

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 7183 PCB HCR 10-03 Reorganization of the Department of Health
SPONSOR(S): Health Care Appropriations Committee; Health Care Regulation Policy Committee; Thompson
TIED BILLS: **IDEN./SIM. BILLS:**

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
Orig. Comm.:	Health Care Regulation Policy Committee	11 Y, 2 N	Quinn	Calamas
1)	Health Care Appropriations Committee	7 Y, 4 N, As CS	Clark	Massengale
2)				
3)				
4)				
5)				

SUMMARY ANALYSIS

Committee Substitute for House Bill 7183 reorganizes and focuses the mission of the Department of Health (DOH) from 13 statutory responsibilities to eight responsibilities related to: surveillance of communicable disease; accumulation of health statistics; implementation of interventions that prevent or limit the spread of disease; preparedness functions related to public health emergencies; regulation of environmental activities impacting the state; administration of health and related services to target populations; collection and management of vital statistics data; and regulation of health care practitioners. The bill requires DOH to submit a proposal to the Legislature by November 1, 2010, for a new department structure based upon these responsibilities. Additionally, the bill repeals legislative intent language related to DOH's public health mission, revises some of its statutory duties consistent with the revised responsibilities, and defines DOH's role in managing and coordinating emergency preparedness and disaster response functions.

The bill sunsets ten of the 11 departmental divisions on July 1, 2011, unless reviewed and reenacted by the Legislature, and sunsets Division of Medical Quality Assurance on July 1, 2011 pursuant to a type-two transfer of the Division to the Department of Business and Professional Regulation (DBPR). The Drugs, Devices and Cosmetics Program administered by DOH pursuant to Part I of Chapter 499, is also transferred to DBPR via a type-two transfer. The bill exempts certain drug device manufacturers from DOH permitting requirements and certain medical convenience kits from the pedigree paper requirements. The bill also requires DOH to develop a plan to transfer patients from the A.G. Holley Hospital to private or non-state public hospitals meeting certain requirements within 90 days. The plan must be submitted to the Legislature by November 1, 2010, for future consideration.

The bill expands the Cancer Drug Donation Program to all sealed, noncontrolled substance prescription drugs, renames the Program the Prescription Drug Donation Program, and expands entities that can participate in the program.

The bill removes provisions authorizing DOH to use state and federal funds to administer a variety of promotional programs and public health campaigns and a provision authorizing DOH to hold copyrights, trademarks, and service marks. Beginning in Fiscal Year 2010-2011, DOH is precluded from initiating or commencing new programs, including federally-funded or grant-supported programs, without express legislative authority, and must seek approval from the LBC before applying for continuation grants.

The bill amends the definition of group care facilities regulated in the DOH environmental health program and redefines "food service establishment" for purposes of its food service program, and authorizes DOH to advise other agencies about food service inspections. Additionally, the bill creates a physician workforce advisory council in DOH to advise the department with regard to physician workforce needs, and modifies information to be included in physician workforce surveys.

Finally, the bill repeals the Office and Officer of Women's Health Strategy, the statewide injury prevention program, and the defunct Children's Early Investment Act and related sections, and makes conforming changes.

The bill has a positive net savings in state trust funds of \$1,762,649 (See Fiscal Impact Statement and Comments).

The bill has an effective date of July 1, 2010.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

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HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Department of Health

Prior to 1991, most of Florida's health and human services programs were administered by a single state agency, the Department of Health and Rehabilitative Services (DHRS). From 1991 through 1997, the Legislature subdivided the programmatic functions of DHRS, now the Department of Children and Family Services, and created four new agencies to achieve more effective program management.

By 1997, the Department of Children and Family Services, and the four new agencies—the Department of Elder Affairs, the Agency for Health Care Administration, the Department of Juvenile Justice, and the Department of Health¹—were responsible for administering the majority of Florida's health and human services programs.

The Department of Health (DOH) is established pursuant to section 20.43, Florida Statutes. Since being established in 1996, DOH's mission has persistently grown and diversified. Currently, DOH's statutory mission comprises the following:²

- Prevent the occurrence and progression of communicable and noncommunicable diseases and disabilities.
- Maintain a constant surveillance of disease occurrence and accumulate health statistics to establish disease trends and design health programs.
- Conduct special studies of the causes of diseases and formulate preventive strategies.
- Promote the maintenance and improvement of the environment as it affects public health.
- Promote the maintenance and improvement of health in the residents of the state.
- Provide leadership, in cooperation with the public and private sectors, to establish statewide and community public health delivery systems.
- Provide health care and early intervention services to infants, toddlers, children, adolescents, and high-risk perinatal patients who are at risk for disabling conditions or have chronic illnesses.
- Provide services to abused and neglected children through child protection teams and sexual abuse treatment programs.

¹ Created by s. 8, Ch. 96-403, Laws of Florida.

² s. 20.43(1), F.S.

- Develop working associations with all agencies and organizations involved and interested in health and health care delivery.
- Analyze trends in the evolution of health systems, and identify and promote the use of innovative, cost-effective health delivery systems.
- Serve as the statewide repository of all aggregate data accumulated by state agencies related to health care; analyze that data and issue periodic reports and policy statements, as appropriate; require that all aggregated data be kept in a manner that promotes easy utilization by the public, state agencies, and all other interested parties; provide technical assistance as required; and work cooperatively with the state's higher education programs to promote further study and analysis of health care systems and health care outcomes.
- Include in the department's strategic plan developed under section 186.021, Florida Statutes, an assessment of current health programs, systems, and costs; projections of future problems and opportunities; and recommended changes that are needed in the health care system to improve the public health.
- Regulate health practitioners, to the extent authorized by the Legislature, as necessary for the preservation of the health, safety, and welfare of the public.

Generally, the State Surgeon General has statutory authority to be the leading voice on wellness and disease prevention efforts through specified means; advocate on health lifestyles; develop public health policy; and build collaborative partnerships with other entities to promote health literacy.³

DOH has 11 statutory divisions: Administration, Environmental Health, Disease Control, Family Health Services, Children's Medical Services Network, Emergency Medical Operations, Medical Quality Assurance, Children's Medical Services Prevention and Intervention, Information Technology, Health Access and Tobacco, and Disability Determinations.⁴ DOH operates numerous programs, provides administrative support for 29 statutory health care boards and commissions, contracts with thousands of vendors, oversees 67 county health departments, and performs a variety of regulatory functions.

DOH is authorized to use state and federal funds to protect and improve the public health by administering health education campaigns; providing health promotional items such as shirts, hats, sports items, and calendars; planning and conducting promotional campaigns to recruit health professionals to work for DOH or participants for DOH programs; or providing incentives to encourage health lifestyles and disease prevention behaviors.⁵

When DOH was created in 1996, it received a total appropriation of \$1.4 billion, including \$384 million in general revenue funds, and had approximately 14,000 full-time equivalents (FTE) positions.⁶ In Fiscal Year 2009-2010, DOH received more than \$470 million in general revenue fund and is authorized to spend a total of \$2.9 billion. Today, more than 17,000 persons are employed by DOH.⁷

Medical Quality Assurance

DOH's Division of Medical Quality Assurance (MQA) was created to regulate health care professionals to protect the health and safety of all citizens and visitors to the state who access health care services.⁸

MQA performs three primary functions:⁹

- **Enforcement**—The program analyzes and investigates complaints against healthcare practitioners and facilities from intake to final resolution, inspects facilities, assists in prosecuting practice act violations, and investigates unlicensed activity.

³ s.20.43(2), F.S.

⁴ s. 20.43(3), F.S.

⁵ s. 20.43(7), F.S.

⁶ This figure includes County Health Department staff.

⁷ Including County Health Department staff.

⁸ s. 20.43(2)(g), F.S.

⁹ Department of Health, Division of Medical Quality Assurance website, located at <http://www.doh.state.fl.us/mqa/med-boards.html> (last viewed on March 15, 2010).

- **Licensure**—The program administers professional testing and processes licensure applications and renewals.
- **Public Information**—The program provides current licensure information for all licensed health care providers and more extensive profile information for members of specific professions, including the person's educational and professional background and any disciplinary action taken against the practitioner within the past ten years.

Most health care practitioners are governed by 29 independent, statutory professional licensing boards or councils, which are assigned to DOH for administrative purposes. MQA provides staff support for the boards and councils and directly regulates some practitioner groups that are not governed by a board or council, including pharmacies. Overall, in conjunction with the boards and councils, MQA regulates approximately 40 health care professions, including:¹⁰

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|-----------------------------------|-------------------------------|
| • Acupuncture | • Naturopaths |
| • Athletic Training | • Nursing |
| • Audiology | • Nursing Home Administrators |
| • Certified Nursing Assistants | • Nutrition |
| • Chiropractic Medicine | • Occupational Therapy |
| • Clinical Laboratory Personnel | • Opticianry |
| • Health Care Clinic Registration | • Optometry |
| • Clinical Social Work | • Orthotists |
| • Dental Hygiene | • Osteopathic Medicine |
| • Dentistry | • Paramedic |
| • Dietetics | • Pharmacy |
| • Electrolysis | • Physical Therapy |
| • Emergency Medical Technician | • Physician Assistants |
| • Hearing Aid Specialists | • Podiatric Medicine |
| • Marriage and Family Therapy | • Prosthetists |
| • Massage | • Psychology |
| • Medical Physicists | • Radiologic Technology |
| • Medicine | • Respiratory Care |
| • Mental Health Counseling | • School Psychology |
| • Midwifery (Licensed) | • Speech Language Pathology |

MQA also regulates the following health care facilities:

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| • Dental Labs | • Optometry Branch Facilities |
| • Electrolysis Facilities | • Optical Establishments |
| • Massage Establishments | • Pharmacies |

For Fiscal Year 2009-2010, the Legislature authorized 640.5 FTE positions and appropriated \$62.4 million¹¹ for the program from the Medical Quality Assurance Trust Fund.¹²

Regulation of Drugs, Devices, and Cosmetics

DOH's Community Public Health Division, Bureau of Statewide Pharmaceutical Services, ensures drug, device, and cosmetic quality and safety and regulates oversight of the manufacture and distribution of drugs, devices, cosmetics, either within or into Florida, pursuant to part I of chapter 499, Florida Statutes.¹³

¹⁰ *Id.*
¹¹ The Trust Fund receives revenues from the various licensure and fee requirements for health professionals.
¹² s. 3, ch. 2009-81, L.O.F. (line items 518-530).
¹³ Among many other provisions, chapter 499 provides for: criminal prohibitions against the distribution of contraband and adulterated prescription drugs; regulation of the advertising and labeling of drugs, devices, and cosmetics; establishment of permits for manufacturing and distributing drugs, devices, and cosmetics; regulation of the wholesale distribution of prescription drugs, which

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The bureau regulates the wholesale market by permitting, inspecting, and investigating drug wholesalers. Drug wholesalers must obtain a permit from the bureau to legally sell drugs in Florida. Bureau inspectors inspect in-state wholesaler facilities as part of the initial application process and annually thereafter. If inspections reveal infractions, the bureau investigates and may impose administrative fines and penalties. The bureau also investigates wholesalers suspected of misconduct such as counterfeiting or diverting drugs. To combat illegal activities in the wholesale market, the bureau works closely with local, state, and federal law enforcement officials, the Agency for Health Care Administration, the Medicaid Fraud Control Unit, the Statewide Prosecutor's Office, and the Food and Drug Administration.

Medical Kits

Medical convenience kits contain a combination of finished products, prescription drugs and medical devices, which are packaged together, with each product retaining individual forms and packaging.¹⁴ Any prescription drug in a medical convenience kit is subject to federal pedigree paper requirements, the elements of which are found in 21 C.F.R. 203.50.¹⁵ The bureau regulates compliance with state pedigree paper requirements in section 499.01212, Florida Statutes.

Currently, Florida law does not provide specific pedigree paper requirements for drugs contained in a medical convenience kit. The only medical convenience kit statutory requirement is found in section 499.003(5), Florida Statutes, which provides that a wholesale distributor is not required to open a sealed, medical convenience kit to authenticate a pedigree paper for a prescription drug contained within the kit. The department is currently drafting an administrative rule clarifying the authentication requirement in section 499.003(5), Florida Statutes.¹⁶ Any change to state pedigree paper requirements for prescriptions drugs in medical convenience kits would not disturb the Food and Drug Administration's (FDA) guidance regarding medical convenience kit compliance or federal pedigree paper requirements generally.

Medical Devices

The bureau also regulates medical device manufactures pursuant to sections 499.01 and 499.015, Florida Statutes. However, section 499.015(8), Florida Statutes, provides an exemption from registration with the department for any medical device manufacturer that is registered with the FDA. The FDA provides a pervasive regulatory scheme for medical device manufacturers pursuant to 21 C.F.R. 807. Medical device manufacturers are divided into three classes with increasing levels of regulatory control corresponding to Class I, Class II and Class III. Classification is based on based on "the intended use of the device and also upon indications for use."¹⁷ Most Class I manufacturers are exempt from some inspection criteria. Classes II and III are subject to five regulatory categories available for inspection, including product safety and manufacturing quality compliance.¹⁸

The FDA requires facilities inspection for registered manufactures at least once every two years.¹⁹ Medical manufacturers must pay an annual establishment registration fee to FDA. The Federal Fiscal Year 2010 fee is \$2,008.²⁰

includes pedigree papers; regulation of the provision of drug samples; establishment of the Cancer Drug Donation Program; establishment of numerous enforcement avenues for the Department of Health, including seizure and condemnation of drugs, devices, and cosmetics.

¹⁴ Food and Drug Administration, *Guidance for Industry: Prescription Drug Marketing Act (PDMA) Requirements* (November 2006).

¹⁵ *Id.*

¹⁶ Florida Department of Health, Proposed Rule 64F-12.013, F.A.C., *Prescription Drugs; Receipt, Storage and Security*, see <https://www.flrules.org/gateway/ruleNo.asp?id=64F-12.013> (last visited March 30, 2010).

¹⁷ Food and Drug Administration, "Device Classification," see <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm> (last visited March 30, 2010).

¹⁸ Food and Drug Administration, "Inspection of Medical Device Manufacturer," see <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072753.htm#p3> (last visited March 30, 2010).

¹⁹ *Id.*

In Florida, the bureau performs inspections on medical device manufacturing facilities under its permitting authority in section 499.01, Florida Statutes. The bureau checks the FDA establishment registration number as an element of the initial permitting process²¹ and may investigate manufacturer permit holders at the bureau's discretion.²² The initial application fee is \$150 and the biennial permitting fee is \$1,200 for medical device manufacturers.²³

A.G. Holley State Hospital

According to the United States Census Bureau, there are approximately four active tuberculosis hospitals in the United States.²⁴ Florida operates one of these tuberculosis hospitals, known as the A.G. Holley State Hospital. A.G. Holley was opened in 1950 as the Southeast Tuberculosis Hospital, the second of four state tuberculosis hospitals built in Florida between 1938 and 1952.²⁵ Today, however, A.G. Holley is the only state-operated tuberculosis (TB) hospital in the state and is the last of the original American sanatoriums dedicated to treating tuberculosis patients.²⁶ A.G. Holley operates a complete X-ray department, bronchoscopy suite, dental office, optometric clinic, and pharmacy.

A.G. Holley is located in the City of Lantana on a 134 acre plot. In May 2007, the land was appraised at \$34.1 million. The hospital is four stories and encompasses 194,000 square feet. It was originally built to serve 500 patients, with living accommodations for the physicians, nurses and administrative staff. However, by 1971 the daily census at the hospital dropped to less than half of the original 500. By 1976, the beds and staff at A.G. Holley were reduced to serve a maximum of 150 patients. Currently, the hospital does not operate at full capacity and receives state funding for 50 beds, of which, sixteen are isolation (negative air pressure) rooms.

Today, the hospital receives funding for approximately 160 FTE positions for an average daily census of 37 patients, some of whom are involuntarily committed to the hospital. It costs approximately \$10 million a year to manage the hospital, and the hospital consistently runs an annual deficit. Moreover, the hospital will require significant outlay for capital improvements in the near future.

In addition to the main hospital, the campus includes a lab that is part of the state laboratory service (16,700 sq. ft.), a county health department (35,000 sq. ft.), a warehouse (26,500 sq. ft.), a boiler room (4,552 sq ft), a water treatment plant (880 sq. ft.), an additional building (26,500 sq. ft.), and ten small residential cottages.

According to a recent research memorandum issued by the Office of Program Policy Analysis and Government Accountability (OPPAGA), only one other large state, Texas, operates a state-run infectious disease hospital that treats TB patients. In other large states, such as California, Illinois, Michigan, New York, North Carolina, and Ohio, local health departments use local or regional hospitals to treat such medically complex TB patients.²⁷

In 2006, the department proposed developing the A.G. Holley hospital and campus into a Florida Institute for Public Health at a cost of approximately \$10 million. In 2008, the Legislature directed DOH to procure a new TB hospital more suited to modern treatment and caseloads, and to outsource the management functions to a private vendor. The procurement was not successful. In 2009, the Legislature gave new, more specific direction to DOH to initiate a second procurement. DOH received one proposal, but the bidder did not meet the requirements of the procurement.

²⁰ Food and Drug Administration, "Device Registration and Listing," see <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm> (last visited March 30, 2010).

²¹ Rule 64F-12.015, F.A.C.

²² Rule 64F-12.019, F.A.C.

²³ Rule 64F-12.018, F.A.C.

²⁴ United States Census Bureau, Hospitals-Summary Characteristics, <http://www.census.gov/compendia/statab/2007/tables/07s0162.xls> (last viewed March 30, 2010).

²⁵ Bureau of TB and Refugee Health, Florida Department of Health, A.G. Holley Hospital History; <http://www.doh.state.fl.us/AGHolley/history.htm> (last viewed March 30, 210).

²⁶ *Id.*

²⁷ "Tuberculosis Hospitalization in Other States," OPPAGA Research Memorandum (March 11, 2010).

Cancer Drug Donation Program

In 2006, the Legislature adopted the “Cancer Drug Donation Program Act.”²⁸ DOH maintains the program under which a donor may donate cancer drugs or supplies used to administer cancer drugs to a participant facility for dispensing to eligible recipients.

Section 499.029(8), F.S., authorizes the department to adopt rules relating to recipient eligibility criteria, standards and procedures for participant facilities, forms for administration of the program, fees charged by a participant facility, categories of cancer drugs and supplies accepted in the program, and maintenance and distribution of the participant facility registry.

Recipient Eligibility Requirements

A Florida resident who is diagnosed with cancer and has a valid prescription from his or her physician is eligible to receive drugs or supplies through the Cancer Drug Donation Program (program). A person is ineligible to participate in the program if he or she is eligible to receive cancer drugs or supplies through the Medicaid program, third-party insurer, or any other prescription drug program funded in whole or in part by the state or federal government, unless these benefits have been exhausted, or a certain cancer drug or supply need is not covered by the program.²⁹

Donor Eligibility Requirements

Cancer drugs and supplies may be donated to a participant facility by the following individuals or entities located within Florida:³⁰

- A patient or a patient representative, donated through a closed drug delivery system³¹ by the facility where the patient is receiving treatment;
- Health care facilities, nursing homes, hospices, or hospitals with a closed drug delivery system;
- Pharmacies, drug manufacturers, medical device manufacturers or suppliers, or wholesalers of drugs or supplies; or
- A licensed allopathic or osteopathic physician who receives cancer drugs or supplies directly from a pharmacy, drug manufacturer, or drug wholesaler.

Standards and Procedures for Participant Facilities

A Class II Institutional Pharmacy³² that accepts, stores, and dispenses donated cancer drugs and supplies may participate in the program.³³ Participation is voluntary. A pharmacy that elects to participate in the program must complete and submit a notice of participation form to the department. Likewise, a pharmacy may discontinue its participation in the program by completing and submitting to the department a notice of withdrawal form.

A participant pharmacy may decline to accept a donation. A cancer drug or supply may not be donated to a specific cancer patient.³⁴ A dispenser of donated cancer drugs or supplies is not allowed to submit a claim or seek reimbursement for donated products dispensed under the program. However, a participant pharmacy may charge the recipient of the drug or supply a handling fee of no more than 300 percent of the Medicaid dispensing fee or no more than \$15, whichever is less, for each cancer drug or supply dispensed.³⁵

²⁸ ch 2006-310, Laws of Florida

²⁹ Rule 64F-12.026(1)(b), F.A.C. and s. 499.029(9), F.S.

³⁰ s. 499.029(3)(c), F.S.

³¹ s. 499.029(3)(b), F.S., defines a “closed drug delivery system” as a system in which the actual control of the unit-dose medication package is maintained by the facility rather than by the individual patient.

³² s. 465.019(2)(b), F.S., defines “class II institutional pharmacies” as those institutional pharmacies which employ the services of a registered pharmacist who...shall provide dispensing and consulting services on the premises to patients of that institution, for use on the premises of that institution.” However, section 499.029(4), F.S. states that a participant facility may provide dispensing and consulting services to individuals who are not patients of the hospital.

³³ Rule 64F-12.026(3)(a), F.A.C.

³⁴ s. 499.029(4), F.S. and Rule 64F-12.026(3)(e)5., F.A.C.

³⁵ s. 499.029(7)(b), F.S. and Rule 64F-12.026(5), F.A.C.

The pharmacy must store the donated cancer drugs and supplies in a secure storage area under appropriate environmental conditions and the donated cancer drugs may not be stored with non-donated inventory.³⁶ All donations must be dispensed by a licensed pharmacist. Prior to being dispensed, a pharmacist must inspect the cancer drug or supplies to determine that they do not appear to be tampered with or mislabeled.³⁷

A donation form must be signed by the donor when cancer drugs or supplies are donated to a participant pharmacy. Before a cancer drug or supply is dispensed, the recipient must sign a form and be notified both orally and in writing that the product may have been previously dispensed.³⁸ This form includes: the donor or recipient's name; the recipient or dispensing pharmacy's name; the medication; medication strength, expiration date, lot number, and quantity.³⁹ Each time the pharmacy destroys a donated drug or supply, the person destroying the product must complete a destruction form that includes the medication name, strength, expiration date, lot number, and quantity.⁴⁰ The pharmacy is required to keep all donor, recipient, and destruction records on file for at least three years.⁴¹

As of March 31, 2010, there are four participating pharmacies: Lee Memorial Hospital, Inc., in Ft. Myers; Halifax Medical Center in Daytona Beach; Adventist Health System/Sunbelt Health Care in Winter Park; and Tallahassee Memorial in Tallahassee.⁴²

Standards and Categories of Cancer Drugs and Supplies Accepted in the Program

A cancer drug is eligible for donation under this program only if the drug:⁴³

- Is in its original, unopened, sealed container, or in a tamper-evident⁴⁴ unit-dose packaging;
 - Single-unit dose drugs may be accepted if the single-unit dose packaging is unopened
- Has never been in the actual control of the patient, but rather has been maintained by a health care facility in a closed drug delivery system;
- Will not expire until at least six months after the donation is made; and
- Is accompanied by a completed Cancer Drug Donation Program Donation and Destruction Record that is signed by the donor or that person's authorized representative.⁴⁵

Cancer drugs billed to and paid for by Medicaid in long-term care facilities are not eligible for donation unless they are not reimbursable by Medicaid.⁴⁶ Controlled substances, such as morphine, oxycodone, or lorazepam, are not eligible for donation.⁴⁷

Participant Facility Registry

The department is required in section 499.029(10), F.S., to establish and maintain a participant facility registry on their website,⁴⁸ which includes the participant facility's name, address, and telephone number. The department's website is also required to contain links to cancer drug manufacturers that offer drug assistance programs or free medication.⁴⁹

Liability

³⁶ Rule 64F-12.026(3)(d), F.A.C.

³⁷ s. 499.029(6)(c), F.S.

³⁸ Rule 64F-12.026(3)(e)3., F.A.C.

³⁹ Florida Department of Health, Recipient Record form, see http://www.doh.state.fl.us/mqa/DDC/Cancer/frm_Recipient.pdf (last visited March 31, 2010).

⁴⁰ Rule 64F-12.026(3)(f)2, F.A.C.

⁴¹ Rule 64F-12.026(3)(f)1, F.A.C.

⁴² Florida Department of Health, *Cancer Drug Donation Program Participation Report*, see http://www.doh.state.fl.us/mqa/DDC/Cancer/info_registry.doc (last visited March 31, 2010).

⁴³ s. 499.029(6)(a)-(b), F.S.

⁴⁴ Tamper evident packaging means a package that seals an individual pill in a plastic bubble typically with a foil backing.

⁴⁵ Rule 64F-12.022(6)(a)1. See http://www.doh.state.fl.us/mqa/DDC/Cancer/frm_DDRRecord.pdf (last visited March 31, 2010).

⁴⁶ Rule 64F-12.026(6)(a)4, F.A.C.

⁴⁷ Rule 64F-12.026(6)(c)1., F.A.C.

⁴⁸ Florida Department of Health, *Cancer Drug Donation Program Participation Report*, see http://www.doh.state.fl.us/mqa/DDC/Cancer/info_registry.doc (last visited March 31, 2010).

⁴⁹ s. 499.029(10), F.S. The requisite information is not currently available on the Florida Department of Health website. See <http://www.doh.state.fl.us/mqa/DDC/Cancer/index.html> (last visited March 31, 2010).

Any donor of cancer drugs or participant in the program who exercises reasonable care in participating in the program is immune from civil or criminal liability and from professional disciplinary action for any injury, death, or loss to person or property relating to the program. A pharmaceutical manufacturer is not liable for a claim or injury arising from the transfer of a cancer drug donation.⁵⁰

Physician Workforce

In 2007, the Legislature directed the department to serve as the coordinating and strategic planning body to actively assess Florida's current and future physician workforce needs and work with multiple stakeholders to develop strategies and alternatives to address current and projected workforce needs.⁵¹ Under section 381.4018, Florida Statutes, the department is directed to maximize the use of existing programs in the department and coordinate with other governmental and nongovernment stakeholders to develop a state physician workforce strategic plan.

Under sections 458.3191 and 459.0081, Florida Statutes, all Florida-licensed allopathic and osteopathic physicians are required to participate in a physician survey in conjunction with their biennial licensure renewal. The law provides the department with rulemaking authority to develop and administer the physician survey. The department is required to issue a nondisciplinary citation to any physician licensed under chapters 458 or 459, Florida Statutes, who fails to complete the physician workforce survey within 90 days of licensure renewal.⁵² The citation notifies a physician who fails to complete the survey that he or she cannot subsequently renew his or her license, until the survey is completed.

Under sections 458.3192 and 459.0082, Florida Statutes, the department is required to analyze the results of the physician surveys and determine, by geographic area and specialty, the number of physicians who:

- Perform deliveries of children in Florida;
- Read mammograms and perform breast-imaging-guiding procedures in Florida;
- Perform emergency care on an on-call basis for a hospital emergency department;
- Plan to reduce or increase emergency on-call house in a hospital emergency department; or
- Plan to relocate their allopathic or osteopathic practice outside the state.

Office of Women's Health Strategy

In 2004, the Legislature passed CS/SB 2448, creating the Women's Health Strategy.⁵³ The strategy is administered by a Women's Health Officer and is intended to focus on the unique health care needs of women.

The Officer of Women's Health Strategy is tasked with:⁵⁴

- Ensuring state policies and programs are responsive to sex and gender differences and women's health needs;
- Organizing an interagency Committee for Women's Health with DOH, the Agency for Health Care Administration, the Department of Education, the Department of Elderly Affairs, the Department of Corrections, the Office of Insurance Regulation and the Department of Juvenile Justice in order to integrate women's health into current state programs;
- Collecting and reviewing health data and trends to assess the health status of women;
- Reviewing the state's insurance code as it relates to women's health issues;
- Working with medical school curriculum committees to integrate women's health issues into course requirements and promote clinical practice guidelines;
- Organizing statewide Women's Health Month activities;
- Coordinating a Governor's statewide conference on women's health;

⁵⁰ s. 499.029(11) and (12), F.S.

⁵¹ ch. 2007-172 and ch. 2007-96, L.O.F.

⁵² Rule 64B-9.002, F.A.C.

⁵³ s. 381.04015, F.S. (ch. 2004-350, L.O.F.)

⁵⁴ s. 381.04015(4), F.S.

- Promoting research, treatment, and collaboration on women's health issues at universities and medical centers in the state;
- Promoting employer incentives for wellness programs targeting women's health programs.
- Serving as the primary state resource for women's health information;
- Developing a statewide women's health plan emphasizing collaborative approaches to meeting the health needs of women;
- Promoting clinical practice guidelines specific to women;
- Serving as the state's liaison with other states and federal agencies and programs to develop best practices in women's health;
- Developing a statewide, web-based clearinghouse on women's health issues and resources; and
- Promoting public awareness campaigns and education on the health needs of women.

The Women's Health Officer provides an annual report to the Governor and presiding officers of the Legislature that includes recommended policy changes for implementing the strategy.⁵⁵ According to the National Conference on State Legislatures, at least 18 states have created either offices or commissions dedicated to women's health, while three states—Florida, Illinois and Maine—have designated a women's health officer or coordinator.⁵⁶

Food Safety Programs

Three state departments operate food safety programs in Florida: the Department of Agriculture and Consumer Services, the Department of Business and Professional Regulation, and DOH. The three agencies carry out similar regulatory activities, but have varying statutory authority, regulate separate sectors of the food service industry, and are funded at different levels because of statutory fee caps.⁵⁷ Each agency issues food establishment licenses or permits, conducts food safety inspections and enforces regulations through fines and other disciplinary actions.⁵⁸

Each agency has authority over specific types of food establishments. In general, DOH licenses facilities that serve high-risk populations such as hospitals, nursing homes, group care facilities, child care facilities, detention centers, and schools.⁵⁹ The Department of Business and Professional Regulation licenses restaurants, clubs, theaters, truck stops and gas stations.⁶⁰ The Department of Agriculture and Consumer Services regulates grocery stores and supermarkets, food packaging and processing plants.⁶¹ While these agencies do not perform duplicate inspections, a single establishment with multiple food operations could be licensed or have food permits from multiple departments.⁶²

Of the food establishments regulated by DOH, several hold licenses issued by other departments, such as the Agency for Health Care Administration (AHCA) or the Department of Children and Family Services (DCF), which include some food service regulations and inspections. For example, nursing homes licensed and regulated by AHCA have a federal food safety requirement, which requires a complete kitchen inspection by a surveyor who has been trained, passed the Surveyor Minimum Qualifications Test and is qualified to conduct a Quality Indicator Survey Process.⁶³ AHCA also uses hospital surveyors to inspect sanitary conditions in hospitals under the Condition of Infection Control using the FDA Food Code.

⁵⁵ s. 381.04015(2)(p), F.S.

⁵⁶ "Laws and Initiatives on Women's Health," National Conference of State Legislatures (Updated February 2010); located at <http://www.ncsl.org/default.aspx?tabid=14377> (last viewed on March 17, 2010).

⁵⁷ Office of Program Policy Analysis & Government Accountability, State Food Safety Programs Should Improve Performance and Financial Self-Sufficiency, Report No. 08-67 (December 2008).

⁵⁸ Office of Program Policy Analysis & Government Accountability, State Food Safety Programs Should Improve Performance and Financial Self-Sufficiency, Report No. 08-67 (December 2008).

⁵⁹ s. 381.0072, F.S.

⁶⁰ ch. 509, F.S.

⁶¹ ch. 500, F.S.

⁶² ⁶² Office of Program Policy Analysis & Government Accountability, State Food Safety Programs Should Improve Performance and Financial Self-Sufficiency, Report No. 08-67 (December 2008).

⁶³ Email correspondence with AHCA staff on file with the Health Care Regulation Policy Committee (March 16, 2010).

DCF licenses or certifies and inspects child care facilities, as well as family day care and large family day care homes. DOH also inspects child care facilities.⁶⁴ On December 30, 2009, the Office of Program Policy Analysis and Government Accountability (OPPAGA) issued a memorandum which highlighted the overlap in agency regulatory functions for child care facilities and determined that both DOH and DCF inspect 66 percent of the licensed child care establishments (DCF alone inspects the remaining 34 percent) for a variety of environmental health issues.⁶⁵ With regard to food service inspections, the two agencies consider the following:

Department of Children and Families ⁶⁶	Department of Health ⁶⁷
<ul style="list-style-type: none"> • Cleanliness/sanitary conditions • Handwashing • Drinking water • Types of meals provided – Nutrition & Menu • Proper refrigeration • Proper use of single service items (forks and spoons) 	<ul style="list-style-type: none"> • Source/wholesomeness of food • Food storage • Equipment/Preparation • Sanitizing • Handwash sink • Hot and cold water • Temperatures • Other

DCF also certifies and regulates Florida’s 42 certified domestic violence centers. Most centers have kitchen areas that are equipped with basic supplies and tools residents may use to prepare their own meals; however, they do not provide meals for the residents. Only one center provides meals to residents.⁶⁸

Emergency Management

The Florida Department of Emergency Management has designated DOH the lead agency for Emergency Support Function – 8 (ESF-8), which concerns medical and health issues. ESF-8, through DOH and at least 12 other support agencies such as AHCA, DCF and the American Red Cross, oversees medical and health-related preparedness, recovery, mitigation, and response efforts in the event of a major natural or man-made disaster. ESF-8 agencies coordinate and manage overall public health response, triage, treatment and transportation of victims of a disaster, including transporting people out of a potentially affected area prior to an event. These agencies provide immediate support to hospitals and nursing homes, provide emergency behavioral health services and crisis counseling for victims, and assist in reestablishing health and medical systems post-event.⁶⁹

Statewide Injury Prevention Program

In 2004, the Legislature tasked DOH with establishing an injury prevention program to provide for statewide coordination and expansion of injury-prevention activities.⁷⁰ Pursuant to the program, DOH is required to collect data, provide surveillance, provide education, and promote interventions related to injury prevention, including:⁷¹

- Provide communities, county health departments, and other state agencies with expertise and guidance in injury prevention;
- Seek, receive, and expend funds received from grants, donations, or contributions from public or private sources for program purposes; and
- Develop, and revise as necessary, a comprehensive state plan for injury prevention.

⁶⁴ The report also analyzed the overlap in regulation between DCF and the Agency for Workforce Innovation, which also inspects child care facilities.

⁶⁵ Child Care Services Placement Options for Legislative Consideration, OPPAGA Research Memorandum (December 30, 2009)

⁶⁶ DCF Child Care Facility Standards Classification Summary, CF-FSP Form 5316 (October 2007).

⁶⁷ DOH County Health Department Child Care Facility Inspection Report.

⁶⁸ Department of Children and Family Services Staff Analysis and Economic Impact for House Bill 295 (November 5, 2009).

⁶⁹ Florida Field Operations Guide, Chapter 16; located at

<http://www.floridadisaster.org/FOG/Final%202005Chapter%2016%20111205.pdf> (last visited on March 19, 2010).

⁷⁰ s. 401.243, F.S. (created in CS/HB 2448; ch. 2004-350, L.O.F.)

⁷¹ s. 401.243, F.S.

The program collaborates with other state agencies regarding injury prevention issues and administers the following:

- Florida Bicycle Helmet Promotion Program
- Florida Special Needs Occupant Protection Program
- Drowning Prevention Awareness Campaign
- Public Information, Education and Relations for EMS Program; and
- Safe Kids Florida

Children's Early Investment Program

In 1989, the Legislature created the Children's Early Investment Program.⁷² The program targeted young children who are at risk of developmental dysfunction or delay and their families. The services provided were to enhance family independence and provide social and educational resources needed for healthy child development. According to DOH, the Children's Early Investment Act was created as a pilot initiative that was executed through a contract with The Ounce of Prevention Fund of Florida.⁷³ The pilot initiative and all funding ceased more than ten years ago.⁷⁴

Effect of the Bill

The bill amends section 20.43, Florida Statutes, to modify the current responsibilities of DOH and reduce its responsibilities—by combining some functions and deleting others—from 13 responsibilities to the following eight:

- Identifying, diagnosing, investigating and conducting surveillance of communicable diseases in the state;
- Maintaining a constant surveillance of disease occurrence and accumulating health statistics necessary to establish disease trends and to design health programs.
- Implementing interventions that prevent or limit the impact or spread of disease in the state;
- Maintaining and coordinating preparedness and response for public health emergencies in the state;
- Regulating environmental activities that have a direct impact on public health in the state;
- Administering and providing health and related services for targeted populations in the state;
- Collecting, managing, and analyzing vital statistics data in the state; and
- Regulating health practitioners, to the extent authorized by the Legislature, as necessary for the preservation of the health, safety, and welfare of the public.

Although the bill focuses DOH's mission in section 20.43, Florida Statutes, it does not repeal DOH's specific authority to administer the majority of programs it currently administers, such as:

- Children's Medical Services—authorized by chapter 391, Florida Statutes.
- Child Protection Teams—authorized by section 39.303, Florida Statutes.
- Early Intervention Programs—authorized by section 391.308, Florida Statutes.
- Coordination with schools related to child immunizations—authorized by section 1003.22, Florida Statutes.
- Chronic Disease Prevention and Control Program—authorized by chapter 381, Florida Statutes.
- Statewide Cancer Registry—authorized section 385.202, Florida Statutes.
- Communicable Disease Program—authorized by section 381.003, Florida Statutes
- Control of Sexually Transmitted Diseases, including AIDS—authorized by chapter 384, Florida Statutes.
- Immunization Registry—authorized by section 381.003(1) (e), Florida Statutes.

⁷² s. 411.232, F.S.

⁷³ Email correspondence with Department of Health staff on file with the Health Care Regulation Policy Committee (March 9, 2010)

⁷⁴ *Id.*

- Lead Poisoning Screening Program—authorized by sections 381.982–381.985, Florida Statutes.
- Closing the Gap Program—authorized by section 381.7353, Florida Statutes.
- Healthy Start Program—authorized by chapter 383, Florida Statutes

Instead, the bill requires DOH to submit a proposal to the President of the Senate, Speaker of the Florida House of Representatives, and the appropriate substantive legislative committees by November 1, 2010, for a new department structure based upon the eight revised responsibilities. The proposal must include reductions in the number of departmental bureaus and divisions and a limit on the number of executive positions pursuant to the new responsibilities assigned to DOH. DOH must identify existing functions and activities that are inconsistent with its responsibilities and provide a job description of all bureau chief or division director positions proposed for retention.

The bill sunsets ten of DOH's 11 departmental divisions on July 1, 2011, unless reviewed and reenacted by the Legislature. The eleventh, the Division of Medical Quality Assurance, is sunset on July 1, 2011, without the requirement for future reenactment because the bill transfers—via a type-two transfer—this division to the Department of Business and Professional Regulation (DBPR) at that time. Because regulation of health practitioners is one of the core DOH responsibilities in the bill, the bill also sunsets this core responsibility effective July 1, 2011, because of the type-two transfer. Thus, effective July 1, 2011, DOH will have seven core responsibilities.

The bill amends the State Surgeon General's statutory authority to provide that the State Surgeon General must manage the department in carrying out its delegated responsibilities. Additionally, the bill modifies DOH authority to establish service areas to carry out the duties of the county health departments. Currently, DOH is limited to establishing 15 service areas, which are statutorily required to have the same boundaries as the DCF service districts established in section 20.19, Florida Statutes, and to the extent practicable, the boundaries of the jobs and education regional boards. The bill removes the 15-area limit and does not specify the boundaries for such service areas.

The bill removes a provision that authorizes division directors to appoint ad hoc advisory committees. Additionally, the bill removes subsection (7) of section 20.43, Florida Statutes, which provides DOH with the authority to use state and federal funds to protect and improve the public health by: providing incentives for encouraging healthy lifestyles, disease prevention behaviors, and patient compliance with medical treatments; planning and conducting health campaigns to protect and improve health, including purchasing promotional items and advertising for certain health-related behaviors; and planning and conducting promotional campaigns to recruit health professionals and participants in departmental programs.

The bill deletes a subsection allowing DOH to hold copyrights, trademarks, and service marks, and enforce its rights with respect to those interests. Beginning in Fiscal Year 2010-2011, the bill precludes DOH from initiating or commencing new programs, including federally-funded or grant-supported programs, or making changes in existing programs without express legislative authority. This does not prohibit DOH from continuing grants initiated or commenced prior to July 1, 2010. DOH is also prohibited from applying for continuation federal or private grants without prior approval from the Legislative Budget Commission (LBC). The LBC request must include detailed information about the purpose of the grant, the proper use of the grant, the need for continuation, the intended use of the continuation funds, and the number of full-time temporary or permanent employees that participate in administering the grant. The request is subject to the LBC's notice, review and objection procedures set forth in section 216.177, Florida Statutes.

The bill also amends section 381.0011, Florida Statutes, relating to the duties and powers of DOH. Generally, the duties are amended to comply with the revised departmental responsibilities. In this section, the bill also expands upon DOH's role in managing and coordinating emergency preparedness and disaster response functions by providing that DOH:

- Investigate and control the spread of disease;
- Coordinate the availability and staffing of special needs shelters;

- Support patient evacuation;
- Assure the safety of food and drugs;
- Provide critical incident stress debriefing; and
- Provide surveillance and control of radiological, chemical, biological, and other environmental hazards.

The bill requires that the DOH strategic long-term plan relate to its delegated responsibilities. The bill specifies that DOH can continue to issue health alerts and advisories, after conducting a workshop in non-emergency situations, but removes a provision authorizing DOH to disseminate information to the public about general prevention, control and cure of diseases, illnesses, and hazards to human health. Furthermore, the bill removes from the list of duties, authorization for DOH to cooperate with other entities for “the improvement and preservation of public health” and to maintain a statewide injury prevention program. DOH’s authority to cooperate with other entities is either specified in statutory programs delegated to DOH to administer or implied by general operation of a state agency. The bill prohibits DOH from writing rules to inspect buildings or facilities it is not authorized to inspect by law.

The bill amends section 381.006, Florida Statutes, relating to DOH’s environmental health program. For purposes of this program, s. 381.006(16), F.S. defines group care facilities to include:

[a] public or private school, housing, building or buildings, section of a building, or distinct part of a building or other place, whether operated for profit or not, which undertakes, through its ownership or management, to provide one or more personal services, care, protection, and supervision to persons who require such services and who are not related to the owner or administrator.

The bill amends this definition to specifically reference the following facilities: public or private schools; assisted living facilities; adult family-care homes; adult day care centers; short term residential treatment centers; residential treatment facilities; home for special services transitional living facilities; crisis stabilization units; hospices; prescribed pediatric extended care centers; intermediate care facilities for persons with developmental disabilities (ICF/DDs); or boarding schools. The bill limits DOH’s rulemaking authority to these entities, except that the Department of Education shall develop rules related to public and private schools in consultation with DOH.

The bill also amends section 381.0072, Florida Statutes, relating to food service protection. The bill amends the definition of “food service establishment.” Currently, food service establishments are defined, in part, as:

[a]ny facility, as described in this paragraph, where food is prepared and intended for individual portions service, and includes the site at which individual portions are provided. The term includes any such facility regardless of whether consumption is on or off the premises and regardless of whether there is a charge for the food

The bill amends the definition of “food service establishment” to the following specific entities: detention facilities, public or private schools, migrant labor camps, assisted living facilities, adult family-care homes, adult day care centers, short term residential treatment centers, residential treatment facilities, crisis stabilization units, hospices, prescribed pediatric care centers, ICF/DDs, boarding schools, civic or fraternal organizations, bars and lounges, and vending machines dispensing potentially hazardous foods at facilities these facilities. The bill authorizes DOH to advise Agency for Health Care Administration (AHCA), Department of Business and Professional Regulation (DBPR), Department of Agriculture and Consumer Services, and Department of Children and Family Services (DCF) concerning procedures related to the storage, preparation, serving and display of food at any building, structure or facility not expressly included in this section that may be inspected, licensed or regulated by those agencies. Additionally, the bill exempts civic organizations and facilities not regulated by DOH under this section from the requirement to have a certified food manager.

The bill amends section 381.0101, Florida Statutes, relating to environmental health professionals. Current law authorizes DOH to determine which programs are essential for providing basic environmental and sanitary protection to the public. The bill limits this authority to programs the department is expressly authorized in statute to administer, which are the food protection at food service establishments and onsite sewage treatment and disposal system evaluations.

To conform with the amended definition of food service establishments, the bill amends section 509.013, F.S., to provide that any facility licensed or certified by AHCA or DCF or other similar place regulated under section 381.0072, Florida Statutes, are exempt from the definitions of “public lodging establishments” and “public food service establishment” for purposes of inspections conducted by DBPR. This will ensure that hospitals, nursing homes, group homes, child care facilities, and domestic violence centers will not fall under the purview of DBPR for food service inspections because they are no longer included in the definition of “food service establishments” under section 381.0072, Florida Statutes.

The bill amends section 381.4018, Florida Statutes, relating to physician workforce assessment and development. The bill creates definitions for “consortium” and “consortia,” “council,” “department,” “graduate medical education program,” and “primary care specialty.” Additionally, the bill specifies legislative intent that physician workforce strategies should include the availability and capacity of quality medical school and graduate medical education programs. The bill creates the “Physician Workforce Advisory Council” within DOH, which is composed of 23 members. The State Surgeon General appoints: a designee from DOH; an individual recommended by the AHEC Network; 2 individuals recommended by the Council of Florida Medical School Deans; 2 individuals recommended by the Florida Hospital Association; 2 individuals recommended by the Florida Medical Association; 2 individuals recommended by the Florida Osteopathic Medical Association; 2 program directors of accredited graduate medical education programs; an individual recommended by the Florida Justice Association; an individual representing a profession in the field of health services administration; and a layperson member. Additionally, the following individuals, or their designees, are on the Advisory Council: Commissioner of Education, chancellor of the State University System, secretary of AHCA, executive director of the Florida Department of Veterans’ Affairs, secretary of the Department of Elder Affairs, President of the Senate, and Speaker of the House. The State Surgeon General serves as the chair and appoints a vice chair. Each council member may serve up to two, four-year terms.

The bill provides terms for removal of a member of the Advisory Council and methods for replacing any removed member. The Advisory Council is required to meet twice a year—in person or by teleconference—and members are not entitled to receive compensation, per diem, or reimbursement for travel expenses. The advisory council is responsible for:

- Advising DOH and the Surgeon General on current and future physician workforce issues;
- Reviewing physician survey materials and the compilation of survey information;
- Providing DOH recommendations regarding additional survey questions;
- Assisting DOH in preparing the annual physician workforce report to the Legislature;
- Assisting DOH in preparing an initial and future strategic plans and providing advice on implementing recommendations;
- Monitoring the need for additional primary care physicians; and
- Monitoring the status of graduate medical education in the state, including the role of medical residents and medical faculty in the provision of health care, the relationship of graduate medical education in the state’s physician workforce, and the availability and use of state and federal funds for graduate medical education.

Additionally, the bill amends sections 458.3192 and 459.0082, Florida Statutes, by requiring that the analysis of physician and osteopathic physician workforce surveys, respectively, include information regarding the number of physicians who practice medicine in the state and the number who have reduced or modified the scope of their practice. DOH is required to include the advisory council’s findings, recommendations and other information in its report to the Governor, Speaker of the House and Senate President.

The bill amends section 392.69, Florida Statutes, by requiring DOH to submit a plan to the Governor, President of the Senate, and Speaker of the House by November 1, 2010, to provide treatment to cure, hospitalization, and isolation exclusively by private and non-state public hospitals for contagious cases of tuberculosis. The plan must include:

- Identification of hospitals functionally capable of caring for such patients;
- Reimbursement for hospital inpatient and other medically necessary services at the Medicaid rate;
- Projected cost estimates; and
- A transition plan for closing the A.G. Holley Hospital and transitioning patients to such hospitals over a 90-day period of time.

The bill does not require DOH to implement the plan. Any plan would be subject to consideration by, and direction from, a future Legislature before implementation. The bill also amends section 392.51, Florida Statutes, by removing a reference to the A.G. Holley Hospital to conform to these changes.

The bill reduces DOH regulation under part I of chapter 499 relating to drugs, devices and cosmetics by amending section 499.01, Florida Statutes to exempt medical device manufacturers who do not manufacture, repackage, or assemble any medical devices and components that are not already exempt from medical device manufacture registration requirements under section 499.015(8), Florida Statutes, from permitting requirements. The bill also amends section 499.01212, Florida Statutes, to exempt the wholesale distribution of prescription drugs contained within a sealed medical convenience kit from the pedigree paper requirement as long as the medical convenience kit is assembled in an establishment that is registered as a medical device manufacturer with the Food and Drug Administration and the kit does not contain a controlled substance.

The bill amends section 499.029, Florida Statutes, relating to the Cancer Drug Donation Program. The bill renames the program the Prescription Drug Donation Program and modifies the current program by:

- Expanding the types of drugs that may be donated, from cancer drugs and supplies to all nonscheduled prescription drugs and supplies; and
- Expanding the facilities that participate in the program, from a class II hospital pharmacy to any pharmacy or dispensing practitioner.

The bill deletes the definition of “cancer drug,” and includes a definition of “dispensing practitioner” and “prescription drug.”

In sections 18 and 19 of the bill, the bill transfers, via type-two transfer, both MQA and DOH’s statutory powers, duties and functions related to administering part 1 of chapter 499 relating to drugs, devices and cosmetics, from DOH to DBPR on July 1, 2011. Pursuant to section 20.06(2), Florida Statutes, a type-two transfer results in the transfer of all statutory powers, duties, and functions; records; personnel; property; unexpended balances of appropriations, allocations, or other funds, except those transferred elsewhere or abolished from one agency to another. The bill establishes such a transfer and provides that the administrative rules of DOH related to MQA and Drugs, Devices and Cosmetics, as well as lawful DOH issued orders or licenses, permits or certifications shall remain and full force and effect. The transfer does not affect the validity of any judicial or administrative action pending as of the time of the transfer.

Finally, the bill repeals section 381.001, Florida Statutes, which provides legislative intent language related to DOH’s public health mission; section 381.04015, Florida Statutes, relating to the Office and Officer of Women’s Health Strategy; section 401.243, Florida Statutes relating to the statewide injury prevention program. The bill also repeals sections 411.23-232, Florida Statutes, relating to the now defunct Children’s Early Investment Act, and amends sections 411.401 and 411.224, Florida Statutes, by deleting cross references to the Children’s Early Investment Act to conform.

B. SECTION DIRECTORY:

Section 1. Amends s. 20.43, F.S., relating to the Department of Health.

Section 2. Amends s. 381.0011, F.S., relating to duties and powers of the Department of Health.

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- Section 3.** Amends s. 381.006, F.S., relating to environmental health.
- Section 4.** Amends s. 381.0072, F.S., relating to food service protection
- Section 5.** Amends s. 381.0101, F.S. relating to environmental health professionals.
- Section 6.** Repeals ss. 381.001, 381.04015, 401.243, 411.23, 411.231, and 411.232, F.S., relating to legislative intent; public health system; Women's Health Strategy, legislative intent; duties of Officer of Women's Health Strategy; other state agency duties; injury prevention; short title; legislative intent; purpose; and relating to Children's Early Investment Program, respectively.
- Section 7.** Amends s. 381.4018, F.S., relating to physician workforce assessment and development
- Section 8.** Amends s. 392.51, F.S., relating to findings and intent
- Section 9.** Amends s. 392.69, F.S., relating to appropriation, sinking, and maintenance trust funds; additional powers of the department.
- Section 10.** Amends s. 411.01, F.S., relating to school readiness programs; early learning coalitions.
- Section 11.** Amends s. 411.224, F.S., relating to family support planning process.
- Section 12.** Amends s. 458.3192, F.S., relating to analysis of survey results; report.
- Section 13.** Amends s. 459.0082, F.S., analysis of survey results; report.
- Section 14.** Amends s. 499.01, F.S., relating to permits.
- Section 15.** Amends s. 499.01212, F.S., relating to pedigree paper.
- Section 16.** Amends s. 499.029, F.S., relating to Cancer Drug Donation Program.
- Section 17.** Amends s. 509.013, F.S., relating to definitions.
- Section 18.** Provides for a type-two transfer of the statutory duties and administration of Part 1, Chapter 499 from the Department of Health to the Department of Business and Professional Regulation effective July 1, 2011.
- Section 19.** Provides for a type-two transfer of the Division of Medical Quality Assurance from the Department of Health to the Department of Business and Professional Regulation effective July 1, 2011.
- Section 20.** Provides an effective date of July 1, 2010.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

	FY 2010-11	FY 2011-12
Environmental Health Food Service Inspections		
\$250 fee for 1080 hospitals/nursing homes	(\$270,000)	\$0
\$110 fee for 5,027 child care centers	(\$552,970)	\$0
\$190 fee for 156 theaters	(\$29,640)	\$0
Subtotal Estimated Revenues	(\$852,610)	\$0
Office of Injury Prevention		
Injury Prevention Grant	(\$113,173)	\$0
Bicycle Helm Grant	(\$127,934)	\$0
Special Needs Grant	(\$157,955)	\$0
Teen Dating Violence Grant	(\$166,666)	\$0
Indirect Earnings	(\$37,056)	\$0
In-Kind Donations	(\$248,000)	\$0
Subtotal Estimated Revenues	(\$850,784)	\$0
Total Estimated Revenues	(\$1,703,394)	\$0

Note: As part of the grant requirements, the department's Division of Family Health will lose the Teen Dating Violence Grant as a result of the loss of the Injury Prevention Grant and Program.

2. Expenditures:

	FY 2010-11	FY 2011-12
Environmental Health Food Service Inspections		
Salaries		
49 FTE @ \$36,000 annually	(\$1,764,000)	\$0
Other Personal Services	(\$591,724)	\$0
Expense		
49 FTE @ \$12,076	(\$591,724)	\$0
Human Resources Services		
49 FTE @ \$285	(\$13,965)	\$0
Subtotal Estimated Expenditures		
County Health Department Trust Fund	(\$2,961,413)	\$0
Office of Injury Prevention		
Salaries		
6 FTE - Administrative Trust Fund	(\$379,329)	\$0
1 FTE - Federal Grants Trust Fund	(\$56,740)	
Other Personal Services		
Administrative Trust Fund	(\$10,000)	\$0
Expense		
Administrative Trust Fund	(\$133,178)	\$0
Federal Grants Trust Fund	(\$334,923)	\$0
Contracted Services		
Administrative Trust Fund	(\$5,623)	\$0
Federal Grants Trust Fund	(\$166,666)	\$0
Operating Capital Outlay		
Federal Grants Trust Fund	(\$7,000)	\$0
Human Resources Services		
Administrative Trust Fund	(\$2,496)	\$0
Federal Grants Trust Fund	(\$399)	\$0
Subtotal Estimated Expenditures		
Administrative Trust Fund	(\$1,096,354)	\$0
Federal Grants Trust Fund	(\$530,626)	\$0
Federal Grants Trust Fund	(\$565,728)	\$0
Total Estimated Expenditures	(\$4,057,767)	\$0
Administrative Trust Fund	(\$530,626)	\$0
County Health Department Trust Fund	(\$2,961,413)	\$0
Federal Grants Trust Fund	(\$565,728)	\$0

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill will reduce the number of inspections at certain facilities in the state, which will reduce duplicative regulatory burdens on private facilities.

D. FISCAL COMMENTS:

The fiscal impact in this analysis pertains only to the portions of the bill that will have an immediate impact on DOH. Because transfers of MQA and DDC will not occur until Fiscal Year 2011-2012 and the provisions in the bill pertaining to A.G. Holley simply require DOH to develop a plan, a fiscal analysis of those provisions of the bill was not included.

According to DOH's bill analysis, Economic Impact Statement, and Fiscal Note, the bill stops county health departments from performing group care facility inspections at child care centers, domestic violence centers, group care homes and residential child caring agencies. That inspection workload is estimated to equal 22 FTE positions. Similarly, the bill stops county health departments from performing food service inspections at child care centers, nursing homes, hospitals, and group care homes. The inspection workload for child care centers, nursing homes, and hospitals is estimated to be 27 FTE positions. It is not known if the health departments will have enough work in other programs to assign these 49 staff to that handled this workload or if they will have to lay off some staff. The workload and accompanying FTE estimates were determined using the department's workload unit program, which was developed in part for this purpose.

Additionally, DOH indicated that 61 percent of the total funds invested in the Injury Program are from federal grants and in-kind donations. The remaining 39 percent of the investment is for positions that are responsible for statewide coordination of injury activities, surveillance, data analysis, state plan activities, and intervention programs such as bicycle helmet, child passenger safety, drowning prevention, and senior fall prevention.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

2. Other:

In its analysis, DOH asserts that the "legislative approval required for grant applications or 'program' development" may violate section 3, Article II, of the Florida Constitution, which provides in part, "No person belonging to one branch shall exercise any powers appertaining to either of the other branches unless expressly provided herein." It is unclear to which executive power this statement pertains.

B. RULE-MAKING AUTHORITY:

The bill modifies DOH's existing rulemaking authority; however, DOH has sufficient rulemaking authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

On March 26, 2010, the Health Care Appropriations Committee adopted a strike-all amendment and five amendments to the strike all amendment. The strike-all amendment retained the existing bill provisions with the following additions:

- Transfers the Division of Medical Quality Assurance (MQA) to the Department of Business and Professional Regulation via type-two transfer effective July 1, 2011.
- Requires DOH to submit a plan by November 1, 2010 to transition state tuberculosis care to qualified community hospitals, to be paid at Medicaid rates, and close the A.G. Holley State Hospital. The strike-all does not require DOH to implement the plan.
- Transfers the Division of Drugs, Devices and Cosmetics (DDC) to the Department of Business and Professional Regulation via type-two transfer effective July 1, 2011.
- Exempts drug device manufacturers that are exempt from permitting requirements elsewhere in law from DDC regulation and inspection.
- Expands the Drug Donation Program to cover all non-controlled substance prescription drugs, not just cancer drugs, and allow all pharmacies and dispensing practitioners to accept donated drugs.
- Creates a Physician Workforce Advisory Council and modifies the physician workforce survey information.
- Requires DOH to request approval from the LBC before applying for any continuation grants.

The five amendments to the strike all amendment made the following changes:

- Exempts sealed medical convenience kits meeting certain specification from the pedigree paper requirements.
- Removes a provision repealing the Community Hospital Education Programs (CHEPs)
- Restored a cross reference to the CHEPs to conform.
- Restored language authorizing the department to maintain constant surveillance of disease occurrence and accumulating health statistics necessary to establish disease trends and to design health programs as one of its primary responsibilities.
- Restored the removal of DOH's responsibility to implement interventions that prevent or limit the impact or spread of disease in the state, which was removed by the prior amendment.

The bill was reported favorably as a committee substitute. The analysis reflects the committee substitute.