons: a certified paramedic, or licensed physician and one who is a certified emergency medical technician, certified paramedic, or licensed physician who meets requirements of s. 401.281, F.S., as a driver. The person with the highest medical certifications must be in charge of patient care.

**Section 29.** Amends s. 401.27, F.S., relating to standards and certification of emergency medical services personnel, to grant the Department of Health specific authority for its administrative rule (64E-2.008 and 64E-2.009, F.A.C.) that requires applicants for emergency medical technician or paramedic certification and recertification to apply under oath to the department on forms provided by the department. The staff of the Joint Administrative Procedures Committee have raised concerns regarding the department's authority to require documents to be submitted under oath.

**Section 30.** Amends s. 401.30, F.S., 1998 Supplement, relating to records that must be maintained by permitted ambulance services, to grant the Department of Health specific authority for its administrative rule (64E-2.013, F.A.C.) that requires each licensee to maintain records and reports and to submit the record to the department as requested. Licensed ambulance services, basic life support services, and advanced life support services, must provide the receiving hospital with a copy of an individual patient care record for each patient who is transported to the hospital.

The information contained on the record and the method and time frame for providing the record must be prescribed by rule of the department.

**Section 31.** Amends s. 401.35, F.S., relating to the Department of Health's rulemaking authority to enforce provisions relating to the regulation of emergency medical services, to grant the Department of Health with specific rulemaking authority for its administrative rule (64E-2.003, F.A.C.) that requires licensed ambulance services, basic life support services, and advanced life support services to meet specific standards for the security and storage of controlled substances, medications, and fluids that are not inconsistent with requirements of ch. 499, F.S., the Florida Drug and Cosmetic Act or ch. 893, F.S., relating to the regulation of controlled substances.

**Section 32.** Creates s. 401.49, F.S., to grant the Department of Health specific authority for its administrative rule (64E-2.011, F.A.C.) that specifies requirements for the department's approval of programs that educate emergency medical technicians and paramedics.

**Section 33.** Amends s. 409.9126, F.S., 1998 Supplement, relating to services provided through the Children's Medical Services network for children with special health care needs, to revise the implementation of a plan to reimburse providers through the Children's Medical Services program for services provided to Medicaid eligible children with special health care needs on a capitated basis. Beginning July 1, 1999, the Florida Medicaid program must phase in by geographical area, capitation payment to Children's Medical Services for services provided to Medicaid children with special health care needs. By January 1, 2001, the Agency for Health Care Administration must make capitation payments for Children's Medical Services enrollees statewide, to the extent provided by federal law.

**Section 34.** Amends s. 465.019, F.S., 1998 Supplement, relating to institutional pharmacies, to revise the definition of a Class I institutional pharmacy to provide an exception for licensed nursing homes to purchase medical oxygen for administration to residents. Although licensed nursing homes provide medical oxygen to residents through the use of bulk canisters, it is unclear whether current law requires nursing homes to be licensed as Class I institutional pharmacies.

**Section 35.** Amends s. 499.005, F.S., 1998 Supplement, relating to prohibited acts under the Florida Drug and Cosmetic Act, to clarify that a person must be authorized to sell or transfer legend drugs and compressed medical gas under ch. 499, F.S., and that a person acquiring a legend drug must be authorized to do so under the applicable law where the receipt occurs. Providing the department with false information regarding any matter within the jurisdiction of ch. 499, F.S., is prohibited, not just as it relates to a drug, device, or cosmetic. The distribution of a legend device to the patient or ultimate consumer without a prescription or order from a practitioner to use or prescribe the device is prohibited.

**Section 36.** Amends s. 499.007, F.S., relating to misbranded drugs or devices, to conform the prescription statement of labels to match recently enacted federal language.

**Section 37.** Amends s. 499.028, F.S., relating to drug samples or complimentary drugs, to authorize federal, state, and local government employees, acting within the scope of their employment, to possess prescription drug samples.

**Section 38.** Amends s. 499.066, F.S., relating to penalties and remedies under the Florida Drug and Cosmetic Act, to authorize the immediate effect of a cease and desist order relating to persons who have violated ss. 499.001-499.081, F.S., (the Florida Drug and Cosmetic Act), or any rule adopted pursuant to that law. Any person subject to a cease and desist order issued by the Department of Health may request an administrative hearing to abate or modify the cease and desist order.

**Section 39.** Amends s. 499.069, F.S., relating to punishment for violations of the Florida Drug and Cosmetic Act, to revise criminal penalties to make the purchase or receipt of a prescription drug from an unauthorized source a third degree felony punishable by up to a 5 year imprisonment and a \$5,000 fine. The criminal penalties for the purchase of compressed medical gas from an unauthorized source is changed from a third degree felony to a first-degree misdemeanor punishable by imprisonment of up to 1 year and a \$1,000 fine.

**Section 40.** Amends s. 742.10, F.S., relating to establishment of paternity for children born out of wedlock, to conform statutory cross-references.

**Section 41.** Amends s. 39.303, F.S., 1998 Supplement, relating to child protection teams, to conform titles relating to Children's Medical Services.

**Section 42.** Amends s. 385.203, F.S., relating to the Diabetes Advisory Council, to conform titles relating to Children's Medical Services.

**Section 43.** Amends s. 391.021, F.S., 1998 Supplement, relating to definitions applying to Children's Medical Services, to conform titles relating to Children's Medical Services.

**Section 44.** Amends s. 391.221, F.S., 1998 Supplement, relating to the Statewide Children's Medical Services Network Advisory Council to provide conforming language that is needed due to the reorganization of Children's Medical Services.

**Section 45.** Amends s. 391.222, F.S., 1998 Supplement, relating to the Cardiac Advisory Council, to provide conforming language that is needed due the reorganization of Children's Medical Services into two divisions.

**Section 46.** Amends s. 391.223, F.S., 1998 Supplement, relating to technical advisory panels, to provide conforming language that is needed due the reorganization of Children's Medical Services into two division.

**Section 47**. Amends s. 63.162, F.S., relating to hearings and records in adoption proceedings, to clarify the use of the term "intermediary."

**Section 48.** Repeals subsection (3) of s. 381.731, F.S., relating to submission of an initial Healthy Communities plan that was submitted in 1992.

**Section 49.** Repeals subsection (5) of s. 383.307, F.S., relating to the Department of Health's consultation agreements with birth centers that are unable to find consultants.

**Section 50.** Repeals subsection (7) of s. 404.20, F.S., relating to the Department of Health's monitoring requirements of the transportation of radioactive materials.

**Section 51.** Repeals s. 409.9125, F.S., relating to study requirements for Medicaid alternative service networks.

**Section 52.** Provides that the building known as the 1911 State Board of Health Building which is part of a multi-building complex with the address of 1217 Pearl Street, Jacksonville, Florida shall be known as the Wilson T. Sowder, M. D., Building.

**Section 53.** Provides that the building authorized by Chapter 98-307, L.O.F., that will be located on Seagrape Drive on the Tampa Campus of the University of South Florida which will house laboratory facilities for the Department of Health shall be known as the William G. "Doc" Myers, M. D., Building.

**Section 54.** Provides that the Department of Health headquarters building that will comprise approximately 100,000 square feet that is authorized by item 1986 in the 1998-99 Appropriations Act shall be known as the E. Charlton Prather, M. D., Building.

**Section 55.** Authorizes the Department of Health to apply for and to become a National Environmental Laboratory Accreditation program accrediting authority. Legislative intent is provided that the Department of Health shall have authority to adopt rules to enforce the standards of the National Environmental Accreditation program, impose fees, and process applications.

Section 56. Provides an effective date of July 1, 1999.

# **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 Art. VII, s. 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 Art. I, subsections 24(a) and (b), Florida Constitution.

# C. Trust Funds Restrictions:

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

### V. Economic Impact and Fiscal Note:

#### A. Tax/Fee Issues:

Amendments adopted in committee pass along increase in examination fees for radiological certification to the tested applicants. Approximately 2,700 applicants will take or retake such examinations at an additional per person cost of \$50 or \$135,000 annually.

#### B. Private Sector Impact:

The American Registry of Radiologic Technologists in St. Paul, Minnesota is the developer and owner of the examination instruments to whom the additional fees will be paid.

#### C. Government Sector Impact:

The Department of Health estimates that it will save approximately \$3,000 each year by not having to administer a system to monitor the transportation of radioactive materials that is repealed under the bill. The Department of Health estimates that it will retain \$800,000 in fees collected by the Office of Vital Statistics for the issuance of birth certificates. These fees are currently transferred to the general revenue fund.

The bill adds seven members to the Diabetes Advisory Council. Using the nominal amount of \$500 per meeting per member the estimated additional expense associated with this increase is \$10,500 annually.

The bill expands by 34 the statutory list of positions eligible for inclusion in the Selected Exempt Services (SES) personnel class. Assistant directors in county health departments and their financial administrators will receive position, salary and benefit upgrades as follows: discretionary salary increases will total \$104,600; the financial exposure due to the purchase of accrued leave resulting from SES upgrade is another \$200,000; and the employer's share of employee's co-payments for insurance benefits, approximately \$82,000 (\$200/month times 12 months times 34 positions). The affected employees will lose their career service rights and will also receive higher leave credits and year-end accruals. Accrued but unused compensatory leave may transfer with the employees or be cashed out by the sending agency.

#### VI. Technical Deficiencies:

None.

#### VII. Related Issues:

The bill creates a third degree felony offense for any person who makes the purchase or receipt of a prescription drug from an unauthorized source.

Section 27 of the bill exempts the department from all of the planning and budgeting statutes in ch. 216, F.S. The agency is currently engaged in an enterprise operation at one of its hospital facilities in which it derives income from the subleasing of vacant space. The agency would like to

keep these funds rather than having them subject to the budget amendment process. A more appropriate exemption tailored to the activity at hand would cross reference s. 216.181 or s. 216.292, F.S., only.

#### VIII. Amendments:

#1 by Governmental Oversight and Productivity: Amends s. 110.205, F.S., to delete the inappropriate use of plural term.

#2 by Governmental Oversight and Productivity:

Amends s. 381.006, F.S., to delete reference to nursing homes as part of the authority given the Department of Health in the promulgation of rules on environmental health.

#3 by Governmental Oversight and Productivity: Amends s. 392.69, F.S., to provide an exemption from a specific part of the planning and budgeting statutes, s. 216.292, F.S., rather than the entire ch. 216, F.S.

#4 by Governmental Oversight and Productivity:

Amends ss. 401.25, 401.27, 401.2701, 401.2715, 401.30, and 401.35, F.S. to provide specific legal authority for the department to promulgate rules on its basic and advanced life support regulatory programs. (WITH TITLE AMENDMENT)

#5 by Governmental Oversight and Productivity: Deletes amendments to s. 499.066, F.S., providing additional administrative enforcement authority to the department. (WITH TITLE AMENDMENT)

#6 by Governmental Oversight and Productivity:

Deletes from the bill proposed amendments to s. 63.162, F.S., revising the requirements for the release of the identity of birth parents in an adoption proceeding. (WITH TITLE AMENDMENT)

#7 by Governmental Oversight and Productivity: Corrects an incorrect street address reference to a state building designation.

#8 by Governmental Oversight and Productivity: Substitutes revised language for the designation of the Department of Health as a nationally approved accrediting authority for laboratories.

#9 by Governmental Oversight and Productivity:

Amends s. 381.0022, F.S., to maintain the confidential and exempt status of any information on Medicaid recipients shared by the Department of Health with other agencies when auditing payments for services. (WITH TITLE AMENDMENT)

#10 by Governmental Oversight and Productivity:

Amends s. 383.011, F.S., to give the Department of Health permissive rather than mandatory authority to rules consistent with regulations of the federal Child Care Food Program. (WITH TITLE AMENDMENT)

#11 by Governmental Oversight and Productivity:

Amends s. 468.304, F.S., to pass along increases in examination costs to applicants for radiological certification. (WITH TITLE AMENDMENT)

#12 by Governmental Oversight and Productivity: Amends s. 468.306, F.S., to pass along increased costs of purchased examinations to the tested applicants. (WITH TITLE AMENDMENT)

#13 by Governmental Oversight and Productivity: Amends s. 468.309, F.S., to revise the renewal period of a radiological technologist license from December 31 to the birth month. (WITH TITLE AMENDMENT)

#14 by Governmental Oversight and Productivity: Amends s. 455.557, F.S., to exempt hospital interns from physician profiling requirements. (WITH TITLE AMENDMENT)

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.