

**The Florida Senate**  
**BILL ANALYSIS AND FISCAL IMPACT STATEMENT**

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

Prepared By: The Professional Staff of the Health and Human Services Appropriations Committee

**BILL:** CS/CS/SB 2614

**INTRODUCER:** Health and Human Services Appropriations Committee, Health Regulation Committee and Senator Gaetz

**SUBJECT:** Healthy and Fit Florida Act

**DATE:** April 20, 2009      **REVISED:** \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HR	Fav/CS
2.	Peters	Peters	HA	Fav/CS
3.				
4.				
5.				
6.				

**Please see Section VIII. for Additional Information:**

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|------------------------------|-------------------------------------|---|
| A. COMMITTEE SUBSTITUTE..... | <input checked="" type="checkbox"/> | Statement of Substantial Changes        |
| B. AMENDMENTS.....           | <input type="checkbox"/>            | Technical amendments were recommended   |
|                              | <input type="checkbox"/>            | Amendments were recommended             |
|                              | <input type="checkbox"/>            | Significant amendments were recommended |

**I. Summary:**

The Department of Health (DOH) is consolidating and codifying the chronic disease prevention role of the department under the bill. The DOH is revising the emphasis of its approach to “chronic disease” by renaming chapter 385, F.S., from “Chronic Diseases Act” to the “Healthy and Fit Florida Act.” The bill updates the chronic disease-related statutes to build the foundation for a more comprehensive program. The bill revises a number of chronic disease statutes to avoid duplication and to update some of the provisions.

The bill creates the Pharmacy and Therapeutic Advisory Council in the Executive Office of the Governor to promote quality, consistency, and efficiency in the state purchasing and administration of pharmaceuticals, including the development of a drug-utilization review process across agencies and the review of agency proposals to maximize the cost-effectiveness of the purchasing of pharmaceuticals. The bill requires all state agencies to purchase drugs through the statewide purchasing contract administered by the Department of Health (DOH), unless the Council approves a more cost-effective agency plan or the drugs required are not available through the contract.

The bill revises requirements for the food service and environmental health inspections of domestic violence centers by the DOH. The bill authorizes DOH to establish direct-support organizations and continues Florida Area Health Education Center (AHEC) smoking-cessation initiatives.

Highlights of the bill include:

- Repeals s. 381.0053, F.S., relating to the comprehensive nutrition program, s. 381.0054, F.S., relating to healthy lifestyles promotion, ss. 381.732, 381.733, and 381.734, F.S., relating to the Healthy Communities, Healthy People Act, and s. 381.912, F.S., relating to the Cervical Cancer Elimination Task Force. These concepts are included in new sections created in ch. 385, F.S., by the bill.
- Defines “best practices” under the Comprehensive Statewide Tobacco Education and Use Prevention Program to mean the Best Practices for Comprehensive Tobacco Control Programs as established by the U.S. Centers for Disease Control and Prevention, as amended.
- Continues Florida Area Health Education Center (AHEC) smoking-cessation initiatives.
- Awards \$11 million to the DOH for awarding contracts or grants to the AHEC network for development of components for its smoking-cessation initiatives.
- Limits the DOH’s environmental health and food service inspections of certified domestic violence centers to the requirements applicable to community-based residential facilities with five or fewer residents.
- Substantially modifies the program components and requirements for the Comprehensive Statewide Tobacco Education and Use Prevention Program.
- Revises appointment requirements for the prostate cancer advisory committee.
- Creates the Chronic Disease Prevention program within the DOH.
- Requires the DOH to implement state-level programs for chronic disease.
- Revises the DOH mission, to reflect an integration of community-level programs for chronic disease prevention and health promotion.
- Requires the DOH to develop programs for people at every stage of their lives to promote physical fitness.
- Requires certain practitioners to report information to the cancer registry.
- Revises the DOH rulemaking authority regarding reporting requirements for the cancer registry.
- Authorizes the DOH to establish a direct-support organization to provide assistance, funding, and support for the department in carrying out its mission.
- Creates the Pharmacy and Therapeutic Advisory Council (Council) in the Executive Office of the Governor to advise the DOH and other government agencies.
- Revises the definition of “wholesale distribution” of a prescription drug to persons other than a consumer or patient to provide an exception.
- Adds a representative of the Florida Academy of Family Physicians to the Diabetes Advisory Council.

The bill has minimal fiscal impact on state government. The bill eliminates the limit on administrative expenditures from the Epilepsy Services Trust Fund of five percent of annual receipts. The bill increases the award to the AHEC network to \$11 million to expand smoking-cessation initiatives to each county in Florida for development of components for AHEC smoking-cessation initiatives.

The Agency for Persons with Disabilities has estimated that by consolidating its purchasing of pharmaceuticals with the DOH, and utilization of the DOH central pharmacy would produce a net savings of \$488,258 to the Agency. The Department of Juvenile Justice and the Department of Corrections estimate cost savings associated with increasing department pharmaceutical purchasing through the MMCAP contract and repackaging and filling prescriptions through the DOH Central Pharmacy. The DOH will incur additional costs to handle the increased demand of pharmacy central services. However, the bill provides that cost savings realized by other agencies that use the central pharmacy will be transferred to the DOH to offset the additional workload.

The Pharmacy and Therapeutics Advisory Committee created in the bill is directed to meet at least quarterly. The state will incur a cost to provide reimbursement to Council member for travel expenses and per diem.

This bill amends sections 154.503, 381.006, 381.0072, 381.0203, 381.922, 385.101, 385.102, 385.103, 385.202, 385.203, 385.206, 385.207, 385.210, 409.904, and 499.003, F.S.

This bill amends, transfers, and renumbers 381.84 (385.106), 381.91 (385.2024), 381.911 (385.2023), 381.92 (385.2025), 381.921 (385.20251), 381.93 (385.2021), 381.931 (385.20211), 385.101 – 385.103 (381.101 – 385.301), F.S.

This bill creates sections 385.1021, 385.1022, 385.1023, 385.105, and 385.301, 385.401, F.S., and three undesignated section of law.

This bill repeals sections 381.0053, 381.0054, 381.732, 381.733, 381.734, and 381.912, F.S.

## **II. Present Situation:**

### **Chronic Diseases**

Chronic diseases—such as heart disease, cancer, and diabetes—are the leading causes of death and disability in the United States.<sup>1</sup> Chronic diseases account for 70 percent of all deaths in the United States, or 1.7 million deaths each year. These diseases also cause major limitations in daily living for almost 1 out of 10 Americans or about 25 million people. Chronic disease has a significant impact on the quality of life and is associated with huge medical and social costs. Many chronic diseases are preventable.

Heart disease and stroke, the first and third leading causes of death in the United States, are the most common cardiovascular diseases.<sup>2</sup> Heart disease accounted for 27 percent of deaths in Florida during 2005 and stroke caused 5 percent of deaths. Cancer is the second leading cause of death in the United States and accounts for almost one in every four deaths.<sup>3</sup> In 2005, 24 percent of all deaths in Florida were caused by cancer.

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<sup>1</sup> See website for the U.S. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion at < <http://www.cdc.gov/nccdphp/>> (Last visited on April 3, 2009).

<sup>2</sup> Source: Centers for Disease Control and Prevention.

<sup>3</sup> Source: Centers for Disease Control and Prevention.

Leading a healthy lifestyle by avoiding tobacco use, being physically active, and eating well greatly reduces a person's risk for developing chronic diseases. Access to high-quality and affordable prevention measures save lives and reduce morbidity.

The Florida Department of Health is responsible for public health activities to prevent chronic disease in Florida. The Bureau of Chronic Disease Prevention within the DOH has expanded its capacity to provide a comprehensive approach to preventing, detecting, and reducing complications of chronic diseases in Florida. The bureau currently houses the following programs: Heart Disease and Stroke Prevention, Chronic Disease Health Promotion and Education, Obesity Prevention, Diabetes Prevention and Control, Comprehensive Cancer Control, Arthritis Prevention and Education, Epilepsy, and Coordinated School Health. The bureau receives funding from a variety of federal and state sources, including the Preventive Health and Health Services Block Grant, the U.S. Centers for Disease Control and Prevention (CDC), state trust funds, and general revenue.

Chapter 381, F.S., contains general public health provisions under the DOH. The DOH must conduct environmental health and food service inspections. Several sections of ch. 381, F.S., relate to prevention of chronic diseases. Chapter 385, F.S., relates to chronic diseases. The chapter include provisions relating to: community intervention programs; the statewide cancer registry; the Diabetes Advisory Council; the hematology-oncology care center program; care and assistance of persons with epilepsy; and arthritis prevention and education.

### **Domestic Violence Centers**

Domestic violence centers are community-based agencies that provide services to adult victims of domestic violence and their children. Minimum services include temporary emergency shelter; information and referrals; safety planning, counseling and case management; a 24-hour emergency hotline; educational services for community awareness; assessment and appropriate referral of resident children; and training for law enforcement and other professionals.<sup>4</sup> Domestic violence centers are regulated under ch. 39, F.S., by the Department of Children and Family Services.<sup>5</sup> Rule 65H-1.003, F.A.C., provides the standards for certification of domestic violence centers. The Department of Children and Family Services has adopted requirements for the physical plant of domestic violence centers.<sup>6</sup> Centers are required to meet county and municipal building code enforcement requirements, have an annual fire inspection, have an annual sanitation inspection, and otherwise take precautionary measures to ensure the physical safety of residents. As of March 19, 2008, there were 42 certified domestic violence centers in Florida.<sup>7</sup> . The DOH inspects domestic violence centers for compliance with food safety, sanitation, and health standards twice per year.

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<sup>4</sup> Department of Children and Family Services website found at: < <http://www.dcf.state.fl.us/domesticviolence/about.shtml> > (Last visited on April 21, 2009).

<sup>5</sup> See also Rule 65H-1, Florida Administrative Code.

<sup>6</sup> See Rule 65H-1.003, Florida Administrative Code.

<sup>7</sup> Florida Coalition Against Domestic Violence <<http://www.fcadv.org/centers.php>> (Last visited on April 21, 2009).

## **OPPAGA Research Memorandum – Consolidating Statewide Pharmaceutical Services**

The Office of Program Policy Analysis and Government Accountability (OPPAGA) was required by Chapter 2009-15, Laws of Florida, to assess the feasibility of consolidating statewide pharmaceutical services for state agencies, including the purchasing, repackaging, and dispensing of pharmaceuticals. The OPPAGA research memorandum, released March 3, 2009, found that:

- Five state agencies spent \$232 million on pharmaceuticals for agency clients in FY 2007-08. These five agencies purchase 92 percent of their pharmaceuticals through a bulk purchasing contract through the DOH that lowers the prices for all participating purchasers.
- The state could attain additional cost savings by consolidating drug repackaging under the DOH's central pharmacy or a private vendor. The OPPAGA compared the unit dose and script dispensing fees paid by the Agency for Persons with Disabilities with the Department of Corrections' and the Department of Juvenile Justice' current contracts for repackaging and filling prescriptions with the DOH's central pharmacy costs and determined that consolidation under the DOH may be the more cost-effective option.
- The DOH may be able to expand its drug purchasing through the federal 340B drug pricing program, which could bring significant savings to the state.

### **Pharmaceutical Purchasing in Florida**

Section 381.0203, F.S., authorizes the DOH to contract on a statewide basis for the purchase of drugs for use by other state agencies and political subdivisions. The DOH's Bureau of Statewide Pharmaceutical Services is responsible for managing the statewide contract with the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP), a group-purchasing organization, and has contracted with Cardinal Health, Inc., to serve as the wholesale distributor for statewide drug purchasing.<sup>8</sup>

The DOH, the Department of Corrections, the Department of Children and Families, the Department of Juvenile Justice, and the Agency for Persons with Disabilities purchase pharmaceuticals and fill prescriptions for their agency clients. These agencies have consolidated most of their pharmaceutical purchasing through the bulk purchasing MMCAP contract administered by the DOH. However, the agencies often need the purchased drugs repacked into unit doses to be dispensed to clients. Most agencies contract with private firms to perform the drug repackaging. Agency staff is responsible for dispensing most of the prescriptions, although some agencies contract with private firms to dispense prescriptions at some state residential and secure facilities.

In order to control costs the five agencies that directly purchase pharmaceuticals have either established a formulary or use the Medicaid formulary. The agencies also require senior staff to approve requests to prescribe drugs not on the agency formulary. Formularies and prescribing policies are set by agency pharmacy and therapeutic committees which review physician prescribing patterns and patient utilization trends to establish appropriate drug preferences for the most cost-effective treatments. There is no statewide formulary, but drug utilization data collected by the DOH, show that the agency drug formularies are similar. The OPPAGA memo

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<sup>8</sup> 64F-15.001, Florida Administrative Code.

suggests that it would be feasible to consolidate formulary management under a statewide pharmacy and therapeutic advisory council. The Governor's Chief Medical Officers' Task Force is currently assessing the possibility of creating a statewide formulary.

The AHCA, the Department of Veterans' Affairs, and the Department of Management Services administer reimbursement or drug benefit plan arrangements for Medicaid recipients, veterans, and state employees, respectively, but do not purchase pharmaceuticals directly, repackage drugs, or fill and dispense prescriptions.

### **340B Drug Pricing Program**

The 340B Drug Pricing program was established in U.S. Public Law 102-585, of the Veterans Health Care Act of 1992. Section 340B of the law limits the costs of drugs for federal purchasers and for certain federal agency grantees. The program is administered by the federal Office of Pharmacy Affairs. As of April 1, 2007, the 340B program had 12,290 participants including Federally Qualified Health Centers (FQHC), HIV/AIDS clinics (Ryan White Title I-IV), family planning clinics, and certain Disproportionate Share Hospitals.<sup>9</sup> Participants in the 340B program purchase pharmaceuticals through a wholesaler or directly from the manufacturer. A recent survey found that 340B prices are approximately 24 percent lower than that available to group purchasing organizations.<sup>10</sup>

The DOH is the only state agency that can purchase drugs at the federal 340B prices because the DOH is the recipient of federally awarded programs and responsible for the administration of the FQHC. However, Florida may be able to expand some of its pharmaceutical purchasing through the 340B program. The Department of Corrections is piloting an initiative with the DOH to purchase drugs for patients with HIV/AIDS and sexually transmitted diseases through the 340B program. Physicians employed by the DOH will treat inmates in the pilot, and because of the direct treating relationship, the DOH will be authorized to purchase drugs for inmates in the pilot project.

### **Department of Health Central Pharmacy**

The DOH is authorized to establish and maintain a pharmacy services program under s. 381.0203(2), F.S. The pharmacy services provided by the DOH include a central pharmacy to support pharmaceutical services provided by the county health departments, including pharmaceutical repackaging, dispensing, and the purchase and distribution of immunizations and other pharmaceuticals. The DOH is also the agency responsible for the regulation of drugs, cosmetics, and household products under ch. 499, F.S. According to the OPPAGA memo, the DOH central pharmacy could provide cost-effective pharmaceutical repackaging and prescription filling services to other state agencies.

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<sup>9</sup> See <http://www.ncsl.org/legis/HEALTH/drug340b.htm> (Last visited on March 29, 2009).

<sup>10</sup> National Conference of State Legislatures, Pharmacy Bulk Purchasing: Multi-state and Inter-agency Plans, 2008. Found at: < <http://www.ncsl.org/programs/health/bulkrx.htm> > (Last visited on March 29, 2009).

### III. Effect of Proposed Changes:

**Section 1** amends s. 154.503, F.S., to eliminate a requirement for the DOH to coordinate with the primary care program developed under the Healthy Communities, Healthy People program, which is repealed in section 2 of the bill.

**Section 2** repeals s. 381.0053, F.S., relating to the comprehensive nutrition program, s. 381.0054, F.S., relating to healthy lifestyles promotion, and ss. 381.732, 381.733, and 381.734, F.S., relating to the Healthy Communities, Healthy People Act. Similar provisions are incorporated into s. 385.105, F.S., created in section 22 of the bill.

**Section 3** amends s. 381.006, F.S., relating to environmental health program inspections, to require the DOH to limit its environmental health inspections of certified domestic violence centers to the requirements applicable to community-based residential facilities with five or fewer residents.

**Section 4** amends s. 381.0072, F.S., relating to food service inspections, to require the DOH to limit its food service inspections of certified domestic violence centers to the requirements applicable to community-based residential facilities with five or fewer residents.

**Section 5** amends s. 381.0203, F.S., to require the DOH to contract on a statewide basis for the purchase of pharmaceutical drugs, to be used by state agencies and political subdivisions. The bill requires all state agencies, with the exception of the Agency for Health Care Administration, the Department of Management Services, and the Department of Veterans' Affairs, to purchase drugs through the statewide contract unless:

- The Pharmacy and Therapeutic Advisory Council created in the bill approves a more cost-effective purchasing plan; or
- The drugs required are not available through the statewide purchasing contract.

Of the eight state agencies that provide prescription drugs services to their clients, five already purchase most of their pharmaceuticals through the statewide purchasing contract administered by the DOH.

The DOH currently operates a central pharmacy that repackages, dispenses, and purchases pharmaceuticals and immunizations for county health departments. The bill directs the DOH to provide central pharmacy services to other state agencies and political subdivisions upon written agreement. The bill provides that cost savings realized by the state through the utilization of the central pharmacy may be used by the DOH to offset any additional costs.

**Section 6** amends, transfers, and renumbers s. 381.84, F.S., as s. 385.106, F.S., (The Comprehensive Statewide Tobacco Education and Use Prevention Program). The bill defines "best practices" to mean the Best Practices for Comprehensive Tobacco Control Programs as established by the CDC, as amended. The bill deletes the definitions for "department," "tobacco," and "youth." These definitions are included in section 14 of the bill, which provides definitions for ch. 385, F.S. The bill requires all program components to include efforts to educate youth and their parents about tobacco usage, and a youth-directed focus must exist in all components outlined in the section.

The bill substantially revises the program components and requirements for the Comprehensive Statewide Tobacco Education and Use Prevention Program. The bill establishes the content of the following components of the program:

- State and community interventions;
- Health communication interventions;
- Cessation interventions;
- Surveillance and evaluation;
- Administration and management;
- Training;
- County health departments; and
- Enforcement and awareness of related laws.

The bill repeals certain existing requirements of the program, including: the requirement that one-third of the total annual appropriation be spent on counter-marketing and advertising; the requirement to maintain a cyberspace resource center for copyrighted materials and information.

The bill revises the provisions relating to the Tobacco Education and Use Prevention Advisory Council to require the council to adhere to all state ethics laws, public records and meetings requirements, and ch. 112, F.S., relating to public officers and employees. The bill makes it clear that the council is assisting the DOH when it is fulfilling its responsibilities under the law.

The bill revises contract requirements for the Comprehensive Statewide Tobacco Education and Use Prevention Program to make a school or college of medicine that is represented on the Tobacco Education and Prevention Advisory Council eligible to receive a contract or grant under the program. The bill revises the date when the annual report for the Comprehensive Statewide Tobacco Education and Use Prevention Program is due to Legislature and Governor from January 31 to February 28 of each year. The bill continues AHEC network efforts to expand smoking-cessation initiatives to each county in the state. The bill awards \$11 million to the DOH for awarding contracts or grants to the AHEC network for development of components for its smoking-cessation initiatives.

The bill also repeals rulemaking authority for the DOH for the program, however section 28 of the bill gives the DOH rulemaking authority to administer ch. 385, F.S.

**Section 7** renumbers and transfers s. 381.91, F.S., relating to the Jessie Trice Cancer Prevention program, as s. 385.2024, F.S. The Jessie Trice Cancer Prevention program is focused on reducing the rates of lung cancer and other cancers and to improve the quality of life among low-income African-American and Hispanic populations through increased access to early, effective screening and diagnosis, education, and treatment programs.

**Section 8** amends, renumbers and transfers s. 381.911, F.S., relating to the Prostate Cancer Awareness program, as s. 385.2023, F.S. The section revises appointment requirements for the prostate cancer advisory committee within the DOH to allow scientists or clinicians from nonpublic universities or research organizations to serve on the committee.



**Section 9** repeals s. 381.912, F.S., relating to the Cervical Cancer Elimination Task Force.

**Section 10** renumbers and transfers s. 381.92, F.S., relating to the Florida Cancer Council, as s. 385.2025, F.S.

**Section 11** renumbers and transfers s. 381.921, F.S., relating to duties of the Florida Cancer Council, as s. 385.20251, F.S.

**Section 12** amends s. 381.922, F.S., relating to William G. “Bill” Bankhead, Jr., and David Coley Cancer Research program, to correct statutory cross-references to conform to changes in the bill.

**Section 13** transfers and renumbers s. 381.93, F.S., relating to the Breast and Cervical Cancer Early Detection program, as s. 385.2021, F.S.

**Section 14** transfers and renumbers s. 381.931, F.S., relating to the annual report on Medicaid program expenditures made under the Mary Brogan Breast and Cervical Cancer Early Detection Program Act, as s. 385.20211, F.S.

**Section 15** creates an undesignated section of law, to rename chapter 385, F.S., currently entitled “Chronic Diseases Act,” to “Healthy and Fit Florida Act.”

**Section 16** amends s. 385.101, F.S., to rename the title of ch. 385, F.S., from the “Chronic Diseases Act” to the “Healthy and Fit Florida Act.”

**Section 17** amends s. 385.102, F.S., relating to legislative intent regarding chronic diseases, to revise the legislative intent to emphasize the DOH’s focus on prevention to deal with chronic diseases. The section is updated with new statistical information regarding the impact of chronic preventable diseases.

**Section 18** creates s. 385.1021, F.S., to provide definitions for ch. 385, F.S., relating to chronic disease, to emphasize the DOH integrated approach to dealing with the preventative aspects of a “Healthy and Fit Florida” rather than “chronic disease.”

**Section 19** creates s. 385.1022, F.S., to create the Chronic Disease Prevention program within the DOH. Under the program, the DOH must support public health programs to reduce the incidence of mortality and morbidity from diseases for which risk factors can be identified. Some risk factors include being overweight or obese, physical inactivity, poor nutrition and diet, tobacco use, sun exposure, and other detrimental practices to health.

**Section 20** creates s. 385.1023, F.S., to require DOH to implement state-level prevention programs for chronic disease. The program must address preventable chronic disease factors of poor nutrition and obesity, tobacco use, sun exposure, and physical inactivity. The bill specifies activities that must be included in the state-level programs.

**Section 21** amends s. 385.103, F.S., relating to community intervention programs, to revise the DOH mission, to reflect an integration of community-level programs for chronic disease

prevention and health promotion. Elements of the DOH programmatic approach are outlined in the section. The DOH is directed to use evidence-based interventions as well as best promising practices to guide specific activities and effect change. The DOH community health education program is revised to encourage the use of appropriate medical, research-based interventions to enable and encourage changes in behaviors which reduce or eliminate health risks and other methods specified in the section.

The bill requires the DOH to develop and implement a comprehensive, community-based program for chronic disease prevention and health promotion. The program must be designed to reduce major behavioral risk factors that are associated with chronic disease. The emphasis of the program is outlined in the section and includes the development of policies that encourage the use of alternative community delivery sites for health promotion, disease prevention, and preventive care programs and promote the use of the neighborhood delivery sites that are close to work, home, and school.

**Section 22** creates s. 385.105, F.S., relating to physical activity, obesity, nutrition, and other health-promotion services and wellness programs, to require the DOH to develop programs for people at every stage of their lives to promote physical fitness. The DOH is required to promote healthy lifestyles to reduce the prevalence of excess weight gain and being overweight or obese through directed programs to target Florida residents. The DOH is directed to promote and maintain optimal nutritional status in the population through the various activities specified in the section. The DOH is granted rulemaking authority to administer its duties regarding nutrition. The DOH is required to promote personal responsibility by encouraging residents of Florida to be informed, follow health recommendations, and adhere to other activities specified in the section that will promote health.

Every state agency is authorized to conduct employee wellness programs by use of existing resources or resources obtained through grant funding. The DOH must provide by rule, any requirements for nominal participation fees, when applicable, which may not exceed the department's actual costs.

**Section 23** amends s. 385.202, F.S., relating to the statewide cancer registry, to require laboratories and certain practitioners to report information to the cancer registry. The bill revises the DOH's rulemaking authority regarding reporting requirements for the cancer registry. Such rulemaking authority includes the data required, the timeframe for reporting, and those professionals who are responsible for ensuring compliance with reporting requirements. The DOH is also authorized to adopt rules regarding the establishment and operation of a statewide cancer registry program.

The bill authorizes the DOH to use cancer registry information for public health surveillance. The bill also requires each practitioner or facility that reports information to the cancer registry to make their records available for onsite review by the DOH or its authorized representative.

**Section 24** amends s. 385.203, relating to the Diabetes Advisory Council, to add a representative of the Florida Academy of Family Physicians to the Diabetes Advisory Council.

**Section 25** amends s. 385.206, F.S., relating to the Hematology-Oncology Care Center program to rename the program to the Pediatric Hematology-Oncology Center program. The definition of “patient” is revised to mean a person under the age of 21 who is in need of hematologic-oncologic services and who is enrolled in the Children’s Medical Services Network. The requirements for grant agreements, affiliated programs, and program and peer review are updated.

**Section 26** amends s. 385.207, F.S., relating to care and assistance to persons with epilepsy, to revise the DOH duties to require the department, as part of its contract with a provider of epilepsy services, to collect information regarding the number of clients served, the outcomes reached, the expense incurred, and fees collected by such providers for the provision of services and make this information available to the Legislature and Governor upon request. Language that limits the DOH’s total administrative expenditures from the Epilepsy Services Trust Fund to 5 percent of the annual receipts is deleted.

**Section 27** amends s. 385.210, F.S., relating to arthritis prevention and education to update and make minor housekeeping changes to the section.

**Section 28** creates s. 385.301, F.S., to grant rulemaking authority to the DOH for duties conferred on the department under ch. 385, F.S.

**Section 29** creates s. 385.401, F.S., to authorize DOH to establish a direct-support organization to provide assistance, funding, and support for the department in carrying out its mission. The section specifies requirements for the creation, use, powers, duties of the direct-support organization. The direct-support organization must be governed by a board of directors which consists of no fewer than seven members appointed by the State Surgeon General. The DOH is authorized to allow the direct-support organization to use the department’s fixed property and facilities. The direct-support organization must provide for an annual financial audit.

**Section 30** amends s. 409.904, F.S., relating to optional payments under the Medicaid program, to correct statutory cross-references to conform to other changes in the bill.

**Section 31** creates the Pharmacy and Therapeutic Advisory Council (Council) in the Executive Office of the Governor to advise the DOH and other government agencies. The members of the Council and the chair will be appointed by the Governor to 4–year staggered terms or until their successors are appointed and members may be appointed to more than one term. Council members must be residents of Florida, and must be selected on the basis of specialty, board certification, prior pharmacy and therapeutic experience, experience treating medical assistance recipients, ability to represent a broad base of constituents, and number of years in practice. Council membership must include at least one physician, pharmacist, and nurse licensed under chapters 458, 465, and 464, F.S., respectively. The bill specifies requirements for the Council to govern its work.

The Council is directed to use Medicaid’s processes as a guide for assisting state agencies in:

- Developing an unbiased clinical perspective on drug evaluations and utilization protocols that are relevant to patient care provided by state agencies;
- Developing drug-utilization-review processes relevant to state agencies;

- Building a formulary structure that enforces formulary compliance or adherence within each agency;
- Performing pharmacoeconomic analyses on formulary management so that the state maximizes the cost effectiveness of the its pharmaceutical purchasing;
- Reviewing new and existing therapies using criteria established for efficacy, safety, and quality in order to maximize cost-effective purchasing; and
- Reviewing state agency proposals to maximize the cost of effectiveness of pharmaceutical purchasing in compliance with s. 381.0203, F.S.

The bill requires the Council to verify the cost-effectiveness and clinical efficacy of any state bulk purchasing contract under s. 381.0203(1), F.S., at least once every two years.

**Section 32** amends s. 499.03, F.S., to specify that a “wholesale distribution” of a prescription drug to persons other than a consumer or patient does not include: the sale, purchase, trade, or transfer of a prescription drug among agencies and health care entities of the state to complete the dispensing of a prescription drug to a patient under the care of a state agency or health care entity, or to a patient for whom the state is responsible for providing or arranging health care services. The bill provides that the agency or health care entity that receives the prescription drug on behalf of the patient is deemed the patient’s agent.

This provision will facilitate the purchasing of prescription drugs by the DOH on behalf of other state agencies and the dispensing of the drugs by the DOH.

**Section 33** provides an effective date of July 1, 2009.

#### **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, Section 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. Fiscal Impact Statement:**

##### **A. Tax/Fee Issues:**

None.

**B. Private Sector Impact:**

None.

**C. Government Sector Impact:**

The DOH reports that they will work within current funding to maintain current programs and will continue to seek grants and other funding sources to expand activities consistent with the provisions of the bill.

The bill eliminates the limit on administrative expenditures from the Epilepsy Services Trust Fund of five percent of annual receipts. It is unknown if this will allow increased expenditures for administrative costs or if there will be a shift from expenditures for direct client services.

The bill increases the award to the AHEC network to \$11 million to expand smoking-cessation initiatives to each county in Florida for development of components for AHEC smoking-cessation initiatives.

The Agency for Persons with Disabilities has estimated that by consolidating its purchasing of pharmaceuticals with the DOH, and utilization of the DOH central pharmacy would produce a net savings of \$488,258 to the Agency. The cost saving estimated does not include Medicaid recipients served by the Agency.

The Department of Juvenile Justice and the Department of Corrections estimate cost savings associated with increasing department pharmaceutical purchasing through the MMCAP contract and repackaging and filling prescriptions through the DOH Central Pharmacy.

The DOH will incur additional costs to handle the increased demand of pharmacy central services. However, the bill provides that cost savings realized by other agencies that use the central pharmacy will be transferred to the DOH to offset the additional workload.

The Pharmacy and Therapeutics Advisory Committee created in the bill is directed to meet at least quarterly. The state will incur a cost to provide reimbursement to Council member for travel expenses and per diem.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Additional Information:**

- A. **Committee Substitute – Statement of Substantial Changes:**  
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

**CS by Health and Human Services Appropriations Committee on April 20, 2009:**

The committee substitute no longer repeals the requirement for the AHEC network to expand smoking-cessation initiatives to each county in Florida. The bill awards \$11 million to the DOH for awarding contracts or grants to the AHEC network for development of components for AHEC smoking-cessation initiatives. The DOH is required to limit its environmental health and food service inspections of certified domestic violence centers to the requirements applicable to community-based residential facilities with five or fewer residents. The DOH is authorized to establish a direct-support organization to provide assistance, funding, and support for the department in carrying out its mission.

The Pharmacy and Therapeutic Advisory Council is created in the Executive Office of the Governor to advise the DOH and other government agencies. to require the DOH to contract on a statewide basis for the purchase of pharmaceutical drugs, to be used by state agencies and political subdivisions.

The bill requires all state agencies, with the exception of the Agency for Health Care Administration, the Department of Management Services, and the Department of Veterans' Affairs, to purchase drugs through the statewide contract unless: the Pharmacy and Therapeutic Advisory Council created in the bill approves a more cost-effective purchasing plan; or the drugs required are not available through the statewide purchasing contract.

Amends s. 499.003, F.S., to specify that a "wholesale distribution" of a prescription drug to persons other than a consumer or patient does not include: the sale, purchase, trade, or transfer of a prescription drug among agencies and health care entities of the state to complete the dispensing of a prescription drug to a patient under the care of a state agency or health care entity, or to a patient for whom the state is responsible for providing or arranging health care services. The bill provides that the agency or health care entity that receives the prescription drug on behalf of the patient is deemed the patient's agent.

**CS by Health Regulation on April 7, 2009:**

The committee substitute reinstates the prohibition that a recipient of a contract or grant for surveillance and evaluation under the Comprehensive Statewide Tobacco Education and Use Prevention Program is not eligible for a contract or grant for any other program component in the same state fiscal year. The bill revises contract requirements for the Comprehensive Statewide Tobacco Education and Use Prevention Program to make a school or college of medicine that is represented on the Tobacco Education and Prevention Advisory Council eligible to receive a contract or grant under the program. The committee substitute revises the date when the annual report for the Comprehensive

Statewide Tobacco Education and Use Prevention Program is due to Legislature and Governor from January 31 to February 28 of each year.

The committee substitute no longer creates an Office of Public Health Nutrition in the DOH. The committee substitute adds a representative of the Florida Academy of Family Physicians to the Diabetes Advisory Council.

**B. Amendments:**

None.

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This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

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