The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

HEALTH REGULATION
Senator Garcia, Chair
Senator Sobel, Vice Chair

MEETING DATE: Tuesday, March 22, 2011
TIME: 8:00 —10:00 a.m.
PLACE: *Pat Thomas Committee Room,* 412 Knott Building

MEMBERS: Senator Garcia, Chair; Senator Sobel, Vice Chair; Senators Altman, Bennett, Diaz de la Portilla, Fasano, Gaetz, Gardiner, Jones, Latvala, Norman, and Ring

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	**SB 1282** Storms (Similar H 1085)	Women's Health; Cites this act as the "Gynecologic and Ovarian Cancer Education and Awareness Act." Establishes the Gynecologic and Ovarian Cancer Awareness Program in the Department of Health. Requires the Department of Health to disseminate information on gynecologic cancers to the extent that funding is available. Directs the department to establish a Women's Gynecologic Cancer Information Advisory Council. HR 03/22/2011 BC	
2	**SB 1372** Storms (Compare H 1083)	Persons with Developmental Disabilities/Medication; Requires a registered nurse or physician to assess and validate a direct service provider's competency in all routes of medication administration at an onsite setting with an actual client. Provides an exception. HR 03/22/2011 CF BC	
3	**SB 1118** Bogdanoff (Similar H 919, Compare H 305, S 454)	Nursing Services; Requires that hospitals establish nurse staffing collaborative councils. Provides for membership and responsibilities. Requires the council to produce annual hospital nurse staffing plans. Requires the chief nurse executive to communicate with the council to ensure appropriate implementation of the nurse staffing plan. Requires that the council conduct a semiannual review of the nurse staffing plan. Requires the nurse staffing plan to be reviewed with the nurse personnel and made available to the public upon request, etc. HR 03/22/2011 BC	

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
4	**SB 1586** Hays (Similar H 1437)	Authority/Certain Professionals/Practice in State; Deletes provisions that limit the practice privileges of out-of-state or foreign health professionals or veterinarians who are in this state for a specific sporting event. HR 03/22/2011 RI BC	
5	**CS/SB 1086** Criminal Justice / Hill (Compare H 779) **(If Received)**	Restraint of Incarcerated Pregnant Women; Prohibits use of restraints on a prisoner known to be pregnant during labor, delivery, and postpartum recovery unless a corrections official makes an individualized determination that the prisoner presents an extraordinary circumstance requiring restraints. Provides that a doctor, nurse, or other health care professional treating the prisoner may request that restraints not be used, in which case the corrections officer or other official accompanying the prisoner shall remove all restraints, etc. CJ 03/14/2011 Fav/CS HR 03/22/2011 If received CA BC	
6	**SB 1990** Health Regulation	Ratification of Rules; Ratifies a specified rule for the sole and exclusive purpose of satisfying any condition on effectiveness established by a provision, which requires ratification of any rule that meets any of the specified thresholds that may likely have an adverse impact or excessive regulatory cost. HR 03/22/2011 BC	
7	**SB 1522** Gaetz (Similar CS/H 445, Compare H 119, S 1736, S 1972)	Wellness or Health Improvement Programs; Authorizes insurers to offer rewards or incentives to health benefit plan members to encourage or reward participation in wellness or health improvement programs. Authorizes insurers to require plan members not participating in programs to provide verification that their medical condition warrants nonparticipation. Provides application. HR 03/22/2011 BI RC	

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
8	**SB 720** Gaetz (Identical H 377)	Cancer Research and Control; Changes the carryforward period of certain funds of the Biomedical Research Trust Fund. Modifies the terms and membership and establishes a staggered membership for appointed members of the Biomedical Research Advisory Council. Authorizes the council to recommend a portion of the allocation for the James and Esther King Biomedical Research Program for specified purposes and to develop a grant application and review mechanism, etc. HR 03/22/2011 HE BC	
9	**SB 1052** Altman (Identical H 673, H 1463)	Crisis Stabilization Units; Increases the number of client beds a crisis stabilization unit is authorized to provide. HR 03/22/2011 BC	
10	**SB 1456** Garcia (Identical H 1473, Compare H 1125, S 1922)	Public Records/Florida Health Choices Program; Creates an exemption from public records requirements for personal, identifying information of a registrant, applicant, participant, or enrollee in the Florida Health Choices Program. Provides exceptions. Authorizes an enrollee's legal guardian to obtain confirmation of certain information about the enrollee's health plan. Provides for applicability. Provides a penalty for unlawful disclosure of personal, identifying information. Provides for future legislative review and repeal of the exemption under the Open Government Sunset Review Act, etc. HR 03/22/2011 CF GO	
11	**CS/SB 432** Criminal Justice / Evers (Similar CS/H 155)	Privacy of Firearms Owners; Provides that inquiries by physicians or other medical personnel concerning the ownership of a firearm by a patient or the family of a patient or the presence of a firearm in a private home or other domicile of a patient or the family of a patient violates the privacy of the patient or the patient's family members, respectively. Prohibits entry of certain information concerning firearms into medical records or disclosure of such information by specified individuals. Provides noncriminal penalties. Provides for prosecution of violations, etc. CJ 02/22/2011 Fav/CS HR 03/14/2011 Temporarily Postponed HR 03/22/2011 JU BC	

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
12	**SB 1448** Garcia (Similar H 619)	Sale or Lease of a Public Hospital; Requires that the sale or lease of a county, district, or municipal hospital to a for-profit or not-for-profit Florida corporation receive prior approval by the Attorney General. Requires the governing board to first determine whether there are any qualified purchasers or lessees of the hospital before considering whether to sell or lease the hospital. Authorizes the Attorney General to employ independent consultants to determine the fair marked value of the proposed sale or lease, etc. HR 03/22/2011 CA JU BC RC	
13	**SB 100** Ring (Identical H 1431)	Autism; Requires that a physician refer a minor to an appropriate specialist for screening for autism spectrum disorder under certain circumstances. Requires that certain insurers and health maintenance organizations provide direct patient access to an appropriate specialist for screening for or evaluation or diagnosis of autism spectrum disorder, etc. HR 03/22/2011 BI BC	
14	**SB 1736** Latvala (Similar H 119, Compare CS/H 445, H 1295, H 4051, S 694, S 1458, S 1522, S 1972)	Health Care; Amends provisions relating to the Drug-Free Workplace Act. Deletes a provision that requires a laboratory to submit to the AHCA a monthly report containing statistical information regarding the testing of employees and job applications. Repeals provisions relating to confidentiality of inspection reports of licensed birth center facilities. Provides for the DCFS rather than the DOH to perform certain functions with respect to child protection cases, etc. HR 03/22/2011 BC	
15	**SB 1454** Garcia (Identical H 1105)	Treatment of a Surrendered Newborn Infant; Presumes that the birth mother of a surrendered newborn infant is eligible for coverage under Medicaid as is the infant. HR 03/22/2011 BC	

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Fasano) recommended the following:

Senate Amendment (with title amendment)

Delete lines 44 - 45
and insert:
Section 1. This act may be cited as the "Kelly Smith Gynecologic and Ovarian Cancer Education and Awareness Act."

========== T I T L E A M E N D M E N T ==========
And the title is amended as follows:
Delete lines 3 - 4
and insert:
Kelly Smith Gynecologic and Ovarian Cancer Education

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and Awareness Act; amending s. 381.04015, F.S.;
establishing the

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 Regulation Committee

BILL:	SB 1282
INTRODUCER:	Senator Storms
SUBJECT:	Women's Health
DATE:	March 18, 2011
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	O'Callaghan	Stovall	HR	**Pre-meeting**
2.			BC	
3.				
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I. Summary:

This bill makes certain findings related to women's health including: the Department of Health's (DOH) role in reducing the number of deaths of women diagnosed with cancer or other diseases; the need for DOH to develop a program to educate women and make them aware of gynecologic cancers; the number of women affected by, and the survival rate associated with, gynecologic cancers; and the importance of early detection and treatment of gynecologic cancers.

The bill creates the "Gynecologic and Ovarian Cancer Education and Awareness Act" (act). The bill amends s. 381.04015, F.S., to establish within the DOH a Gynecologic and Ovarian Cancer Awareness Program (program). The bill requires the DOH to implement the program, to the extent funds are appropriated to fulfill this purpose or existing federal or state resources are made available to the DOH, by:

- Providing information to the public regarding women's gynecologic cancers;
- Publishing information related to gynecologic cancers on the DOH website along with a link to the Centers for Disease Control and Prevention's website:
- Developing and providing public service announcements and advertisements informing the public about gynecologic cancers;
- Forming and executing a distribution plan to disseminate gynecologic cancer educational materials and information;
- Encouraging health care providers to display and distribute gynecologic cancer education materials; and
- Appointing, by October 1, 2011, a Women's Gynecologic Cancer Information Advisory Council (council).

The bill also provides requirements as to the membership of the council and requires the council to meet at least biannually.

This bill substantially amends s. 381.04015, F.S.

This bill also creates an undesignated section of the Florida Statutes.

II. Present Situation:

Gynecologic Cancers

Gynecologic cancer is any cancer that starts in a woman's reproductive organs. There are five main gynecologic cancers (cervical, ovarian, uterine, vaginal, and vulvar). Each year in the United States, approximately 71,500 women are diagnosed with gynecologic cancer, and approximately 26,500 women die from it.[1]

It is unknown what exactly causes gynecologic cancers, but it is clear that certain changes in cells can cause such cancers. Cell changes can be acquired or inherited. If the changes are acquired, they are caused by environmental factors, such as smoking. Almost all cervical cancers and some vaginal and vulvar cancers are caused by human papillomavirus, also called HPV, which is an acquired virus. If cell changes are inherited, they are passed from parent to child through genes.[2]

The Centers for Disease Control and Prevention (CDC) recommend the following to prevent or detect gynecologic cancers:

- Pay attention to your body and know what is normal for you.
- Make healthy lifestyle choices.
- Know your family health history and share it with your doctor.
- Get the HPV vaccine if you are at an age when it is recommended.
- Get regular Pap (Papanicolaou) tests.[3]

According to the CDC, some symptoms of gynecologic cancer include:

- Abnormal vaginal bleeding or discharge.
- Pelvic pain or pressure.
- Abdominal or back pain.
- Bloating.
- Changes in bathroom habits.
- Itching or burning of the vulva.
- Changes in vulva color or skin, such as a rash, sores, or warts.[4]

[1] Centers for Disease Control and Prevention, *Get the Facts About Gynecologic Cancer*, available at: http://www.cdc.gov/cancer/knowledge/pdf/CDC_GYN_Comprehensive_Brochure.pdf (Last visited on March 18, 2011).
[2] *Id.*
[3] *Id.*
[4] *Id.*

The Department of Health

Section 20.43, F.S., creates the DOH. The DOH is responsible for the state's public health system, which is designed to promote, protect, and improve the health of all people in the state. The mission of the state's public health system is to foster the conditions in which people can be healthy, by assessing state and community health needs and priorities through data collection, epidemiologic studies, and community participation; by developing comprehensive public health policies and objectives aimed at improving the health status of people in the state; and by ensuring essential health care and an environment which enhances the health of the individual and the community.[5] The State Surgeon General is the State Health Officer and the head of the DOH.

Officer of Women's Health Strategy

In 2004, Florida passed legislation establishing the Department of Health Officer of Women's Health Strategy with the charge to direct public policy to address the distinct health needs of women across the life span.[6]

Under s. 381.04015, F.S., it is the duty of the Officer of Women's Health Strategy to:

- Ensure that the state's policies and programs are responsive to sex and gender differences and to women's health needs across women's life spans.
- Organize an interagency Committee for Women's Health for the purpose of integrating women's health programs in current operating and service delivery structures and setting priorities for women's health.
- Assess the health status of women in the state through the collection and review of health data and trends.
- Review the state's insurance code as it relates to women's health issues.
- Work with medical school curriculum committees to develop course requirements on women's health and promote clinical practice guidelines specific to women.
- Organize statewide Women's Health Month activities.
- Coordinate a Governor's statewide conference on women's health, co-sponsored by the agencies participating in the Committee for Women's Health and other private organizations and entities impacting women's health in the state.
- Promote research, treatment, and collaboration on women's health issues at universities and medical centers in the state.
- Promote employer incentives for wellness programs targeting women's health programs.
- Serve as the primary state resource for women's health information.
- Develop a statewide women's health plan emphasizing collaborative approaches to meeting the health needs of women.
- Promote clinical practice guidelines specific to women.
- Serve as the state's liaison with other states and federal agencies and programs to develop best practices in women's health.
- Develop a statewide, web-based clearinghouse on women's health issues and resources.
- Promote public awareness campaigns and education on the health needs of women.

[5] Section 381.001, F.S.
[6] Section 3, ch. 2004-350, L.O.F.

- By January 15 of each year, provide the Governor, the President of the Senate, and the Speaker of the House of Representatives a report with policy recommendations for implementing the provisions of s. 381.04015, F.S.

The Comprehensive Cancer Control Program

The Comprehensive Cancer Control Program, housed under the Bureau of Chronic Disease Prevention and Health Promotion in the DOH, is funded through a cooperative agreement with the Centers for Disease Control and Prevention. The program focuses on colorectal, lung, ovarian, prostate, and skin cancers. The main objective of the cooperative agreement is to reduce the cancer burden through a collaborative effort with public and private partners throughout Florida. This is accomplished by working with the existing governor-appointed Cancer Control Research Advisory Board (C-CRAB) and a myriad of statewide cancer stakeholders including the National Cancer Institute's Cancer Information Services, the American Cancer Society, and Florida Comprehensive Cancer Control Initiative, among others.[7]

Statewide Cancer Registry

Section 385.202, F.S., requires each hospital or other licensed facility to report to the DOH information that indicates diagnosis, stage of disease, medical history, laboratory data, tissue diagnosis, and radiation, surgical, or other methods of diagnosis or treatment for each cancer diagnosed or treated by that facility. The DOH, or a medical organization pursuant to a contract with the DOH, is required to maintain and make available for research such information in a statewide cancer registry.

Cancer Control and Research Act

The Cancer Control and Research Act (Research Act) is created in s. 1004.435, F.S. The Florida C-CRAB is established within the Research Act to advise the Board of Governors, the State Surgeon General, and the Legislature with respect to cancer control and research in Florida. The C-CRAB consists of 34 members. Annually the C-CRAB approves the Florida Cancer Plan, which is a program for cancer control and research that must be consistent with the State Health Plan and integrated and coordinated with existing programs in this state. Additional responsibilities of the C-CRAB include:

- Recommending to the State Surgeon General a plan for the care and treatment of persons suffering from cancer and standard requirements for cancer units in hospitals and clinics in Florida;
- Recommending grant and contract awards for the planning, establishment, or implementation of programs in cancer control or prevention, cancer education and training, and cancer research;
- Pursuant to Legislative appropriations, providing written summaries that are easily understood by the average adult patient, informing actual and high-risk breast cancer patients, prostate cancer patients, and men who are considering prostate cancer screening of the medically viable treatment alternatives available to them and explaining the relative advantages, disadvantages, and risks associated therewith;

[7] Florida Department of Health, *Florida Cancer Plan*, available at http://www.doh.state.fl.us/family/cancer/plan/ (Last visited on February 3, 2011).

- Implementing an educational program for the prevention of cancer and its early detection and treatment;
- Advising the Board of Governors and the State Surgeon General on methods of enforcing and implementing laws concerning cancer control, research, and education; and
- Recommending to the Board of Governors or the State Surgeon General rulemaking needed to enable the C-CRAB to perform its duties.

Advisory Councils

Section 20.03(7), F.S., defines "advisory council" to mean "an advisory body created by specific statutory enactment and appointed to a function on a continuing basis for the study of the problems arising in a specified functional or program area of state government and to provide recommendations and policy alternatives." Section 20.052, F.S., establishes requirements for advisory bodies created by a specific statutory enactment. An advisory body may not be created unless:

- It meets a statutorily defined purpose;
- Its powers and responsibilities conform with the definitions for governmental units in s. 20.03, F.S.;
- Its members, unless expressly provided otherwise in the State Constitution, are appointed for 4-year staggered terms; and
- Its members, unless expressly provided otherwise by specific statutory enactment, serve without additional compensation or honorarium, and are authorized to receive only per diem and reimbursement for travel expenses as provided in s. 112.061, F.S.

III. Effect of Proposed Changes:

This bill makes certain findings related to women's health including: the DOH's role in reducing the number of deaths of women diagnosed with cancer or other diseases; the need for DOH to develop a program to educate women and make them aware of gynecologic cancers; the number of women affected by, and the survival rate associated with, gynecologic cancers; and the importance of early detection and treatment of gynecologic cancers.

The bill creates the "Gynecologic and Ovarian Cancer Education and Awareness Act" (act).

The bill amends s. 381.04015, F.S., to establish within the DOH a Gynecologic and Ovarian Cancer Awareness Program (program). The bill requires the DOH to implement the program, to the extent funds are appropriated to fulfill this purpose or existing federal or state resources are made available to the DOH, by:

- Providing information to the public regarding women's gynecologic cancers, including signs and symptoms, risk factors, benefits of early detection through appropriate diagnostic testing, and treatment options;
- Publishing information related to gynecologic cancers on the DOH website along with a link to the Centers for Disease Control and Prevention's website for in-depth gynecologic health information or offer such information in audio, video, electronic or other media format;
- Developing and providing public service announcements and advertisements that emphasize the early warning signs and risk factors associated with gynecologic cancers, indicate how

educational materials can be obtained, and encourage women to discuss the risks of such cancers with their health care providers;
- Forming and executing a distribution plan and strategy to disseminate gynecologic cancer educational materials and information, which must recommend and encourage individual public health facilities to obtain gynecologic cancer educational materials made available by federal, state, and other resources and display and distribute those materials to their consumers and patients;
- Encouraging, through a distribution plan, health care providers to display and distribute gynecologic cancer education materials to their consumers and patients; and
- Appointing, by October 1, 2011, a Women's Gynecologic Cancer Information Advisory Council (council).

The bill provides that the council shall be chaired by the Officer of Women's Health Strategy or other officer designated by the Deputy Secretary of the DOH. The council is required to meet at least biannually. Members of the council must include health care professionals, health care providers, consumers, patients, and representatives of nonprofit organizations that concentrate on gynecologic cancers, and other appropriate representatives as determined by the department. Members of the council are not entitled to compensation for the performance of their duties, but may be reimbursed for reasonable and necessary expenses incurred while engaged in the performance of those duties.

The bill provides that it will take effect on July 1, 2011.

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 the 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:

Private health care providers may incur costs if they elect to disseminate information to the public related to gynecologic cancers, which is encouraged by the program.

C. Government Sector Impact:

The DOH is only required to implement the program to the extent that funds are appropriated or existing federal or state resources are made available for the purpose of the program. Therefore, the DOH should not incur any costs that would affect existing resources.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The provisions in the bill creating the council may not comport with the requirements of s. 20.052, F.S. For example, the purpose of the council is not explicit, the members are not appointed for 4-year staggered terms, and the bill may authorize reimbursement for expenses other than travel.

VIII. Additional Information:

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

None.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Fasano) recommended the following:

Senate Amendment (with title amendment)

Between lines 12 and 13
insert:

Section 1. Paragraph (a) of subsection (1) of section 393.125, Florida Statutes, is amended to read:

393.125 Hearing rights.—

(1) REVIEW OF AGENCY DECISIONS.—

(a) For Medicaid programs administered by the agency, any developmental services applicant or client, or his or her parent, guardian advocate, or authorized representative, may request a hearing in accordance with federal law and rules

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applicable to Medicaid cases and has the right to request an administrative hearing pursuant to ss. 120.569 and 120.57. These hearings shall be provided by the Department of Children and Family Services pursuant to s. 409.285 and shall follow procedures consistent with federal law and rules applicable to Medicaid cases. At the conclusion of the hearing, the department shall submit its recommended order to the agency as provided in s. 120.57(1)(k) and the agency shall issue the final order as provided in s. 120.57(1)(l).

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete lines 2 - 3

and insert:

An act relating to the Agency for Persons with Disabilities; amending s. 393.125, F.S.; requiring the Department of Children and Family Services to submit its recommended order to the Agency for Persons with Disabilities at the conclusion of an administrative hearing; requiring that the agency issue the final agency order; amending s.

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 Regulation Committee

BILL:	SB 1372
INTRODUCER:	Senator Storms
SUBJECT:	Persons with Developmental Disabilities/Medication
DATE:	March 18, 2011 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	O'Callaghan	Stovall	HR	**Pre-meeting**
2.			CF	
3.			BC	
4.				
5.				
6.				

I. Summary:

This bill amends s. 393.506, F.S., to require a registered nurse or a physician to annually assess and validate the competency of a direct service provider, who is not licensed to administer prescription medication, in certain routes of medication administration, including oral, ophthalmic, rectal, inhaled, and enteral. The bill provides that topical, transdermal, and otic routes of medication administration do not require annual revalidation.

This bill substantially amends s. 393.506, F.S.

II. Present Situation:

Agency for Persons with Disabilities

In October 2004, the Agency for Persons with Disabilities (APD) became an agency separate from the DCF, specifically tasked with serving the needs of Floridians with developmental disabilities.[1] Prior to that time, it existed as the Developmental Disabilities Program.[2]

The primary purpose of the APD is to work in partnership with local communities to ensure the safety, well-being, and self-sufficiency of the people served by the agency, provide assistance in identifying needs, and funding to purchase supports and services.[3]

[1] Section 393.063(9), Florida Statutes, defines the term "developmental disability" as a disorder or syndrome that is attributable to retardation, cerebral palsy, autism, spina bifida, or Prader-Willi syndrome; that manifests before the age of 18; and that constitutes a substantial handicap that can reasonably be expected to continue indefinitely.

[2] Agency for Persons with Disabilities website, http://apd.myflorida.com/about (last visited on March 18, 2011).

Developmental Disabilities Institutions

Clients of the APD may receive services through home or community settings, private intermediate care facilities, or state-run developmental services institutions. Developmental services institutions provide secure[4] residential services for individuals who have been charged with a serious crime and who have been found by the court to be incompetent to proceed through the court process due to mental retardation.[5] There are currently two non-secure developmental services institutions which are staffed by state employees: Marianna Sunland and Tacachale.[6]

Direct Service Provider

A direct service provider is a person 18 years of age or older who has direct face-to-face contact with a client while providing services to the client or has access to a client's living areas or to a client's funds or personal property.[7]

Currently, the APD requires that each direct service provider submit to a Level 2 employment screening pursuant to s. 435.03, F.S.[8] Section 393.0657, F.S., currently exempts a person who has undergone any portion of the background screening requirements required in s. 393.0655, F.S., within the last year from being required to repeat those screening requirements.

Section 402.3057, F.S., exempts certain individuals from background screening requirements pursuant to ch. 393, F.S. The exemption does not apply to an individual who has had a 90-day break in employment.[9]

Administration of Medication

Section 393.506, F.S., provides that a direct service provider who is not currently licensed to administer medication may supervise the self-administration of medication or may administer several types of prescription medications to clients, including:[10]

- Oral,[11]
- Transdermal,[12]
- Ophthalmic,[13]

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[3] The Florida Legislature's Office of Program Policy Analysis & Government Accountability, *Agency for Persons with Disabilities*, http://www.oppaga.state.fl.us/profiles/5060 (last visited on March 18, 2011).
[4] The only secure forensic facility under APD is the Mentally Retarded Defendant Program (MRDP) in Chattahoochee. *See* APD website: http://apd.myflorida.com/ddc/mrdp/ (last visited March 18, 2011).
[5] *Supra* fn. 3.
[6] Agency for Persons with Disabilities, http://apd.myflorida.com/ddc/ (last visited March 18, 2011).
[7] Section 393.063(11), F.S.
[8] Section 393.0655, F.S.
[9] Section 402.3057, F.S.
[10] Chapter 2006-37, L.O.F.
[11] Oral means medication taken by mouth. *See* Merriam-Webster, Medline Plus Medical Dictionary, available at: http://www.merriam-webster.com/medlineplus/Oral (last visited on March 19, 2011).
[12] Transdermal means relating to, being, or supplying a medication in a form for absorption through the skin into the bloodstream. *See* Merriam-Webster, Medline Plus Medical Dictionary, available at: http://www.merriam-webster.com/medlineplus/Transdermal (last visited on March 19, 2011).

- Otic,[14]
- Rectal,[15]
- Inhaled,[16]
- Enteral,[17] or
- Topical.[18]

In order to supervise the self-administration of medication or to administer medications, a direct service provider must satisfactorily complete a training course of not less than 4 hours in medication administration and be found competent to supervise the self-administration of medication by a client or to administer medication to a client in a safe and sanitary manner. Competency must be assessed and validated at least annually by a registered nurse licensed pursuant to ch. 464, F.S., or a physician licensed pursuant to ch. 458 or ch. 459, F.S., in an onsite setting and must include the registered nurse or physician personally observing the direct service provider satisfactorily supervising the self-administration of medication by a client, and administering medication to a client.

The client or the client's guardian or legal representative must give his or her informed consent to self-administering medication under the supervision of an unlicensed direct service provider or to receiving medication administered by an unlicensed direct service provider.

III. Effect of Proposed Changes:

This bill amends s. 393.506, F.S., to require a registered nurse licensed under ch. 464, F.S., or an allopathic physician or an osteopathic physician to annually assess and validate the competency of a direct service provider who is not licensed to administer prescription medication in the administration of oral, ophthalmic, rectal, inhaled and enteral prescription medications, in an onsite setting with an actual client. For topical, transdermal, and otic routes of medication administration, a direct service provider's competency in these routes of medication

[13] Ophthalmic means of, relating to, or situated near the eye (meaning administration of medicine to the eye). *See* Merriam-Webster, Medline Plus Medical Dictionary, available at: http://www.merriam-webster.com/medlineplus/Ophthalmic (last visited on March 19, 2011).
[14] Otic means of, relating to, or located in the region of the ear (meaning the administration of medicine to the ear). *See* Merriam-Webster, Medline Plus Medical Dictionary, available at: http://www.merriam-webster.com/medlineplus/otic (last visited on March 19, 2011).
[15] Rectal means relating to, affecting, or being near the rectum (meaning the administration of medicine to the rectum). *See* Merriam-Webster, Medline Plus Medical Dictionary, available at: http://www.merriam-webster.com/medlineplus/rectal (last visited on March 19, 2011).
[16] Inhaled means medicine that is administered by being breathed in. *See* Merriam-Webster, Medline Plus Medical Dictionary, available at: http://www.merriam-webster.com/medlineplus/Inhaled%20 (last visited on March 19, 2011).
[17] Enteral or enteric means being or possessing a coating designed to pass through the stomach unaltered and to disintegrate in the intestines (meaning medication is administered usually by tube in order to pass through the stomach and into the intestines). *See* Merriam-Webster, Medline Plus Medical Dictionary, available at: http://www.merriam-webster.com/medlineplus/enteric (last visited on March 19, 2011).
[18] Topical means designed for or involving application to or action on the surface of a part of the body (meaning the application of medicine on the surface of the body). *See* Merriam-Webster, Medline Plus Medical Dictionary, available at: http://www.merriam-webster.com/medlineplus/topical (last visited on March 19, 2011).

administration may be validated by simulation during a training course required under s. 393.506(2), F.S.,[19] and do not require annual revalidation.

The bill provides that it shall take effect on July 1, 2011.

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:

Direct service providers may save money as they will no longer be required to have a registered nurse licensed under ch. 464, F.S., or a physician licensed under ch. 458 or ch. 459, F.S., perform an annual validation of the administration of certain medicines by the unlicensed direct service provider.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

There is an inconsistency in subsection (4) of this bill and subsection (2) in s. 393.506, F.S. This bill exempts an annual revalidation for the topical, transdermal, and otic routes of administration. However, subsection (2) requires that the competency of a direct service provider be assessed and validated at least annually in an onsite setting and must include personally observing the

[19] A direct service provider who is not licensed to administer medication must satisfactorily complete a training course of not less than 4 hours in medication administration and be found competent to supervise the self-administration of medication by a client or to administer medication to a client in a safe and sanitary manner.

direct service provider satisfactorily supervising the self-administration of medication by a client and administering medication to a client.

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.)

None.

B. Amendments:

None.

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Diaz de la Portilla) recommended the following:

Senate Amendment

Delete line 60

and insert:

committee. Each nurse staffing collaborative council shall consist of an even number of members. Half of the members of the nurse staffing

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Diaz de la Portilla) recommended the following:

Senate Amendment

Delete line 62
and insert:
participate in direct patient care. The chief executive officer

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Diaz de la Portilla) recommended the following:

Senate Amendment (with title amendment)

Delete lines 98 - 99
and insert:
nursing personnel in each patient care unit.

========== T I T L E A M E N D M E N T ==========
And the title is amended as follows:
Delete lines 13 - 14
and insert:
the nursing personnel in each patient care unit;
providing an effective date.

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 Regulation Committee

BILL:	SB 1118
INTRODUCER:	Senator Bogdanoff
SUBJECT:	Nursing Services
DATE:	March 21, 2011
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	O'Callaghan	Stovall	HR	**Pre-meeting**
2.			BC	
3.				
4.				
5.				
6.				

I. Summary:

This bill requires each hospital to establish a nurse staffing collaborative council that is responsible for developing and overseeing an annual staffing plan for each patient care unit and nursing shift. The bill provides factors to be considered in the development of the plan and for the semiannual review of the staffing plan by the council. The staffing plan is to be reviewed annually with nursing personnel in each patient care unit and must be shared with the community upon request.

This bill creates section 395.0192 of the Florida Statutes.

II. Present Situation:

Hospitals

Hospitals are licensed and regulated by the Agency for Health Care Administration (Agency) under ch. 395, F.S., the general licensure provisions of part II, ch. 408, F.S., and administrative rules in Chapter 59A-3, Florida Administrative Code. As of August 2010, there were 297 hospitals in Florida.[1]

A hospital offers more intensive services than those required for room, board, personal services, and general nursing care. A range of health care services is offered with beds for use beyond 24 hours by individuals requiring diagnosis, treatment, or care. Hospitals must make regularly

[1]Florida Hospital Association, *Facts About Florida's Health Care System*, updated August 2010, available at: http://www.fha.org/facts.html (Last visited on March 8, 2011).

available at least clinical laboratory services, diagnostic X-ray services, and treatment facilities for surgery or obstetrical care, or other definitive medical treatment of similar extent.[2]

A general hospital regularly makes its facilities and services available to the general population.[3]

A specialty hospital makes available either:
- A range of medical services offered by general hospitals, but restricted to a defined age or gender group of the population;
- A restricted range of services appropriate to the diagnosis, care, and treatment of patients with specific categories of medical or psychiatric illnesses or disorders; or
- Intensive residential treatment programs for children and adolescents under the age of 18 who have psychiatric disorders to restore these patients to an optimal level of functioning.[4]

All licensed hospitals must have at least the following:
- Inpatient beds;
- A governing authority legally responsible for the conduct of the hospital;
- A chief executive officer or another similarly titled official to who the governing authority delegates the full-time authority for the operation of the hospital in accordance with the established policy of the governing authority;
- An organized medical staff to which the governing authority delegates responsibility for maintaining proper standards for medical and other health care;
- A current and complete medical record for each patient admitted to the hospital;
- A policy requiring that all patients be admitted on the authority of and under the care of a member of the organized medical staff;
- Facilities and professional staff available to provide food to patients to meet their nutritional needs;
- A procedure for providing care in emergency cases;
- A method and policy for infection control; and
- An on-going organized program to enhance the quality of patient care and review the appropriateness of utilization of services.[5]

Magnet Hospitals

A "Magnet hospital" is a hospital that has received special recognition by the American Nurses Credentialing Center, which is a subsidiary of the American Nurses Association. In order to receive this type of recognition, stringent standards must be met by a hospital. In Florida, there are 22 hospitals designated as Magnet hospitals.[6] To be eligible for designation as a Magnet hospital, the following standards must be met.[7]

[2] Section 395.002(12), F.S.
[3] Section 395.002(10), F.S.
[4] Section 395.002(28), F.S. *See also* s. 395.002(15), F.S.
[5] Rule 59A-3.252, Classification of Hospitals, F.A.C.
[6] American Nurses Credentialing Center, *Find a Magnet Facility*, available at: http://www.nursecredentialing.org/Magnet/FindaMagnetFacility.aspx (Last visited on March 8, 2011).
[7] The standards are published on the American Nurses Credentialing Center's website, which is available at http://www.nursecredentialing.org/Magnet/ApplicationProcess/EligibilityRequirements/OrgEligibilityRequirements.aspx (Last visited on March 8, 2011).

Nursing Leadership
The applicant organization must include one or more nursing settings with a single governing authority and one individual serving as the Chief Nursing Officer (CNO). The CNO is ultimately responsible for sustaining the standards of nursing practice in all areas in which nurses practice.

The CNO must participate on the applicant organization's highest governing decision-making and strategic planning body. The CNO must also possess a Master's degree, or at a minimum, a master's degree at the time of application. If the master's degree is not in nursing then either the baccalaureate degree or doctoral degree must be in nursing. The requirement must be maintained throughout the application phase, review phase, and designation as a Magnet organization. Appointees as interim CNOs must also comply with this requirement.

Standards for Nurse Administrators
Applicant hospitals must have the *American Nurses Association's Scope and Standards for Nurse Administrators* (2004), which is a manual providing various nursing standards, currently implemented throughout nursing.

Protected Feedback Procedures
Applicant organizations must have policies and procedures that permit and encourage nurses to confidentially express their concerns about their professional practice environment without retribution. Policies and procedures that discourage nurses to express their concerns about their professional practice environment are prohibited.

Regulatory Compliance
Organizations must comply with all federal laws and regulations administered by the Occupational Safety and Health Review Commission, the Equal Employment Opportunity Commission, the U.S. Department of Health and Human Services or other federal agencies that administer healthcare programs, the U.S. Department of Labor, and the National Labor Relations Board as they relate to registered nurses in the workplace. Institutions that have their Magnet designation revoked, or are prevented from continuing the application process due to an adverse decision, are prohibited from reapplying for Magnet designation for a period of 1 year.

Data Collection
Applicants for Magnet designation must collect nurse-sensitive quality indicators at the unit level and benchmark that data against a database at the highest/broadest level possible (i.e., national, state, specialty organization, regional, or system) to support research and quality improvement initiatives. The intent is to collect data that is applicable and value-added for the particular unit and organization. Organizations must contribute their own data (patient and nurse satisfaction, clinical nurse sensitive indicators) to a national database that compares the organization's data against cohort groups at the national level.

Nurse Staffing and Quality of Patient Care

Hospitals with low nurse staffing levels tend to have higher rates of poor patient outcomes such as pneumonia, shock, cardiac arrest, and urinary tract infections, according to research funded by the Agency for Healthcare Research and Quality and others. Major factors contributing to lower

staffing levels include the needs of today's higher acuity patients for more care and a nationwide gap between the number of available positions and the number of registered nurses qualified and willing to fill them. A 2004 report published by the Agency for Healthcare Research and Quality indicated that the average registered nurse vacancy rate was 13 percent.[8]

A follow-up study, published in March 2007, found that increased nurse staffing in hospitals was associated with lower hospital-related mortality, failure to rescue, and other patient outcomes, but the association is not necessarily causal. The size of the effect of the nurse staffing ratio per patient varied. The reduction in relative risk was greater and more consistent across the studies, corresponding to an increased registered nurse to patient ratio but not hours and skill mix. The report further concluded that estimates of the size of the nursing effect must be tempered by provider characteristics including hospital commitment to high quality care not considered in most of the studies. Greater nurse staffing was associated with better outcomes in intensive care units and in surgical patients.[9]

Florida Nursing Shortage

In 2001, the Florida Legislature established the Florida Center for Nursing to address issues of supply and demand for nursing, including issues of recruitment, retention, and utilization of nurse workforce resources. On December 15, 2007, the Florida Center for Nursing issued a report: *Addressing the Nursing Shortage in Florida: Strategies for Success*.[10] This report noted that by 2020, Florida will be faced with a convergence of an aging nurse population, resulting in decreased supply–and an aging general population, resulting in increased demand. Combined with the unresolved existing shortage, the result will be a critical deficiency of qualified, experienced nurses.

Staffing Requirements

Section 395.1055(1), F.S., requires the Agency to adopt rules for reasonable and fair minimum standards to ensure that health care facilities licensed under ch. 395, F.S., have sufficient numbers and qualified types of personnel and occupational disciplines on duty and available at all times to provide necessary and adequate patient care and safety.

Agency Staffing Rules for Hospitals

The rule[11] that the Agency adopted requires that a sufficient number of qualified registered nurses must be on duty at all times to give patients the nursing care that requires the judgment and specialized skills of a registered nurse. There must be a sufficient number of registered nurses to ensure immediate availability of a registered nurse for bedside care of any patient when

[8] Mark W. Stanton, M.A., *Hospital Nurse Staffing and Quality of Care*, published by the Agency for Healthcare Research and Quality, March 2004, found at: http://www.ahrq.gov/research/nursestaffing/nursestaff.pdf (Last visited on March 8, 2011).
[9] Minnesota Evidence-based Practice Center, Minneapolis, Minnesota; *Nurse Staffing and Quality of Patient Care*; March 2007; prepared for the Agency for Healthcare Research and Quality. The abstract may be found at: http://www.ahrq.gov/clinic/tp/nursesttp.htm and the full report may be found at: http://www.ahrq.gov/downloads/pub/evidence/pdf/nursestaff/nursestaff.pdf (Last visited on March 8, 2011).
[10] Florida Center for Nursing, *Addressing the Nursing Shortage in Florida: Strategies for Success*, available at: http://www.flcenterfornursing.org/files/FCN_Strategies_for_Success_Dec_2007.pdf (Last visited March 8, 2011).
[11] Rule 59A-3.2085(5)(f), F.A.C.

needed to assure prompt recognition of an untoward change in a patient's condition and to facilitate appropriate intervention by nursing, medical, or other hospital staff members.

The rule requires that each hospital employ a registered nurse on a full time basis who has the authority and responsibility for managing nursing services and taking all reasonable steps to assure that a uniformly optimal level of nursing care is provided throughout the hospital. In addition, the rule requires that each Class I[12] and Class II[13] hospital have at least one licensed registered nurse on duty at all times on each floor or similarly-titled part of the hospital for rendering patient care services.[14] Rules for neonatal intensive care services require hospitals to have a nurse to neonate ratio of at least 1:4 in Level II and 1:2 in Level III neonatal intensive care units at all times.[15] No other specific staffing ratios are required in hospitals.

Accreditation Staffing Standards for Hospitals

Section 395.0161(2), F.S., requires the Agency to accept, in lieu of its own periodic inspections for licensure, the survey or inspection of an accrediting organization, provided the accreditation of the licensed facility is not provisional, and provided the licensed facility authorizes release of, and the Agency receives the report of, the accrediting organization. Accrediting organizations establish standards for accreditation, including standards related to staffing, although there are no required staffing ratios for accreditation. The Joint Commission,[16] which is one of the recognized accrediting organizations for hospitals, might assess the adequacy of nurse staffing based on other indicia, such as whether required activities are being performed related to patient care.

Dissemination of Health Care Information

The Agency is required to publish and disseminate information to the public which will enhance informed decision-making in the selection of health care providers, facilities, and services.[17] The information is published on the FloridaHealthFinder website at: http://www.floridahealthfinder.gov.

The Florida Center for Health Information and Policy Analysis (Florida Center) within the Agency is responsible for collecting, compiling, analyzing, and disseminating health-related data and statistics. The State Consumer Health Information and Policy Advisory Council (Council) is established in the Agency to:

- Assist the Florida Center in reviewing the comprehensive health information system, including the identification, collection, standardization, sharing, and coordination of:
  - Health-related data,
  - Fraud and abuse data, and

[12] Class I hospitals include general acute care hospitals, long term care hospitals, and rural hospitals per Rule 59A-3.252, F.A.C.
[13] Class II hospitals include specialty hospitals for children, and specialty hospitals for women per Rule 59A-3.252, F.A.C.
[14] Rule 59A-3.2085(5)(g), F.A.C.
[15] Rule 59C-1.042, F.A.C.
[16] The Joint Commission is an independent, not-for-profit organization that accredits and certifies more than 18,000 health care organizations and programs in the United States. *See* The Joint Commission, *About the Joint Commission*, available at: http://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx (Last visited on March 8, 2011).
[17] Section 408.063, F.S.

- Professional and facility licensing data among federal, state, local, and private entities; and
- Recommend improvements for purposes of public health, policy analysis, and transparency of consumer health care information.[18] The Council advises the Agency regarding making information available for consumers to use to compare health care services.[19]

Hospitals report nurse staffing counts per unit annually in hospital financial reports mandated in s. 408.061(4), F.S. However, the Agency does not report this data on its website. The Council has not recommended the publication of nurse staffing data.

III. Effect of Proposed Changes:

The bill provides for legislative findings regarding the critical role of nurses in patient care, the use of multiple strategies by hospitals to recruit and retain nurses, and the benefit of evidence-based nurse staffing plans to support the legislative intent for nurses and hospital leadership to participate in a joint process regarding decisions about nurse staffing levels in hospitals.

Accordingly, the bill creates s. 395.0192, F.S., to require each hospital licensed under ch. 395, F.S., to establish a nurse staffing collaborative council by September 1, 2011, by creating either a new collaborative council or assigning the functions of the collaborative council to an existing council or committee. The number of members on the committee is not prescribed, but a majority of the council is required to consist of registered nurses who currently participate in direct patient care. The chief nursing executive is to determine the remaining members of the council.

The primary responsibilities of the nurse staffing collaborative council are to develop and oversee an annual nurse staffing plan and semi-annually review the plan.

Factors to be considered in the development of the plan include, but are not limited to:

- Patient census information in the unit by shift, considering activities such as discharges, admissions, and transfers;
- Patient acuity level based on the need for nursing care and the nature of the care to be delivered on each shift;
- Staffing skill mix, such as the number and percentages of registered nurses, licensed practical nurses, certified nursing assistants, and unlicensed assistive personnel;
- The level of education, training, and experience of the nursing personnel providing care;
- The need for specialized equipment;
- The physical layout and design of the patient care unit, such as the placement of patient rooms, treatment areas, nursing stations, medication preparation areas, and equipment;
- Staffing guidelines adopted or published by national professional nursing associations, specialty nursing organizations, and other professional health care organizations;
- Hospital finances and resources; and
- The level of technology and support.

[18] Section 408.05(8), F.S.
[19] Section 408.05(3)(k), F.S.

The chief nurse executive must communicate and collaborate with the council to ensure a safe and appropriate implementation of the staffing plan.

The semiannual review of the staffing plan must consider patient needs and evidence-based staffing information, including the nursing-sensitive quality indicators collected by the hospital. Nursing-sensitive quality indicators are indicators that capture care or the outcomes most affected by nursing care.

The staffing plan must be reviewed annually with nursing personnel in each patient care area and shared with the community upon request.

The bill provides an effective date of July 1, 2011.

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 the 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:

It is indeterminate the costs that may be incurred by private hospitals that are required to establish a nurse staffing collaborative council or any additional costs for implementing a staffing plan that might require additional nursing staff. Those hospitals that are magnet hospitals are not likely to incur costs as they have strict standards that require such staffing plans.

C. Government Sector Impact:

It is indeterminate the costs that may be incurred by public hospitals that are required to establish a nurse staffing collaborative council or any additional costs for implementing a staffing plan that might require additional nursing staff. Those hospitals that are magnet

hospitals are not likely to incur costs as they have strict standards that require such staffing plans.

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.)

None.

B. Amendments:

None.

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 Regulation Committee

BILL:	SB 1586
INTRODUCER:	Senator Hays
SUBJECT:	Authority of Certain Professionals to Practice in this State
DATE:	March 21, 2011 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	O'Callaghan	Stovall	HR	**Pre-meeting**
2.			RI	
3.			BC	
4.				
5.				
6.				

I. Summary:

This bill removes the authority for business professionals and health care professionals (veterinarians) who are licensed out-of-state or in a foreign jurisdiction, who are in Florida for a specific sporting event, and who are employed or designated by the sport's team, to practice on animals used in the sport.

This bill substantially amends the following sections of the Florida Statutes: 455.2185 and 456.023, F.S.

II. Present Situation:

General Provisions for Business Professionals and Health Professionals

Chapter 455, F.S.

The Department of Business and Professional Regulation (DBPR) was established in 1993 with the merger of the Department of Business Regulation and the Department of Professional Regulation.[1] The DBPR is created in s. 20.165, F.S. Section 20.165(2), F.S., creates the following eleven divisions within the department:

- Division of Administration.
- Division of Alcoholic Beverages and Tobacco.
- Division of Certified Public Accounting.
- Division of Florida Condominiums, Timeshares, and Mobile Homes.
- Division of Hotels and Restaurants.

[1] Chapter 93-220, L.O.F.

- Division of Pari-mutuel Wagering.
- Division of Professions.
- Division of Real Estate.
- Division of Regulation.
- Division of Technology.
- Division of Service Operations.

In addition to administering the professional boards, the DBPR processes applications for licensure and license renewal. The DBPR also receives and investigates complaints made against licensees and, if necessary, brings administrative charges.

Chapter 455, F.S., provides the general powers of the DBPR and sets forth the procedural and administrative frame-work for all of the professional boards housed under the DBPR, specifically the Divisions of Certified Public Accounting, Professions, Real Estate, and Regulation.

Section 20.165(4)(a), F.S., establishes the following professional boards within the Division of Professions:

- Board of Architecture and Interior Design, created under part I of ch. 481, F.S.
- Florida Board of Auctioneers, created under part VI of ch. 468, F.S.
- Barbers' Board, created under ch. 476, F.S.
- Florida Building Code Administrators and Inspectors Board, created under part XII of ch. 468, F.S.
- Construction Industry Licensing Board, created under part I of ch. 489, F.S.
- Board of Cosmetology, created under ch. 477, F.S.
- Electrical Contractors' Licensing Board, created under part II of ch. 489, F.S.
- Board of Employee Leasing Companies, created under part XI of ch. 468, F.S.
- Board of Landscape Architecture, created under part II of ch. 481, F.S.
- Board of Pilot Commissioners, created under ch. 310, F.S.
- Board of Professional Engineers, created under ch. 471, F.S.
- Board of Professional Geologists, created under ch. 492, F.S.
- Board of Veterinary Medicine, created under ch. 474, F.S.

Chapter 456, F.S.

Section 20.43, F.S., creates the DOH. The DOH is responsible for the state's public health system, which is designed to promote, protect, and improve the health of all people in the state. The mission of the state's public health system is to foster the conditions in which people can be healthy, by assessing state and community health needs and priorities through data collection, epidemiologic studies, and community participation; by developing comprehensive public health policies and objectives aimed at improving the health status of people in the state; and by ensuring essential health care and an environment which enhances the health of the individual and the community.[2] The State Surgeon General is the State Health Officer and the head of the DOH.

[2] Section 381.001, F.S.

Section 20.43, F.S., creates several divisions under the DOH, including the Division of Medical Quality Assurance, which is responsible for the following boards and professions established within the division:

- The Board of Acupuncture, created under ch. 457, F.S.
- The Board of Medicine, created under ch. 458, F.S.
- The Board of Osteopathic Medicine, created under ch. 459, F.S.
- The Board of Chiropractic Medicine, created under ch. 460, F.S.
- The Board of Podiatric Medicine, created under ch. 461, F.S.
- The Board of Optometry, created under ch. 463, F.S.
- The Board of Nursing, created under part I of ch. 464, F.S.
- The Board of Pharmacy, created under ch.465, F.S.
- The Board of Dentistry, created under ch. 466, F.S.
- The Board of Speech-Language Pathology and Audiology, created under part I of ch. 468 F.S.
- The Board of Nursing Home Administrators, created under part II of ch. 468, F.S.
- The Board of Occupational Therapy, created under part III of ch. 468, F.S.
- The Board of Athletic Training, created under part XIII of ch. 468, F.S.
- The Board of Orthotists and Prosthetists, created under part XIV of ch. 468, F.S.
- The Board of Massage Therapy, created under ch. 480, F.S.
- The Board of Clinical Laboratory Personnel, created under part III of ch. 483, F.S.
- The Board of Opticianry, created under part I of ch.484, F.S.
- The Board of Hearing Aid Specialists, created under part II of ch. 484, F.S.
- The Board of Physical Therapy Practice, created under ch. 486, F.S.
- The Board of Psychology, created under ch. 490, F.S.
- The Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling, created under ch. 491, F.S.

In addition to the professions regulated by the various aforementioned boards, the DOH also regulates the following professions: naturopathy, as provided under ch. 462, F.S.; nursing assistants, as provided under part II of ch. 464, F.S.; midwifery, as provided under ch. 467, F.S.; respiratory therapy, as provided under part V of ch. 468, F.S.; dietetics and nutrition practice, as provided under part X of ch. 468, F.S.; electrolysis, as provided under ch. 478, F.S.; medical physicists, as provided under part IV of ch. 483, F.S.; and school psychologists, as provided under ch. 490, F.S..

Among other things, the general provisions for licensure, certification, education, examination, and penalties for the above-mentioned professionals are provided for under ch. 456, F.S. In addition, ch. 456, F.S., sets forth the authority of the above-referenced boards to regulate their respective professions.

Veterinary Medical Practice

Veterinarians are regulated under ch. 474, F.S., the Veterinary Medical Practice Act (act). The legislative purpose for the act is to ensure that every veterinarian practicing in Florida meets minimum requirements for safe practice and veterinarians who are not normally competent or

who otherwise present a danger to the public are disciplined or prohibited from practicing in Florida.[3]

The DBPR is the state agency responsible for the licensing of veterinarians, while the Board of Veterinary Medicine (board)[4] within the DBPR is responsible for adopting rules to establish fees and implement the provisions of ch. 474, F.S.

For a person to be licensed as a veterinarian he or she must apply to the DBPR to take a licensure examination. The DBPR must license each applicant who the board certifies has:

- Completed the application form and remitted an examination fee set by the board.[5]
- Graduated from a college of veterinary medicine accredited by the American Veterinary Medical Association Council on Education or graduated from a college of veterinary medicine listed in the American Veterinary Medical Association Roster of Veterinary Colleges of the World and obtained a certificate from the Education Commission for Foreign Veterinary Graduates.
- Successfully completed the examination provided by the department for this purpose, or an examination determined by the board to be equivalent.
- Demonstrated knowledge of the laws and rules governing the practice of veterinary medicine in Florida in a manner designated by rules of the board.[6]

The DBPR is prohibited from issuing a license to any applicant who is under investigation in any state or territory of the United States or in the District of Columbia for an act which would constitute a violation of ch. 474, F.S., until the investigation is complete and disciplinary proceedings have been terminated.[7]

An unlicensed doctor of veterinary medicine who has graduated from an approved college or school of veterinary medicine and has completed all parts of the examination for licensure is permitted, while awaiting the results of the examination for licensure or while awaiting issuance of the license, to practice under the immediate supervision of a licensed veterinarian. A person who fails any part of the examination may not continue to practice, except in the same capacity as other nonlicensed veterinary employees, until the person passes the examination and is eligible for licensure.[8]

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[3] Section 474.201, F.S.

[4] The board consists of seven members, who are appointed by the Governor, and are subject to confirmation by the Senate. Five members of the board must be licensed veterinarians and two members of the board must be laypersons who are not and have never been veterinarians or members of any closely related profession or occupation. Section 474.204, F.S.

[5] For applicants taking the Laws and Rules examination that is not conducted by a professional testing service, the examination fee is $165.00, payable to the DBPR. For applicants taking the Laws and Rules examination that is conducted by a professional testing service, the examination fee is $151.50 payable to the DBPR plus $13.50 payable to the testing service. Rule 61G18-12.002, F.A.C. The applicant for licensure must also pay an initial licensure fee of $200, if the person is licensed in the first 12 months of the biennium, or $100, if the person is licensed in the second 12 months of the biennium. Rule 61G18-12.007, F.A.C.

[6] Section 474.207, F.S.

[7] *Id.*

[8] *Id.*

An applicant may be eligible for temporary licensure if certain requirements are met. In order for the board to certify an applicant to the DBPR for issuance of a temporary license to practice veterinary medicine, an applicant must demonstrate to the board that the applicant:

- Has filed an application for temporary licensure identifying the name and address of the owner of the animals to be treated, the type of animals to be treated and their injury or disease, the location the treatment is to be performed, and the names, addresses, and titles of all persons entering the state with the applicant to perform the treatment; or
- Has filed an application and is responding to an emergency for the treatment of animals of multiple owners.
- Has paid the temporary licensure fee.
- Holds an active license to practice veterinary medicine in another state of the United States and that any license to practice veterinary medicine that the person has ever held has never been revoked, suspended or otherwise acted against by the licensing authority.
- Is neither the subject of any pending prosecution nor has ever been convicted of any offense which is related to the practice of veterinary medicine; and
- Satisfies the qualifications for licensure by endorsement.[9]

A temporary license is valid for a period of 30 days from its issuance. A temporary license does not cover more than the treatment of the animals of the owner identified in the application. Upon expiration of the license, a new license is required.[10]

An applicant may also be eligible for licensure by endorsement if specific requirements are met. The DBPR must issue a license by endorsement to any applicant who, upon applying to the DBPR and remitting the requisite fee,[11] demonstrates to the board that she or he:

- Has demonstrated, in a manner designated by rule of the board, knowledge of the laws and rules governing the practice of veterinary medicine in Florida; and
- Either holds, and has held for the 3 years immediately preceding the application for licensure, a valid, active license to practice veterinary medicine in another state of the United States, the District of Columbia, or a territory of the United States, provided that the requirements for licensure in the issuing state, district, or territory are equivalent to or more stringent than the requirements of ch. 474, F.S.; or meets the application and examination requirements under Florida law and has successfully completed a state, regional, national, or other examination which is equivalent to or more stringent than the examination given by the DBPR.[12]

The department is prohibited from issuing a license by endorsement to any applicant who is under investigation in any state, territory, or the District of Columbia for an act which would constitute a violation of ch. 474, F.S., until the investigation is complete and disciplinary proceedings have been terminated.

[9] Rule 61G18-25.001, F.A.C.
[10] *Id.*
[11] The fee for licensure by endorsement is $500. Rule 61G18-12.011, F.A.C.
[12] Section 474.217, F.S.

Under s. 474.213, F.S., a person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, F.S. (maximum imprisonment of 5 years, maximum fine of $5,000, or penalties applicable for a habitual offender) if the person:

- Leads the public to believe that such person is licensed as a veterinarian, or is engaged in the licensed practice of veterinary medicine, without such person holding a valid, active license pursuant to ch. 474, F.S.;
- Uses the name or title "veterinarian" when the person has not been licensed pursuant to ch. 474, F.S.;
- Presents as her or his own the license of another;
- Gives false or forged evidence to the board or a member thereof for the purpose of obtaining a license;
- Uses or attempts to use a veterinarian's license which has been suspended or revoked;
- Knowingly employs unlicensed persons in the practice of veterinary medicine;
- Knowingly concealing information relative to violations of ch. 474, F.S.;
- Obtains or attempts to obtain a license to practice veterinary medicine by fraudulent representation;
- Practices veterinary medicine in Florida, unless the person holds a valid, active license to practice veterinary medicine pursuant to ch. 474, F.S.;
- Sells or offers to sell a diploma conferring a degree from a veterinary school or college, or a license issued pursuant to ch. 474, F.S., or procures such diploma or license with the intent that it shall be used as evidence of that which the document stands for by a person other than the one upon whom it was conferred or to whom it was granted; or
- Knowingly operates a veterinary establishment or premises without having a premise permit issued under s. 474.215, F.S.

A veterinarian, or applicant for veterinary licensure, may be disciplined for several different types of violations under s. 474.214, F.S. When the board finds any applicant or veterinarian has committed a violation under s. 474.214, F.S., regardless of whether the violation occurred prior to licensure, it may enter an order imposing one or more of the following penalties:

- Denying certification for examination or licensure.
- Revoking or suspending a license.
- Imposing an administrative fine not to exceed $5,000 for each count or separate offense.
- Issuing a reprimand.
- Placing the veterinarian on probation for a period of time and subject to such conditions as the board may specify, including requiring the veterinarian to attend continuing education courses or to work under the supervision of another veterinarian.
- Restricting the authorized scope of practice.
- Imposing costs of the investigation and prosecution.
- Requiring the veterinarian to undergo remedial education.

In determining appropriate disciplinary action, the board must first consider those sanctions necessary to protect the public. Only after those sanctions have been imposed may the disciplining authority consider and include in its order requirements designed to rehabilitate the veterinarian. All costs associated with compliance with any order issued under this subsection are the obligation of the veterinarian. The DBPR must reissue the license of a disciplined veterinarian upon certification by the board that the disciplined veterinarian has complied with

all of the terms and conditions set forth in the final order and is capable of competently and safely engaging in the practice of veterinary medicine.[13]

III. Effect of Proposed Changes:

This bill removes from s. 455.2185, F.S., the authority of a business professional, who is licensed out-of-state or in a foreign jurisdiction, who is in Florida for a specific sporting event, and who is employed or designated by the sport's team, to practice on animals used in the sport. This bill removes from s. 456.023, F.S., the authority of a health care professional, who is licensed out-of-state or in a foreign jurisdiction, who is in Florida for a specific sporting event, and who is employed or designated by the sport's team, to practice on animals used in the sport.

The bill also deletes the language in ss. 455.2185 and 456.023, F.S. that prohibits these professionals from practicing in veterinary facilities without the approval of the facility, which is consistent with the above changes that prohibit the professionals from practicing at all on animals used by the sporting teams while in Florida.

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:

Sports teams from out-of-state or from foreign jurisdictions that participate in events in Florida may incur additional costs associated with hiring a Florida licensed veterinarian for veterinary services.

[13] *Id.*

C. Government Sector Impact:

None.

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.)

None.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Sobel) recommended the following:

Senate Amendment

Delete lines 80 - 81
and insert:
authority of the department or the Department of Juvenile Justice, a county or municipal detention facility, or a detention facility operated by a

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Sobel) recommended the following:

Senate Amendment

Delete line 135
and insert:
within 10 days after the use of restraints as to the extraordinary circumstance that

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Sobel) recommended the following:

Senate Amendment (with title amendment)

Delete line 161

and insert:

violation of this section may file a grievance with the department pursuant to s. 944.331, within 1 year

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete line 31

and insert:

restrained in violation of the act to file a grievance

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 Regulation Committee

BILL:	CS/SB 1086
INTRODUCER:	Criminal Justice Committee and Senator Hill
SUBJECT:	Restraint of Incarcerated Pregnant Women
DATE:	March 17, 2011 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Clodfelter	Cannon	CJ	**FAV/CS**
2.	O'Callaghan	Stovall	HR	**Pre-meeting**
3.			CA	
4.			BC	
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	X	Statement of Substantial Changes
B. AMENDMENTS.....		Technical amendments were recommended
		Amendments were recommended
		Significant amendments were recommended

I. Summary:

This bill creates the "Healthy Pregnancies for Incarcerated Women Act." It generally prohibits the use of restraints during labor, delivery, or postpartum recovery on a women who is known to be pregnant and who is incarcerated in a state, local, or privately-operated adult or juvenile facility. However, exceptions are allowed on an individual basis if there is a substantial flight risk or an extraordinary medical or security circumstance that dictates the use of restraints. The bill also sets standards for restraint of pregnant prisoners at other times during the third trimester. A woman who is restrained in violation of the bill's provisions can file a complaint within 1 year in addition to pursuing any other remedies that are available under state or federal law for harm caused by the restraint.

The bill includes several administrative requirements: (1) any exception must be documented in writing and kept available for public inspection for a period of 5 years; (2) an annual report must be made to the governor's office of every instance in which restraints were used pursuant to the exception or in violation of the provisions of the bill; and (3) the Department of Corrections (DOC) and the Department of Juvenile Justice (DJJ) must adopt rules to administer the new law, and each correctional institution must inform female prisoners of the rules and post the policies in the institution where they will be seen by female prisoners.

This bill creates a new section of the Florida Statutes.
This bill substantially amends, creates, or repeals the following sections of the Florida Statutes:

II. Present Situation:

The issue of whether or not pregnant female inmates should be exempted from normal policies regarding use of restraints has been widely debated during the last few years. A number of states have considered legislation prohibiting or limiting the use of restraints for pregnant inmates, and in 2008 the Federal Bureau of Prisons revised its policy to limit the use of restraints. The National Commission on Correctional Health Care Board of Directors recently adopted a position paper on restraint of pregnant inmates. The introduction states:

> Restraint is potentially harmful to the expectant mother and fetus, especially in the third trimester as well as during labor and delivery. Restraint of pregnant inmates during labor and delivery should not be used. The application of restraints during all other pre-and postpartum periods should be restricted as much as possible and, when used, done so with consultation from medical staff. For the most successful outcome of a pregnancy, cooperation among custody staff, medical staff, and the patient is required.[1]

Department of Corrections Policy
DOC is responsible for the health care of inmates in its custody[2] and treats more than 80 pregnant inmates per year.[3] Florida refers each pregnant inmate to an OB/GYN physician to provide prenatal care and to follow her throughout her pregnancy. Inmates receive prenatal counseling, vitamins, and exams. They also receive an extra nutritional meal each day[4]

DOC has an established procedure regarding the use of restraints. Key components include:

- After it is learned that an inmate is pregnant (and during her postpartum period), her hands are not restrained behind her back and leg irons are not used. The use of waist chains or black boxes is also prohibited when there is any danger that they will cause harm to the inmate or fetus. The inmate's hands can be handcuffed in front of her body during transport and at the medical facility if required by security conditions due to her custody level and behavior. The shift supervisor's approval is required to remove handcuffs for medical reasons, except that approval is not required in an emergency situation.
- Unarmed escort officers are required to maintain close supervision of a pregnant inmate and to provide a "custodial touch" when necessary to prevent falls.
- An inmate in labor is not restrained, but after delivery she may be restrained to the bed with normal procedures (tethered to the bed by one ankle) for the remainder of her hospital stay. A

[1] Position Paper on Restraint of Pregnant Inmates, adopted by the National Commission on Correctional Health Care Board of Directors (October 10, 2010), http://www.ncchc.org/resources/statements/restraint_pregnant_inmates.html , last viewed March 10, 2011.
[2] Section 945.6034, F.S.
[3] DOC Analysis of Senate Bill 1086 (March 10, 2011), page 4.
[4] Guidelines for the care and treatment of pregnant inmates are defined in DOC Procedure 506.201 (*Pregnant Inmates and the Placement of Newborn Infants*) and Health Services Bulletin 15.03.39 (*Health Care for Pregnant Inmates*).

correctional officer is stationed in the room with the inmate to be sure that she has access to the bathroom or can perform other needs that require movement.[5]

DOC reports that its procedures for the use of restraints on pregnant inmates are consistent with national guidelines. It also reports that there were no formal medical grievances submitted regarding the application of restraints during pregnancy from January 1, 2009 to the present.[6]

Department of Juvenile Justice Policy
DJJ policy is that pregnant youth must be handcuffed in the front when they are transported outside the secure area. Leg restraints, waist chains, and restraint belts cannot be used on pregnant youth.[7] There is no formal rule addressing the use of restraints during labor and delivery. However, the practice is for restraints to be removed during labor and delivery and whenever requested by the treating health care professional.[8]

III. Effect of Proposed Changes:

The bill generally prohibits corrections officials from using restraints on a prisoner who is known to be pregnant during labor, delivery, or postpartum recovery. It also regulates the use of restraints during the third trimester. The following are summarized definitions of terms used in the bill:

- "Corrections official" refers to the person who is responsible for oversight of a correctional facility, or his or her designee.
- "Restraints" include any physical restraint or mechanical device used to control the movement of the body or limbs. Examples include flex cuffs, soft restraints, hard metal handcuffs, black boxes, chubb cuffs, leg irons, belly chains, security chairs, and convex shields.
- "Prisoner" includes any person who is incarcerated or detained in a correctional institution at any time in relation to a criminal offense, including both pre-trial and post-trial actions. It also includes any woman who is detained in a correctional institution under federal immigration laws.
- "Correctional institutions" include any facility under the authority of DOC or DJJ as well as county and municipal detention facilities. It includes facilities operated by private entities.
- "Labor" is the time before birth when contractions bring about effacement and progressive cervical dilation.
- "Postpartum recovery" is the time immediately following delivery, including recovery time in the hospital or infirmary. The duration of postpartum recovery is determined by the physician.

Despite the general rule, restraints can be used during labor, delivery or post-partum recovery if the corrections official makes an individualized determination of extraordinary circumstances that require their use. This is permissible in two situations: (1) when the prisoner presents a

[5] DOC Procedure 506.201, section 12, and DOC Analysis, page 2.
[6] DOC Analysis, pages 2 and 4.
[7] DJJ Basic Curricula (PAR) 63H-1.001-.016(10).
[8] DJJ Analysis of Senate Bill 1086 (2011), pages 1-2.

substantial flight risk; or (2) when there is an extraordinary medical or security circumstance that dictates the use of restraints for the safety and security of the prisoner, corrections or medical staff, other prisoners, or the public. However, there are situations that override the exceptions: (1) the corrections official accompanying the prisoner must remove all restraints if removal is requested by the treating doctor, nurse, or other health care professional; and (2) use of leg and waist restraint are completely prohibited during labor and delivery.

The corrections official who authorizes the use of restraints due to an extraordinary circumstance must document the reasons for the exception within 10 days of their use. The correctional institution must maintain this documentation on file and available for public inspection for at least 5 years. However, the prisoner's identifying information may not be made public without the prisoner's consent.

The bill also establishes additional requirements regarding restraint of pregnant prisoners during the last trimester of pregnancy. These additional requirements also apply at any time during pregnancy if requested by the treating doctor, nurse, or other health care professional. These requirements are:

- Waist restraints that directly constrict the area of pregnancy cannot be used.
- Any wrist restraints must be applied so that the pregnant prisoner can protect herself in the event of a forward fall (handcuff must be in front).
- Leg and ankle restraints that restrain the legs close together cannot be used when the prisoner is required to sit or stand.

In addition to the specific requirements during the third trimester and during labor, delivery, and post-partum recovery, the bill provides that any restraint of a prisoner who is known to be pregnant must be done in the least restrictive manner necessary. The purpose of this general requirement is to reduce the possibility of adverse clinical consequences.

The secretaries of DOC and DJJ and the official responsible for any local correctional facility where a pregnant prisoner was restrained pursuant to an exception, or in violation of the provisions of the bill, during the previous year must submit a written report to the Executive Office of the Governor with an account of every instance in which restraint was used.

The bill requires DOC and DJJ to adopt rules to administer the new law, and each correctional institution must inform female prisoners of the rules when they are admitted to the institution, include the policies and practices in the prison handbook, and post the policies in appropriate places within the institution that are visible to female prisoners.

The bill also specifies that a woman who is harmed may file a complaint within one year in addition to any other remedies that might be available under state or federal law. However, it is not clear to whom such a complaint would be directed or what relief would be available.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

The requirement for correctional institutions to keep records of incidents in which extraordinary circumstances dictated the use of restraints includes a prohibition against releasing the name of the prisoner without her consent. This appears to be consistent with existing public records exemptions found in s. 945.10, F.S.

C. Trust Funds Restrictions:

None.

D. Other Constitutional Issues:

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

C. Government Sector Impact:

It does not appear that the bill would have a significant fiscal impact on the government sector. In its analysis of the bill, DOC notes that staff will have to maintain files and prepare the annual report to the Governor but does not quantify any costs.

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 Criminal Justice on March 14, 2011:

- Clarifies that the bill is only intended to apply to restraint of pregnant inmates during specified times in the latter stages of pregnancy.
- Establishes regulations for restraint of pregnant women during the third trimester.
- Modifies annual report requirement to apply only to instances when an exception is made to allow restraint or when the requirements are violated, not to all instances of shackling during pregnancy.
- Clarifies that the bill applies to correctional facilities operated by private companies.

B. Amendments:

None.

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 Regulation Committee

BILL:	SB 1990
INTRODUCER:	Health Regulation Committee
SUBJECT:	Ratification of Rules
DATE:	March 17, 2011 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Stovall	HR	**Pre-meeting**
2.			BC	
3.				
4.				
5.				
6.				

I. Summary:

The bill ratifies a rule relating to Standards of Practice for Physicians Practicing in Pain Management Clinics that has been filed for adoption by the Department of Health, Board of Medicine.

This bill does not amend, create, or repeal any section of the Florida Statutes.

II. Present Situation:

Current Law

Chapter 2010-279, Laws of Florida (L.O.F.), became effective on November 17, 2010,[1] when the Legislature over-rode the Governor's veto of CS/CS/HB 1565, which was passed during the 2010 Regular Session. This law requires a proposed administrative rule that has an adverse impact or regulatory costs that exceed certain thresholds to be submitted to the Legislature for ratification before the rule can take effect. The Legislature provided for a statement of estimated regulatory costs (SERC) as the tool to assess a proposed rule's impact.

[1] House Joint Resolution 9-A passed during the 2010A Special Session on November 16, 2010.

An agency proposing a rule is required to prepare a SERC of the proposed rule if the proposed rule:[2]

- Will have an adverse impact on small business; or
- Is likely to directly or indirectly increase regulatory costs in excess of $200,000 in the aggregate in this state within 1 year after the implementation of the rule.

A SERC is required to include:[3]

- An economic analysis showing whether the rule directly or indirectly:
  - Is likely to have an adverse impact on economic growth, private sector job creation or employment, or private sector investment in excess of $1 million in the aggregate within 5 years after the implementation of the rule;
  - Is likely to have an adverse impact on business competitiveness, including the ability of persons doing business in the state to compete with persons doing business in other states or domestic markets, productivity, or innovation in excess of $1 million in the aggregate within 5 years after the implementation of the rule; or
  - Is likely to increase regulatory costs, including any transactional costs, in excess of $1 million in the aggregate within 5 years after the implementation of the rule.

If the adverse impact or regulatory costs of the rule exceed any of these criteria, then the rule may not take effect until it is ratified by the Legislature;

- A good faith estimate of the number of individuals and entities likely to be required to comply with the rule, together with a general description of the types of individuals likely to be affected by the rule;

- A good faith estimate of the cost to the agency, and to any other state and local government entities, of implementing and enforcing the proposed rule, and any anticipated effect on state or local revenues;

- A good faith estimate of the transactional costs likely to be incurred by individuals and entities, including local government entities, required to comply with the requirements of the rule. "Transactional costs" are direct costs that are readily ascertainable based upon standard business practices, and include filing fees, the cost of obtaining a license, the cost of equipment required to be installed or used or procedures required to be employed in complying with the rule, additional operating costs incurred, the cost of monitoring and reporting, and any other costs necessary to comply with the rule;

- An analysis of the impact on small businesses,[4] and an analysis of the impact on small counties and small cities.[5] The impact analysis for small businesses must include the

[2] *See* s. 120.54(3)(b)1., F.S.
[3] *See* s. 120.241(2), F.S.

basis for the agency's decision not to implement alternatives that would reduce adverse impacts on small businesses;

- Any additional information that the agency determines may be useful; and

- A description of any regulatory alternative submitted by a substantially affected person and a statement adopting the alternative or a statement of the reasons for rejecting the alternative in favor of the proposed rule.

Regulation of Pain Management Clinics

The 2010 Legislature enacted CS/CS/SB 2272 and CS/CS/SB 2722[6] to help address the prescription drug abuse epidemic that is fueled by "pill mills." This law created ss. 458.3265 and 459.0137, F.S., to create a registration and inspection program for pain management clinics in which allopathic physicians and osteopathic physicians who primarily engage in the treatment of pain by prescribing or dispensing controlled substance medications may practice. These two sections of law are similar for the respective practice acts.

Among other things, this law requires the Board of Medicine and the Board of Osteopathic Medicine to adopt rules setting forth standards of practice for physicians and osteopathic physicians practicing in pain management clinics, as they are defined in law. The rules are required to address, at a minimum, facility operations; physical operations; infection control requirements; health and safety requirements; quality assurance requirements; patient records; training requirements for all facility health care practitioners who are not regulated by another board; inspections; and data collection and reporting requirements.[7]

Both boards proceeded through the rulemaking process, with similar language. The Board of Osteopathic Medicine filed its rule 64B15-14.0051, Standards of Practice for Physicians Practicing in Pain Management Clinics, on October 10, 2010, and the rule became effective on November 11, 2010. The Board of Medicine filed its rule for adoption on November 8, 2010. However, ch. 2010-279, L.O.F., became effective on November 17, 2010, before the Board of Medicine's rule became effective.[8]

The Board of Medicine's rule 64B8-9.0131 that was filed for adoption provides standards of practice in pain management clinics in the following broad categories:

- Evaluation of patient and medical diagnosis;
- Treatment plan;

[4] "Small business" is defined to mean an independently owned and operated business concern that employs 200 or fewer permanent full-time employees and that, together with its affiliates, has a net worth of not more than $5 million or any firm based in this state which has a Small Business Administration 8(a) certification. As applicable to sole proprietorships, the $5 million net worth requirement shall include both personal and business investments.
[5] "Small county" and "small city" are defined to mean any county that has an unincarcerated population of 75,000 or less and any municipality that has an unincarcerated population of 10,000 or less, respectively, according to the most recent decennial census.
[6] Ch. 2010-211, L.O.F.
[7] *See* ss. 458.3265(4)(d) and 459.0137(4)(d), F.S.
[8] A proposed rule is adopted on being filed with the Department of State and becomes effective 20 days after being filed, on a later date specified in the notice of proposed rulemaking, or on a date required by statute. *See* s. 120.54(3)(d)6., F.S.

- Informed consent and agreement for treatment;
- Periodic review;
- Consultation;
- Patient drug testing;
- Patient medical records;
- Denial or termination of controlled substance therapy;
- Facility and physical operations;
- Infection control;
- Health and safety;
- Quality assurance; and
- Data collection and reporting.

SERC for Rule 64B8-9.0131

The Center for Economic Forecasting and Analysis (CEFA), part of the Florida State University Institute of Science and Public Affairs, was engaged to estimate the costs for the Department of Health and the Pain Management Clinics for proposed rule 64B8-9.0131, Standards of Practice for Physicians Practicing in Pain Management Clinics, for the Board of Medicine. For purposes of determining whether the proposed rule requires Legislative ratification, the SERC indicates the proposed rule "is likely to increase regulatory costs, including any transactional costs, in excess of $1 million in the aggregate within 5 years after the implementation of the rule."[9]

Specifically, the SERC indicates the expected statewide transactional costs are $64.459 million in the first year, with $60,912 million in costs expected in the following years. On a per-clinic basis, this represents estimated costs of $69,162 in the first year with an expected $65,356 in costs in the following years. On a per-patient basis for an existing patient, the costs average $43.73 in the first year and $40.91 per year for years 2 through 5. For a new patient, the first year costs average $60.83 per year.[10]

In summary, the bulk of the expected statewide transactional costs is related to the patient drug testing requirement. The proposed rule provides:

> Patient Drug Testing. To assure the medical necessity and safety of any controlled substances that the physician may consider prescribing as part of the patient's treatment plan, patient drug testing shall be performed in accordance with one of the collection methods set forth below[11] and shall be conducted and the results reviewed prior to the initial issuance or dispensing of a controlled substance prescription, and thereafter, on a random basis at least twice a year and when requested by the treating physician. Nothing

[9] *See* The SERC of Proposed Rules in Regulation of Pain Management Clinics in Florida, BOM 64B8-9.0131, Standards of Practice for Physicians Practicing in PMC, January 18, 2011, page 15, paragraph (a)3. A copy of the SERC is on file in the Senate Health Regulation Committee.
[10] *Id*, page 17, paragraph (d).
[11] The collection methods set forth in the proposed rule include referral to an outside laboratory, specimen collection in the pain management clinic and sent to an outside laboratory for testing, and specimen collected and tested in the office.

in this rule shall preclude a pain management clinic from employing additional measures to assure the integrity of the urine specimens provided by patients.[12]

The SERC bases this component of the estimate on several assumptions and statistical modeling methods. To provide a perspective, estimates included 932 pain management clinics and 1,314 full time physicians seeing between 20 – 30 patients per day, for 250 annual work days.

III. Effect of Proposed Changes:

The bill provides for Legislative ratification of the Board of Medicine's Rule 64B8-9.0131, Standards of Practice for Physicians Practicing in Pain Management Clinics.

The act shall take effect upon becoming a law.

Other Potential Implications: The Board of Osteopathic Medicine adopted a similar rule with an effective date of November 8, 2010. Osteopathic physicians or allopathic physicians, or both, may practice in a pain management clinic. The absence of similar practice standards could prove unmanageable from a quality of care perspective, an operational perspective, and an enforcement perspective.

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:

The bill ratifies a rule for which its SERC indicates the expected statewide transactional costs are $64.459 million in the first year, with $60,912 million in costs expected in the

[12] *See* proposed rule 64B8-9.0131(2)(f).

following years. On a per-clinic basis, this represents estimated costs of $69,162 in the first year with an expected $65,356 in costs in the following years. On a per-patient basis for an existing patient, the costs average $43.73 in the first year and $40.91 per year for years 2 through 5. For a new patient, the first year costs average $60.83 per year.

C. Government Sector Impact:

None.

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.)

None.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Gaetz) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Subsection (4) is added to section 626.9541, Florida Statutes, to read:

626.9541 Unfair methods of competition and unfair or deceptive acts or practices defined.—

(4) WELLNESS OR HEALTH IMPROVEMENT PROGRAMS.—

(a) *Authorization to offer rewards or incentives for participation.*—An insurer issuing a group or individual health benefit plan may offer a voluntary wellness or health

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improvement program and may encourage or reward participation in the program by authorizing rewards or incentives, including, but not limited to, merchandise, gift cards, debit cards, premium discounts or rebates, contributions to a member's health savings account, or modifications to copayment, deductible, or coinsurance amounts. Any advertisement of the program is not subject to the limitations set forth in paragraph (1)(m).

(b) *Verification of medical condition by nonparticipants due to medical condition.*—An insurer may require a health benefit plan member to provide verification, such as an affirming statement from the member's physician, that the member's medical condition makes it unreasonably difficult or inadvisable to participate in the wellness or health improvement program in order for that nonparticipant to receive the reward or incentive.

(c) *Disclosure requirement.*—A reward or incentive offered under this subsection shall be disclosed in the policy or certificate.

(d) *Other incentives.*—This subsection does not prohibit insurers from offering other incentives or rewards for adherence to a wellness or health improvement program if otherwise authorized by state or federal law.

Section 2. Section 627.6402, Florida Statutes, is amended to read:

627.6402 Insurance rebates or rewards for healthy lifestyles.—

(1) Any rate, rating schedule, or rating manual for an individual health insurance policy filed with the office may provide for an appropriate rebate of premiums paid in the last

year when the individual covered by such plan is enrolled in and maintains participation in any health wellness, maintenance, or improvement program approved by the health plan. The rebate may be based on premiums paid in the last calendar year or the last policy year. The individual must provide evidence of demonstrative maintenance or improvement of the individual's health status as determined by assessments of agreed-upon health status indicators between the individual and the health insurer, including, but not limited to, reduction in weight, body mass index, and smoking cessation. Any rebate provided by the health insurer is presumed to be appropriate unless credible data demonstrates otherwise, or unless such rebate program requires the insured to incur costs to qualify for the rebate which equal or exceed the value of the rebate, but in no event shall the rebate exceed 10 percent of paid premiums.

(2) The premium rebate authorized by this section shall be effective for an insured on an annual basis, unless the individual fails to maintain or improve his or her health status while participating in an approved wellness program, or credible evidence demonstrates that the individual is not participating in the approved wellness program.

(3) Rebates or rewards are permitted pursuant to s. 626.9541(4).

Section 3. Section 627.65626, Florida Statutes, is amended to read:

627.65626 Insurance rebates or rewards for healthy lifestyles.—

(1) Any rate, rating schedule, or rating manual for a health insurance policy that provides creditable coverage as

defined in s. 627.6561(5) filed with the office shall provide for an appropriate rebate of premiums paid in the last policy year, contract year, or calendar year when the majority of members of a health plan have enrolled and maintained participation in any health wellness, maintenance, or improvement program offered by the group policyholder and health plan. The rebate may be based upon premiums paid in the last calendar year or policy year. The group must provide evidence of demonstrative maintenance or improvement of the enrollees' health status as determined by assessments of agreed-upon health status indicators between the policyholder and the health insurer, including, but not limited to, reduction in weight, body mass index, and smoking cessation. The group or health insurer may contract with a third-party administrator to assemble and report the health status required in this subsection between the policyholder and the health insurer. Any rebate provided by the health insurer is presumed to be appropriate unless credible data demonstrates otherwise, or unless the rebate program requires the insured to incur costs to qualify for the rebate which equal or exceed the value of the rebate, but the rebate may not exceed 10 percent of paid premiums.

(2) The premium rebate authorized by this section shall be effective for an insured on an annual basis unless the number of participating members on the policy renewal anniversary becomes less than the majority of the members eligible for participation in the wellness program.

(3) Rebates or rewards are permitted pursuant to s. 626.9541(4).

Section 4. Subsection (40) of section 641.31, Florida Statutes, is amended to read:

641.31 Health maintenance contracts.—

(40) A health maintenance organization that issues individual or group contracts may offer a reward or premium rebate pursuant to s. 656.9541(4) for a healthy lifestyle program.

~~(a) Any group rate, rating schedule, or rating manual for a health maintenance organization policy, which provides creditable coverage as defined in s. 627.6561(5), filed with the office shall provide for an appropriate rebate of premiums paid in the last policy year, contract year, or calendar year when the majority of members of a health plan are enrolled in and have maintained participation in any health wellness, maintenance, or improvement program offered by the group contract holder. The group must provide evidence of demonstrative maintenance or improvement of his or her health status as determined by assessments of agreed-upon health status indicators between the group and the health insurer, including, but not limited to, reduction in weight, body mass index, and smoking cessation. Any rebate provided by the health maintenance organization is presumed to be appropriate unless credible data demonstrates otherwise, or unless the rebate program requires the insured to incur costs to qualify for the rebate which equals or exceeds the value of the rebate but the rebate may not exceed 10 percent of paid premiums.~~

~~(b) The premium rebate authorized by this section shall be effective for a subscriber on an annual basis, unless the number of participating members on the contract renewal anniversary~~

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~~becomes fewer than the majority of the members eligible for participation in the wellness program.~~

~~(c) A health maintenance organization that issues individual contracts may offer a premium rebate, as provided under this section, for a healthy lifestyle program.~~

Section 5. Subsection (15) is added to section 641.3903, Florida Statutes, to read:

641.3903 Unfair methods of competition and unfair or deceptive acts or practices defined.—The following are defined as unfair methods of competition and unfair or deceptive acts or practices:

(15) EXCEPTION FOR WELLNESS OR HEALTH IMPROVEMENT PROGRAMS.—

(a) *Authorization to offer rewards or incentives for participation.*—An organization issuing a group or individual health benefit plan may offer a voluntary wellness or health improvement program and may encourage or reward participation in the program by authorizing rewards or incentives, including, but not limited to, merchandise, gift cards, debit cards, premium discounts or rebates, contributions to a member's health savings account, or modifications to copayment, deductible, or coinsurance amounts.

(b) *Verification of medical condition by nonparticipants.*—An organization may require a health benefit plan member to provide verification, such as an affirming statement from the member's physician, that the member's medical condition makes it unreasonably difficult or inadvisable to participate in the wellness or health improvement program. A reward or incentive offered under this subsection is not a violation of this section

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if the program is disclosed in the contract or certificate. This subsection does not prohibit an organization from offering other incentives or rewards for adherence to a wellness or health improvement program if otherwise authorized by state or federal law.

Section 6. This act shall take effect July 1, 2011.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to wellness or health improvement programs; amending s. 626.9541, F.S.; authorizing insurers to offer a voluntary wellness or health improvement program and to encourage or reward participation in the program by offering rewards or incentives to health benefit plan members; authorizing insurers to require plan members not participating in the wellness or health improvement programs to provide verification that their medical condition warrants nonparticipation in order for the nonparticipants to receive rewards or incentives; requiring that the reward or incentive be disclosed in the policy or certificate; amending s. 627.6402, F.S.; authorizing insurers to offer rewards or incentives to health benefit plan members to encourage or reward participation in wellness or health improvement programs; authorizing insurers to require plan members

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not participating in programs to provide verification that their medical condition warrants nonparticipation; amending s. 627.65626, F.S.; authorizing group health insurers to offer rewards or incentives to health benefit plan members to encourage or reward participation in wellness or health improvement programs; authorizing insurers to require plan members not participating in programs to provide verification that their medical condition warrants nonparticipation; amending s. 641.31, F.S.; deleting provisions authorizing health maintenance organizations to offer rebates of premiums for participation in a wellness program; authorizing health maintenance organizations to offer rewards or incentives to members to encourage or reward participation in wellness or health improvement programs; authorizing the health maintenance organization to require plan members not participating in programs to provide verification that their medical condition warrants nonparticipation; amending s. 641.3903, F.S.; providing for a wellness or health improvement program; providing authorization to offer certain rewards or incentives for participation; authorizing verification of a nonparticipant’s medical condition; providing an effective date.

461906

LEGISLATIVE ACTION

Senate . House

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. .

. .

The Committee on Health Regulation (Gaetz) recommended the following:

Senate Amendment to Amendment (922012)

Delete line 105
and insert:
rebate pursuant to s. 626.9541(4) for a healthy lifestyle

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 Regulation Committee

BILL:	SB 1522
INTRODUCER:	Senator Gaetz
SUBJECT:	Wellness or Health Improvement Programs
DATE:	March 16, 2011 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Brown	Stovall	HR	**Pre-meeting**
2.			BI	
3.			RC	
4.				
5.				
6.				

I. Summary:

The bill amends s. 626.9541, F.S., which is entitled "Unfair methods of competition and unfair or deceptive acts or practices defined." The bill specifies that an insurer issuing a group or individual health benefit plan may offer a voluntary wellness or health improvement program and may encourage participation in the program by way of authorizing rewards or incentives. The bill authorizes insurers to require a plan member to provide verification that the member's medical condition inhibits participation in the wellness or health improvement program. The bill specifies that a reward or incentive authorized under the subsection does not violate s. 626.9541, F.S., if the reward or incentive is disclosed in the policy or certificate and that the subsection does not prohibit any other incentives or rewards that are otherwise allowed by state or federal law.

This bill substantially amends the following section of the Florida Statutes: 626.9541.

II. Present Situation:

Chapters 626 and 627, F.S., regulate health insurance and health insurers within the state of Florida. Chapter 626 governs the practices of insurance agents and the operations of insurance companies.[1] Chapter 627 regulates insurance rates and contracts.[2]

[1] *See* ss. 626.011 through 626.99296, F.S.
[2] *See* ss. 627.011 through 627.987, F.S.

Unfair Methods of Competition and Unfair or Deceptive Acts or Practices

Section 626.9541, F.S., defines unfair methods of competition and unfair or deceptive acts or practices. The section specifies 32 different acts that qualify under the definition.[3] Among the prohibited acts relating to rates that may be charged to policyholders are: "unfair discrimination," which is defined as knowingly making an unfair discrimination between individuals of the same actuarially supportable class in the amount of premium charged for a policy, or in the benefits payable under the contract, or in the terms and conditions of the contract;[4] and "unlawful rebates," which prohibits paying, directly or indirectly, any valuable consideration or inducement not specified in the contract.[5]

Insurance Rebates for Healthy Lifestyles

In 2004, the Legislature required health insurers offering group or individual policies and health maintenance organizations (HMOs), when filing rates, rating schedules, or rating manuals with the Office of Insurance Regulation (OIR), to provide for premium rebates based on participation in health wellness, maintenance, or improvement programs, based on certain parameters.[6]

Insurers issuing individual health insurance policies may provide for a rebate on premiums when a covered individual enrolls in and maintains participation in a health wellness, maintenance or improvement program approved by the health plan. To qualify for a rebate, a covered individual must provide evidence of maintenance or improvement of the individual's health status. The measurement is accomplished by assessing health status indicators, agreed upon in advance by the individual and the insurer, such as weight loss, decrease in body mass index, and smoking cessation. The premium rebate is effective for the covered individual on an annual basis, unless the individual fails to maintain his or her health status while participating in the wellness program or evidence shows that the individual is not participating in the approved wellness program. The rebate may not exceed 10 percent of paid premiums.[7]

For group health plans, a rebate may be provided when the majority of members of the health plan are enrolled in and have maintained participation in any health wellness, maintenance, or improvement program offered by the group policyholder and health plan. Evidence of maintenance or improvement of the enrollees' health status is achieved through assessment of health status indicators similar to those included for individual health policies. The group or health insurer may contract with a third party administrator to gather the necessary information regarding enrollees' health status and provide the necessary report to the insurer. The premium rebate, which may not exceed 10 percent of paid premiums, is effective for an insured on an annual basis unless the number of participating members in the health wellness, maintenance or improvement program becomes less than the majority of total members eligible for participation in the program.[8]

For HMO coverage, a rebate may be provided when the majority of members of a group health plan are enrolled in and have maintained participation in any health wellness, maintenance, or

[3] *See* s. 626.9541(1)(a) through (ff), F.S.
[4] *See* s. 626.9541(1)(g), F.S.
[5] *See* s. 626.9541(1)(h), F.S.
[6] *See* ss. 32 through 34, ch. 2004-297, Laws of Florida.
[7] *See* s. 627.6402, F.S.
[8] *See* s. 627.65626, F.S.

improvement program offered by the group contract holder. Evidence of maintenance or improvement of the enrollees' health status is achieved through assessment of health status indicators similar to those included for individual and group health policies. The premium rebate, which may not exceed 10 percent of paid premiums, is effective for a subscriber on an annual basis unless the number of participating members in the health wellness, maintenance or improvement program becomes less than the majority of total members eligible for participation in the program. In addition to group contracts, HMOs are also allowed to offer a premium rebate on individual contracts for a healthy lifestyle program, consistent with the parameters for group contracts.[9]

III. Effect of Proposed Changes:

Section 1 amends s. 626.9541, F.S., relating to unfair methods of competition and unfair or deceptive acts or practices to specify that rewards or incentives offered by insurers relating to participation in wellness or health improvement programs do not constitute unfair or deceptive acts, despite the statute's prohibition against certain other practices that *do* constitute unfair or deceptive acts, some of which are related to reduced charges for insurance.[10]

The bill creates subsection (4) of s. 626.9541, F.S., and specifies that an insurer issuing group or individual health benefit plans may offer a voluntary wellness or health improvement program and may encourage participation in the program by way of authorizing rewards or incentives. Such rewards or incentives could include, but are not limited to, merchandise, gift cards, debit cards, premium discounts or rebates, contributions to a member's health savings account, or modifications to copayment, deductible, or coinsurance amounts.

The bill authorizes insurers to require a plan member to provide verification that the member's medical condition inhibits participation in the wellness or health improvement program. The bill specifies that a reward or incentive authorized under the subsection does not violate s. 626.9541, F.S., if the reward or incentive is disclosed in the policy or certificate, and that the subsection does not prohibit any other incentives or rewards that are otherwise allowed by state or federal law. The bill penalizes neither the insurer nor the insured for opting not to offer or take part in wellness or health improvement programs.

Section 2 provides an effective date for the bill of July 1, 2011.

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.

[9] *See* s. 641.31(40), F.S.
[10] *See* s. 626.9541(1)(o), F.S.

B. Public Records/Open Meetings Issues:

The provisions of the 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:

To the extent that wellness or health improvement programs are implemented under the bill, and to the extent that insurers provide gift cards, debit cards, premium discounts or rebates not already provided under existing law, contributions to health savings accounts, or modifications to copayments, deductibles, or coinsurance amounts, participants in such wellness or health improvement programs could have an indeterminate amount of increased monetary resources at their disposal. And, to the extent that insurers pay for such rewards, they could experience an indeterminate amount of financial costs; however, those costs could be offset by a reduction in the insurer's medical expenses due to having a healthier insured population.

C. Government Sector Impact:

The OIR advises that under the bill, insurers would need to revise their health insurance contracts and submit the forms for review and approval by the OIR's Life and Health Product Review staff. Each time the rewards or incentive programs are changed, new filings would be necessary. OIR indicates that this additional increase in workload can be absorbed within current resources.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Existing law allows for premium rebates relating to participation in health wellness programs, but does not allow for the other rewards and incentives specified in this bill (merchandise, gift cards, etc.) The OIR advises that, to avoid potential statutory ambiguity, the provisions of this bill should be reconciled with existing law relating to insurance rebates or be amended into those existing statutory provisions.

The OIR also advises that the bill does not apply to HMO coverage under ch. 641, F.S.

VIII. Additional Information:

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

None.

B. Amendments:

None.

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 Regulation Committee

BILL:	SB 720
INTRODUCER:	Senator Gaetz
SUBJECT:	Cancer Research and Control
DATE:	March 21, 2011
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	O'Callaghan	Stovall	HR	**Pre-meeting**
2.			HE	
3.			BC	
4.				
5.				
6.				

I. Summary:

This bill extends the time that any balance of any appropriation from the Biomedical Research Trust Fund, which is not disbursed but which is obligated pursuant to a contract or committed to be expended, may be carried forward. This bill also:

- Establishes a 4-year staggered term of membership for the Biomedical Research Advisory Council and increases the number of members on the council;
- Provides the Biomedical Research Advisory Council may make recommendations to the State Surgeon General for the allocation of funds appropriated to the James and Esther King Biomedical Research Program (King Program) and the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program (Bankhead-Coley Program) for training grants, research fellowships, clinical trial project grants, recruitment of certain researchers, start-up grants for certain research teams, and equipment expenditures related to certain research**;**
- Authorizes the Biomedical Research Advisory Council to develop a grant application and review mechanism which shall ensure fair and rigorous analysis of the merit of any proposals considered for funding under the King Program or Bankhead-Coley Program;
- Authorizes the Department of Health (DOH) to accept gifts, under certain circumstances, and deposit them into the Biomedical Research Trust Fund to be used for grant or fellowship awards in the King Program or Bankhead-Coley Program;
- Specifies that, in part, the purpose of the Bankhead-Coley Program is to expand cancer research and treatment capacity in Florida;
- Expands the list of types of grants for which preference may be given by the Bankhead-Coley Program by including grant proposals that foster the transfer of knowledge gained from research into community practice;

- Requires the Biomedical Research Advisory Council, instead of the DOH, to submit by February 1 of each year a report to the Governor and Legislature indicating the progress towards the Bankhead-Coley Program's mission and to make recommendations;
- Creates the Florida Comprehensive Cancer Control Act;
- Establishes the Florida Cancer Control and Resource Advisory Council to replace the Cancer Control and Research Advisory Council, which is repealed;
- Establishes the Florida Cancer Control Collaborative Program to support future cancer control initiatives; and
- Repeals the Cancer Control and Research Act.

This bill amends sections 20.435, 215.5602, 381.922, 458.324, and 459.0125, Florida Statutes.

This bill creates section 381.923, Florida Statutes.

This bill repeals section 1004.435, Florida Statutes.

II. Present Situation:

The James and Esther King Biomedical Research Program

The purpose of the King Program[1] is to provide an annual and perpetual source of funding to support research initiatives that address the health care problems of Floridians in the areas of tobacco-related cancer, cardiovascular disease, stroke, and pulmonary disease.[2] The long-term goals of the program are to:

- Improve the health of Floridians by researching better prevention, diagnoses, treatments, and cures for cancer, cardiovascular disease, stroke, and pulmonary disease;
- Expand the foundation of biomedical knowledge relating to the prevention, diagnosis, treatment, and cure of diseases related to tobacco use;
- Improve the quality of the state's academic health centers by bringing the advances of biomedical research into the training of physicians and other health care providers;
- Increase the state's per capita funding for research by undertaking new initiatives in public health and biomedical research that will attract additional funding from outside of Florida; and
- Stimulate economic activity in the state in areas related to biomedical research, such as the research and production of pharmaceuticals, biotechnology, and medical devices.

The King Program offers competitive grants to researchers throughout Florida. Grant applications from any university or established research institute[3] in Florida will be considered

[1] The Florida Legislature created the Florida Biomedical Research Program in 1999 within the DOH (ch. 99-167, L.O.F.). The Florida Biomedical Research Program was renamed the James and Esther King Biomedical Research Program during Special Session B of the 2003 Legislature (ch. 2003-414, L.O.F.).
[2] Section 215.5602, F.S.
[3] An "established research institute" is any Florida non-profit or foreign non-profit corporation covered under ch. 617, F.S., with a physical location in Florida, whose stated purpose and power is scientific, biomedical or biotechnological research or development and is legally registered with the Florida Department of State, Division of Corporations. This includes the federal government and non-profit medical and surgical hospitals, including veterans' administration hospitals. *See* James & Esther King Biomedical Research Program, *Call for Grant Applications: Biomedical, Biotechnological, and Social Scientific*

for biomedical research funding. All qualified investigators in the state, regardless of institutional affiliation, have equal access and opportunity to compete for the research funding.[4]

The State Surgeon General, after consultation with the Biomedical Research Advisory Council, is authorized to award grants and fellowships on the basis of scientific merit[5] within the following three categories:

- Investigator-initiated research grants, which are designed to initiate research that can be subsequently funded from a national agency;
- Institutional research grants, which are intended to foster the development of new and promising research investigators to undertake more independent research that would be competitive for national research funding, as well as to attract talented researchers to Florida institutions; and
- Predoctoral and postdoctoral research fellowships.[6]

The King Program was to expire on January 1, 2011, pursuant to s. 215.5602, F.S. However, the Legislature continued the program in 2010 by enacting HB 5311.[7]

The William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program

The 2006 Legislature created the Bankhead-Coley Program within the DOH.[8] The purpose of the program is to advance progress toward cures for cancer through grants awarded for cancer research.

Applications for funding cancer research from any university or established research institute in the state will be considered under the Bankhead-Coley Program. All qualified investigators in the state, regardless of institutional affiliation, have equal access and opportunity to compete for the research funding.[9] The State Surgeon General, after consultation with the Biomedical Research

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Research and Development, Fiscal Year 2009-2010, page 7, available at: http://forms.floridabiomed.com/jek_call/King%20Call%2009-10.pdf (Last visited on March 16, 2011).

[4] Grant award recipients for FY 2010-11 include the following institutions or investigators associated with these institutions: Bay Pines VA Healthcare System, Florida International University (FIU), Florida State University, M.D. Anderson Cancer Center, Mayo Clinic, Miami VA Healthcare System, H. Lee Moffitt Cancer Center & Research Institute (Moffitt Cancer Center), Sanford-Burnham Institute, Scripps Research Institute, Torrey Pines Institute, University of Central Florida, University of Florida, University of Miami, and University of South Florida. *See* James & Esther King Biomedical Research Program, *Florida Biomedical Research Programs Grants Awarded by Institution*, available at: http://forms.floridabiomed.com/Forms/GrantsAwardedbyInstitution.pdf (Last visited on March 16, 2011).

[5] *See* the "Grant Application Review and Processing" section of Senate Interim Report 2010-219, page 7, for more information about assessing scientific merit. The report is available at: http://archive.flsenate.gov/data/Publications/2010/Senate/reports/interim_reports/pdf/2010-219hr.pdf (Last visited on March 16, 2011).

[6] Section 215.5602(5)(b), F.S.

[7] Chapter 2010-161, L.O.F.

[8] Section 381.922, F.S., (ch. 2006-182, L.O.F.).

[9] Grant award recipients for FY 2010-11 include the following institutions or investigators associated with these institutions: Florida A&M University, Florida State University, M.D. Anderson Cancer Center, Mayo Clinic, Moffitt Cancer Center, Sanford-Burnham Institute, Scripps Research Institute, University of Central Florida, University of Florida, University of Miami, and the University of South Florida. *See* James & Esther King Biomedical Research Program, *Florida Biomedical Research Programs Grants Awarded by Institution*, available at: http://forms.floridabiomed.com/Forms/GrantsAwardedbyInstitution.pdf (Last visited on March 16, 2011).

Advisory Council, is authorized to award grants and fellowships on the basis of scientific merit[10] within the following three categories:

- Investigator-initiated research grants;
- Institutional research grants; and
- Collaborative research grants, including those that advance the finding of cures through basic or applied research.

As with the King Program, the Bankhead-Coley Program was to expire on January 1, 2011, pursuant to s. 215.5602, F.S. However, the Legislature also continued this program in 2010 when it enacted HB 5311.[11]

Program Funding

Initially, the King Program was funded with income from $150 million of principal in the Lawton Chiles Endowment Fund.[12] In 2004, the Legislature appropriated additional funding, through a distribution from alcoholic beverage surcharge taxes. In 2006, the Legislature substituted a $6 million dollar annual appropriation commitment from the General Revenue Fund to fund the Biomedical Research Trust Fund within the DOH for the purposes of the King Program.[13] However, in the January 2009 Special Session A, for fiscal year 2008-2009 and each fiscal year thereafter, the annual appropriation from the General Revenue Fund to the Biomedical Research Trust Fund for purposes of the King Program was reduced to $4.5 million.[14] During the regular session in 2009, the Legislature eliminated the general revenue appropriation and provided that 2.5 percent of the revenue generated from the additional cigarette surcharge enacted in 2009, not to exceed $25 million, was to be transferred into the Biomedical Research Trust Fund for the King Program for the 2009-2010 fiscal year.[15]

In 2010, when the Legislature reenacted the King Program, it continued funding for the King Program with an annual appropriation of $20 million.[16] Of the funds appropriated for the King Program, up to $250,000 per year is designated to operate the Florida Center for Universal Research to Eradicate Disease.[17]

The Bankhead-Coley Program was established with a commitment for an appropriation of $9 million per year from the General Revenue Fund.[18] However, in the January 2009 Special Session A, for fiscal year 2008-2009 and each fiscal year thereafter, the annual appropriation from the General Revenue Fund to the Biomedical Research Trust Fund for purposes of the

[10] *Supra* fn. 5.
[11] Chapter 2010-161, L.O.F.
[12] Section 215.5601, F.S. The Lawton Chiles Endowment Fund's principal originated from a portion of the state settlement received from its lawsuit with tobacco companies.
[13] Chapter 2006-182, L.O.F.
[14] Chapter 2009-5, L.O.F.
[15] Chapter 2009-58, L.O.F.
[16] *Supra* fn. 11.
[17] The purpose of the Florida Center for Universal Research to Eradicate Disease is to coordinate, improve, expand, and monitor all biomedical research programs within Florida; facilitate funding opportunities; and foster improved technology transfer or research findings into clinical trials and widespread public use. *See* s. 381.855, F.S.
[18] Section 381.922(5), F.S.

Bankhead-Coley Program was reduced to $6.75 million.[19] During the regular session in 2009, the Legislature eliminated the general revenue appropriation and provided that 2.5 percent of the revenue generated from the additional cigarette surcharge enacted in 2009, not to exceed $25 million, was to be transferred into the Biomedical Research Trust Fund for the Bankhead-Coley Program.[20]

Chapter 2009-58, Laws of Florida, provided that five percent of the revenue deposited into the Health Care Trust Fund pursuant to s. 210.011(9), F.S., related to the cigarette surcharge and s. 210.276(7), F.S., related to the surcharge on tobacco products, are to be reserved for research of tobacco-related or cancer-related illnesses. The sum of the revenue reserved, however, may not exceed $50 million in any fiscal year. The Legislature did not specify an amount to be appropriated annually, after the 2009-2010 fiscal year, for the King Program or the Bankhead-Coley Program from these reserves. However, in 2010, when the Legislature reenacted the Bankhead-Coley Program along with the King Program, it continued funding for the Bankhead-Coley Program with an annual appropriation of $20 million.[21]

Any cash balance in the Biomedical Research Trust Fund at the end of a fiscal year remains in the trust fund to be available for carrying out the purposes of the trust fund. In addition, any balance of an appropriation from the Biomedical Research Trust Fund which has not been disbursed, but which is obligated, may be used for up to 3 years from the effective date of the original appropriation.

Biomedical Research Advisory Council[22] and Peer Review Panel[23]

The purpose of the Biomedical Research Advisory Council is to advise the State Surgeon General as to the direction and scope of the King Program. The Biomedical Research Advisory Council is also required to consult with the State Surgeon General concerning grant awards for cancer research through the Bankhead-Coley Program.[24] Currently there are 11 members on the council, authorized to serve two consecutive 3-year terms.

In order to ensure that proposals for research funding within the King Program and the Bankhead-Coley Program are appropriate and evaluated fairly on the basis of scientific merit, a peer review panel of independent, scientifically qualified individuals is appointed to review the scientific content of each proposal to establish a "scientific"[25] priority score.[26] To eliminate conflicts of interest, peer reviewers come from outside the state of Florida. Reviewers are experts in their fields from universities, government agencies, and private industry who are matched according to application topic and area of expertise. The priority scores must be considered by

[19] Chapter 2009-5, L.O.F.
[20] Chapter 2009-58, L.O.F.
[21] *Supra* fn. 11.
[22] Section 215.5602(3), F.S.
[23] Section 215.5602(6) and (7), and s. 381.922(3)(b), F.S.
[24] Section 381.922(3)(a), F.S. However, s. 215.5602(11), F.S., contains an inconsistency with respect to the responsibility of the Advisory Council concerning awarding grants for cancer research.
[25] The King Program requires a *scientific* priority score in s. 215.5602(6), F.S. The Bankhead-Coley Program requires a priority score in s. 381.922(3)(b), F.S.
[26] A Bridge Grant application is ranked solely by the priority score or percentile assigned to its qualifying federal proposal in an eligible federal review process.

the Biomedical Research Advisory Council in determining which proposals will be recommended for funding to the State Surgeon General.

Meetings of the Biomedical Research Advisory Council and the peer review panel are subject to ch. 119, F.S., relating to public records; s. 286.011, F.S., relating to public meetings; and s. 24, Article I of the State Constitution relating to access to public meetings and records.

Program Administration and Grant Management

The Office of Public Health Research within the DOH manages both the King Program and the Bankhead-Coley Program with support from the Biomedical Research Advisory Council and Lytmos Group, LLC (Lytmos), pursuant to contract.[27]

The law authorizes, but does not require, the DOH, after consultation with the Biomedical Research Advisory Council, to adopt rules as necessary to implement these programs.[28] The DOH has not adopted rules to implement these programs. Instead, the DOH publishes, on its website, the procedures for implementing these two programs.[29]

The *GrantEase*™ online system is used by grantees to access grant information and submit progress reports, invoices, financial reports, and change requests during the life of the grant. At least once during the grant period, the grantee is subjected to on-site monitoring for both scientific and administrative purposes.

Cancer Control and Research Act

The Cancer Control and Research Act (the Act) is created in s. 1004.435, F.S. The Florida Cancer Control and Research Advisory Council (C-CRAB) is established within the Act to advise the Board of Governors, the State Surgeon General, and the Legislature with respect to cancer control and research in Florida. The C-CRAB consists of 34 members. Annually the C-CRAB approves the Florida Cancer Plan, which is a program for cancer control and research that must be consistent with the State Health Plan and integrated and coordinated with existing programs in this state. Additional responsibilities of the C-CRAB include:

- Recommending to the State Surgeon General a plan for the care and treatment of persons suffering from cancer and standard requirements for cancer units in hospitals and clinics in Florida;
- Recommending grant and contract awards for the planning, establishment, or implementation of programs in cancer control or prevention, cancer education and training, and cancer research;
- Pursuant to Legislative appropriations, providing written summaries that are easily understood by the average adult patient, informing actual and high-risk breast cancer patients, prostate cancer patients, and men who are considering prostate cancer screening of the medically viable treatment alternatives available to them and explaining the relative advantages, disadvantages, and risks associated therewith;

[27] James & Esther King Biomedical Research Program, *Annual Report 2010*, available at: http://forms.floridabiomed.com/AnnualReports/Annual10.pdf (Last visited on March 16, 2011).
[28] Section 215.5602(9), F.S.
[29] *See* http://www.doh.state.fl.us/ExecStaff/biomed/ophrsitemap.html, (Last visited on March 16, 2011).

- Implementing an educational program for the prevention of cancer and its early detection and treatment;
- Advising the Board of Governors and the State Surgeon General on methods of enforcing and implementing laws concerning cancer control, research, and education; and
- Recommending to the Board of Governors or the State Surgeon General rulemaking needed to enable the C-CRAB to perform its duties.

III. Effect of Proposed Changes:

Section 1 amends s. 20.435, F.S., to extend the time, from 3 years to 5 years, that any balance of any appropriation from the Biomedical Research Trust Fund, which is not disbursed but which is obligated pursuant to a contract or committed to be expended, may be carried forward.

Section 2 amends s. 215.5602, F.S., to provide for the funding of biomedical research under the King Program, including grants and fellowships awarded by the State Surgeon General for institutional training. The Biomedical Research Advisory Council may recommend an allocation of up to one-third of the program funds for the recruitment of cancer, heart, or lung disease researchers and research teams to institutions in Florida; for operational start-up grants for newly recruited cancer, heart, or lung disease research teams; and for equipment expenditures related to the expansion of cancer, heart or lung disease research and treatment capacity in Florida. The council may develop a grant application and review mechanism for the allocation of such funds, but such mechanism must ensure a fair and rigorous analysis of the merit of any proposals. A member of the Biomedical Research Advisory Council or a peer review panel is prohibited from discussing or making a decision on a research proposal if the member is a part of the governing body of, an employee of, or is contracted with the firm, entity, or agency under review.

This section also expands the Biomedical Research Advisory Council from 11 to 12 members, and requires one member to be the chief executive officer of BioFlorida, or a designee. A member of the council, who is currently required be the chief executive officer of the Florida/Puerto Rico Affiliate of the American Heart Association, is replaced by the chief executive officer of the Greater Southeast Affiliate of the American Heart Association.[30] The appointment of such members is extended from 3-year terms to 4-year staggered terms. However, the first two appointments by the Governor and the first appointment by the President of the Senate and the Speaker of the House of Representatives on or after July 1, 2011, must be for a term of 2 years each.

This section provides that the DOH may accept gifts made willfully and without conditions and may deposit the gifts into the Biomedical Research Trust Fund to be used for grant or fellowship awards under the King Program. The DOH may also accept gifts to which conditions are attached, if it is lawful for the DOH to accept the gift with conditions and the gift is consistent with the provisions of the King Program.

[30] The following states and territories are part of the Greater Southeast Affiliate: Alabama, Florida, Georgia, Louisiana, Mississippi, Puerto Rico, Tennessee, and U.S. Virgin Islands. American Heart Association, *Greater Southeast Affiliate Funding Opportunities*, available at: http://www.americanheart.org/presenter.jhtml?identifier=2471 (Last visited on March 16, 2011).

Section 3 amends s. 381.922, F.S., to specify that the purpose of the Bankhead-Coley Program, in part, is to expand cancer research and treatment capacity in Florida. The program is required to provide grants for cancer clinical trials projects, for recruiting cancer researchers and research teams; for operational start-up grants for newly recruited cancer researchers and research teams; or for equipment expenditures related to the expansion of cancer research and treatment capacity in Florida. An applicant for such grants is given preference if the grant proposal would support the transfer of knowledge gained from research into the practice of community practitioners.

Grants or fellowships may be given for institutional training, predoctoral and postdoctoral research, and clinical trial projects, especially if those clinical trial projects identify prospective clinical trials treatment options for cancer patients in Florida or foster greater rates of participation in clinical trials. At least one clinical trial project per year that has been proposed and that merits an award must be awarded a grant.

The Biomedical Research Advisory Council may recommend an allocation of up to one-third of the program funds for the recruitment of cancer, heart, or lung disease researchers and research teams to institutions in Florida; for operational start-up grants for newly recruited cancer, heart, or lung disease research teams; and for equipment expenditures related to the expansion of cancer, heart or lung disease research and treatment capacity in Florida. The council may develop a grant application and review mechanism for the allocation of such funds, but such mechanism must ensure a fair and rigorous analysis of the merit of any proposals. A member of the Biomedical Research Advisory Council or a peer review panel is prohibited from discussing or making a decision on a research proposal if the member is a part of the governing body of, an employee of, or is contracted with the firm, entity, or agency under review.

This section requires the Biomedical Research Advisory Council to submit, by February 1 of each year, a report to the Governor and the Legislature which indicates progress towards the Bankhead-Coley Program's mission and makes recommendations that furthers the program's purpose.

This section provides that the DOH may accept gifts made willfully and without conditions and may deposit the gifts into the Biomedical Research Trust Fund to be used for grant or fellowship awards under the Bankhead-Coley Program. The DOH may also accept gifts to which conditions are attached, if it is lawful for the DOH to accept the gift with conditions and the gift is consistent with the provisions of the King Program.

Section 4 creates s. 381.923, F.S., to create the "Florida Comprehensive Cancer Control Act" (Cancer Control Act). This section provides legislative intent for the Cancer Control Act, including the importance of research related to cancer and the importance of community outreach to educate Floridians about, and prevent, cancer. The terms "cancer," "council," "department," "plan," "program," and "qualified nonprofit association" are defined for purposes of the Cancer Control Act.

This section creates the Florida Cancer Control and Resource Advisory Council (council) within the H. Lee Moffitt Cancer Center and Research Institute, Inc. Each member of the council must be a resident of Florida. The composition of the 42-member council includes:

- Three members representing the general public, appointed by the Governor;
- A member of the Senate, appointed by the President of the Senate;
- A member of the House of Representatives, appointed by the Speaker of the House of Representatives;
- A representative appointed by:
  - H. Lee Moffitt Cancer Center and Research Institute, Inc.;
  - University of Florida Shands Cancer Center;
  - University of Miami Sylvester Comprehensive Cancer Center;
  - Mayo Clinic, Florida;
  - M.D. Anderson Cancer Center, Florida;
  - American Cancer Society, Florida Division;
  - American Lung Association of the Southeast;
  - American Association for Retired Persons;
  - Department of Health;
  - Department of Education;
  - Florida Tumor Registrars Association;
  - Florida Cancer Data System;
  - Florida Society of Oncology Social Workers;
  - Florida Oncology Nurses Society;
  - Florida Society of Clinical Oncology;
  - Florida Association of Pediatric Tumor Programs, Inc;
  - Florida Medical Association;
  - Florida Hospital Association;
  - Florida Nursing Association;
  - Florida Dental Association;
  - Florida Osteopathic Association;
  - University of Florida College of Medicine;
  - Florida Academy of Family Physicians;
  - University of Miami College of Medicine;
  - University of South Florida College of Medicine;
  - Florida State University College of Medicine;
  - University of Central Florida College of Medicine;
  - Nova Southeastern College of Osteopathic Medicine;
  - Florida International University College of Medicine;
  - Lake Erie School of Osteopathic Medicine;
  - Biomedical Research Advisory Council;
  - Center for Universal Research to Eradicate Disease; and
  - Each of the regional Cancer Control Collaboratives. (Currently there are five regional Cancer Control Collaboratives.)

This section designates membership of an executive committee to coordinate the activities and plan the direction of the full council.

The council must meet at least semiannually and may prescribe, amend, and repeal bylaws governing the council. Members of the council are prohibited from participating in any discussion or decision to recommend an award or contract to any qualified nonprofit association

or to any agency of this state or its political subdivision with which the member is also a member of the governing body, an employee, or has entered into a contractual arrangement.

The council is required to:

- Advise the Governor, Legislature, State Surgeon General, or other policymakers with respect to cancer control and resources in Florida;
- Approve a plan for cancer control to be known as the "Florida Cancer Plan" and review it at least every 2 years;
- Recommend to the Governor, Legislature, State Surgeon General, or other policymakers an evidence-based plan for the prevention and early detection of cancer. The State Surgeon General and other state policymakers are required to consider this plan in developing department priorities and funding priorities and standards under ch. 385, F.S., relating to chronic disease;
- Provide expertise and input in the content and development of the Florida Cancer Plan. Recommendations must include coordination and integration of other state plans concerned with cancer control;
- Advise the State Surgeon General on methods of enforcing and implementing laws that are concerned with cancer control; and
- Report any findings and recommendations to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the State Surgeon General by December 1 of each year.

The council is authorized to form committees to address the following areas for action:

- Cancer plan evaluation, including tumor registry, data retrieval systems, and epidemiology of cancer in Florida;
- Cancer prevention;
- Cancer detection;
- Cancer treatments;
- Support services for cancer patients and caregivers;
- Cancer education for laypersons and professionals; and
- Other cancer-control-related topics.

The council must develop or purchase written summaries of the medical treatment alternatives for breast cancer and prostate cancer patients and for men who are considering prostate cancer screening, if the Legislature specifically appropriates funds for this purpose. Such summaries would have to be printed and provided to allopathic and osteopathic physicians and surgeons in Florida. Also, if such funds are appropriated for this purpose, the council must develop and implement educational programs to inform citizen groups, associations, and voluntary organizations about early detection and treatment of breast cancer and prostate cancer.

The council may recommend to the State Surgeon General rulemaking enabling it to perform its duties and properly administer the Cancer Control Act.

The H. Lee Moffitt Cancer Center and Research Institute must house the council and provide a full-time executive director and additional administrative support for the council.

The DOH is authorized to adopt rules necessary to administer the Cancer Control Act.

The Florida Cancer Plan is established within the DOH. The DOH is required to consult with the council in developing the plan, prioritizing goals, and allocating resources.

The bill establishes the Cancer Control Collaborative Program (collaborative program) within the Bankhead-Coley Program of the DOH. The collaborative program is responsible for overseeing and providing infrastructure for the state cancer collaborative network by implementing the Florida Cancer Plan's initiatives and facilitating the local development of solutions to cancer control needs. The DOH must appoint a collaborative program director to be responsible for supervising the collaborative program and providing support to the regional cancer control collaboratives. This support must include, at a minimum, centralized organization, communications, information technology, shared resources, and cancer control expertise. The collaborative program must submit a report to the council by October 15 of each year. The collaborative program is also required to serve as the infrastructure for expansion or adaption as federal programs or other opportunities arise for future cancer control initiatives. The infrastructure for the local cancer control collaboratives is required, to the extent possible, to be designed to leverage federal funding opportunities.

Each regional cancer control collaborative must bring together local stakeholders, develop bylaws, identify priority cancer control needs of its region, and develop solutions to solve problems. The solutions must be consistent with the Florida Cancer Plan. Each regional cancer control collaborative must meet at least semiannually and send representation to council meetings.

Section 5 amends s. 458.324, F.S., to correct cross-references to conform to changes made by the bill.

Section 6 amends s. 459.0125, F.S., to correct cross-references to conform to changes made by the bill.

Section 7 repeals s. 1004.435, F.S., the Cancer Control and Research Act.

Section 8 provides an effective date of July 1, 2011.

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 the 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:

According to s. 381.922(5), F.S., the Bankhead-Coley Program may only use up to 10 percent of its appropriated funds for administrative purposes. Because this bill establishes the Cancer Control Collaborative Program within the DOH and the program resides within the Bankhead-Coley Program, and no additional appropriation was made for this new program, it is indeterminate whether there will be administrative money available to administer the new program

The Moffitt Cancer Center may incur costs because it is required to provide a full-time director and additional administrative support as reasonably necessary to the Florida Cancer Control and Resource Advisory Council.

VI. Technical Deficiencies:

None.

VII. Related Issues:

This bill appears to allow council members more freedom to discuss research proposals outside of the council setting than what is allowed under current law. The bill only prohibits a member of a council or a peer review panel from discussing or making a decision on a research proposal if the member is a part of the governing body of, an employee of, or is contracted with the firm, entity, or agency under review. Current law under s. 112.3143, F.S., provides that no appointed public officer shall participate in any matter which would inure to the officer's special private gain or loss; which the officer knows would inure to the special private gain or loss of any principal by whom he or she is retained or to the parent organization or subsidiary of a corporate principal by which he or she is retained; or which he or she knows would inure to the special private gain or loss of a relative or business associate of the public officer, without first disclosing the nature of his or her interest in the matter. In addition, the required disclosure is to be made in a written memorandum filed with the person responsible for recording the minutes of the meeting, prior to the meeting in which consideration of the matter will take place, and must be incorporated into the minutes. The memorandum becomes a public record and it must be

immediately provided to the other members of the agency and read publicly at the next meeting held subsequent to the filing of the written memorandum.[31]

The DOH reports that in order to obligate and disburse funds in accordance with the conditions of a gift, the DOH will have to seek specific spending authority from the Legislative Budget Commission.[32]

VIII. Additional Information:

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

None.

B. Amendments:

None.

[31] Department of Health, *Bill Analysis, Economic Statement, and Fiscal Note for SB 720*, dated February 17, 2011. A copy of this analysis is on file with the Senate Health Regulation Committee.
[32] *Id.*

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 Regulation Committee

BILL:	SB 1052
INTRODUCER:	Senator Altman
SUBJECT:	Crisis Stabilization Units
DATE:	March 18, 2011
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	O'Callaghan	Stovall	HR	**Pre-meeting**
2.			BC	
3.				
4.				
5.				
6.				

I. Summary:

This bill increases the number of licensed beds permitted to be in a crisis stabilization unit (CSU) from 30 beds to 50 beds.

This bill substantially amends s. 394.875, F.S.

II. Present Situation:

Crisis Stabilization Units (CSUs)

Part I of ch. 394, F.S., is the Florida Mental Health Act, also known as the Baker Act. In addition to procedural requirements for involuntary examination and voluntary and involuntary treatment of mental illness, this part provides a framework for the public mental health service delivery system.

The "front door" to the system is the public receiving facility. Receiving facilities admit persons for involuntary examination and are defined in statute as "any public or private facility designated by the department to receive and hold involuntary patients under emergency conditions or for psychiatric evaluation and to provide short-term treatment."[1] The Department of Children and Families is responsible for issuing a certificate of designation to a CSU as a Baker Act Receiving Facility.

[1] Section 394.455(26), F.S.

In many communities, the public receiving facility is a CSU. A CSU is defined as "a program that provides an alternative to inpatient hospitalization and that provides brief, intensive services 24-hours-a-day, 7-days-a-week, for mentally ill individuals who are in an acutely disturbed state."[2] The purpose of a CSU is to stabilize and redirect a client to the most appropriate and least restrictive community setting available, consistent with the client's needs. CSUs may screen, assess, and admit for stabilization persons who present themselves to the CSU and persons who are brought in involuntarily. CSUs provide services regardless of a client's ability to pay.[3] Inpatient stays average 3 to 14 days, resulting in return to the patient's own home or placement in a long-term mental health facility or other living arrangements.[4]

The CSUs are licensed by the Agency for Health Care Administration (AHCA),[5] and the rules governing the operation of the CSU, including certification of the number of beds the CSU is authorized to provide, are promulgated by the Department of Children and Families.[6] Currently, there are 54 licensed CSUs in Florida.[7]

Licensure

Facilities must meet license requirements through the submission of a completed application, required documentation, and completion of a satisfactory survey to the AHCA; this includes new facilities and reactivation of an expired license. Rule 65E-12.104, Florida Administrative Code, requires an applicant for licensure to provide the following to AHCA:

- A comprehensive outline of the program and services;
- A staffing pattern description including the name and license number of each employed licensed person;
- A table of organization of all management levels;
- A resume of the facility director or manager;
- Fiscal information;
- Proof of liability insurance coverage from an authorized insurer in an amount of no less than $300,000 per occurrence with a minimal annual aggregate of no less than $1 million;
- Proof of designation as, or affiliation with, a public receiving facility;
- Identification of age groups to be admitted as: adults only, or adults and minors, or minors only;
- A description of services to minors, if minors are admitted; and
- Proof of compliance with statutory requirements.

When all required information is received and acceptable, a licensure survey is scheduled. A license is issued when documentation of a successful licensure survey is complete and filed.[8] A valid license is required before services can be provided. The annual license fee is $96 per bed.[9]

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[2] Section 394.67(4), F.S.
[3] Section 394.875(1)(a), F.S.
[4] Agency for Health Care Administration, *Crisis Stabilization Units*, available at: http://www.fdhc.state.fl.us/mchq/health_facility_regulation/hospital_outpatient/crisis.shtml (Last visited on March 19, 2011).
[5] Sections 394.875(2) and 394.879, F.S.; Rule 65E-12.104, F.A.C.
[6] Sections 394.457(5) and 394.879, F.S.; Rules 65E-12.103-12.107, F.A.C.
[7] Agency for Health Care Administration, *2011 Bill Analysis & Economic Impact Statement for SB 1052*, on file with the Senate Health Regulation Committee.
[8] Agency for Health Care Administration, *Licensure Requirements*, available at: http://www.fdhc.state.fl.us/mchq/health_facility_regulation/hospital_outpatient/crisis.shtml (Last visited on March 19, 2011).

To renew a license, the licensure application, renewal fee and supporting documents must be submitted to the AHCA 120 to 60 days prior to the expiration date. A late fee of $50 per day, up to $500 will be assessed for any application not received 60 days prior to expiration of the license.[10]

Chapter 408.803, F.S., defines "change of ownership" as an event in which the licensee sells or otherwise transfers its ownership to a different individual or entity as evidenced by a change in the federal employer identification number or the taxpayer identification number or an event in which 51 percent or more of the ownership, shares, membership, or controlling interest of a licensee is in any manner transferred or otherwise assigned. This does not apply to a licensee that is publicly traded on a recognized stock exchange. Also, a change solely in the management company or board of directors is not a change of ownership. The licensure application, fee and supporting documents must be submitted at least 60 days prior to the date of acquisition of the CSU. Before the application can be approved, a bill of sale or other closing document signed by the buyer and the seller and showing the effective date of the transfer must be received by the AHCA.[11]

Accreditation

A CSU may choose to be accredited and may ask the AHCA to accept their accreditation, in lieu of on-site licensure surveys, by submitting the required documentation from an approved accreditation organization. The following accreditation organizations are recognized by AHCA for mental health facilities: The Joint Commission; Council on Accreditation (COA); and Commission on Accreditation of Rehabilitation Facilities (CARF). The required documentation includes: the name of the accrediting organization, the beginning and expiration dates of the accreditation, accreditation status, type of accreditation, accreditation survey report, all responses to any compliance issues cited by the accrediting organization, and any follow up reports.[12]

Staffing

Every CSU must have at least one psychiatrist as primary medical coverage as defined in s. 394.455(24), F.S.[13] Back-up coverage may be a physician who will consult with the psychiatrist. The psychiatrist or physician must be on call 24-hours-a-day and must make daily rounds. Counties with a the population of less than 50,000 persons may utilize a licensed physician for on-call activities and daily rounds as long as the physician has postgraduate training and experience in the diagnosis and treatment of mental and nervous disorders.[14] The psychiatrist is responsible for the development of general medical policies, prescription of medications, and medical treatment of persons receiving services. Each person must be provided

[9] Rule 65E-12.104, F.A.C.
[10] Agency for Health Care Administration, *Renewal*, available at: http://www.fdhc.state.fl.us/mchq/health_facility_regulation/hospital_outpatient/crisis.shtml (Last visited on March 19, 2011).
[11] Agency for Health Care Administration, *Change of Ownership*, available at: http://www.fdhc.state.fl.us/mchq/health_facility_regulation/hospital_outpatient/crisis.shtml (Last visited on March 19, 2011).
[12] Agency for Health Care Administration, *Accreditation*, available at: http://www.fdhc.state.fl.us/mchq/health_facility_regulation/hospital_outpatient/crisis.shtml (Last visited on March 19, 2011).
[13] "Psychiatrist" means a medical practitioner licensed under chapter 458 or chapter 459 who has primarily diagnosed and treated mental and nervous disorders for a period of not less than 3 years, inclusive of psychiatric residency. Section 394.455(24), F.S.
[14] Rule 65E-12.105, F.A.C.

medical or psychiatric services as considered appropriate and such services must be recorded by the physician or psychiatrist in the clinical record.[15]

Sufficient numbers and types of qualified staff are required to be on duty and available at all times to provide necessary and adequate safety and care. The program policies and procedures of the CSU must define the types and numbers of clinical and managerial staff needed to provide persons with treatment services in a safe and therapeutic environment. At least one registered nurse is required to be on duty 24-hours-a-day, 7-days-a-week.[16]

Each CSU is required to develop policies and procedures to ensure adequate minimum staffing. These policies must address double shifting, use of temporary registered nurses, use of regular part-time registered nurses and licensed practical nurses. Policies must ensure that nursing staff are not used in dual capacity or in ancillary areas which compromise minimum unit staffing requirements.[17]

III. Effect of Proposed Changes:

This bill increases the number of licensed beds permitted to be in a CSU from 30 beds to 50 beds.

This bill provides that it shall take effect on July 1, 2011.

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.

[15] *Id.*
[16] *Id.*
[17] *Id.*

B. Private Sector Impact:

CSUs may have a positive, but indeterminate, fiscal impact because the CSUs will be able to serve more clients.

C. Government Sector Impact:

The Department of Children and Families will incur an indeterminate amount of costs for initiating rule development, issuing certificates of designation, certifying number of beds, and developing new staffing patterns.[18]

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.)

None.

B. Amendments:

None.

[18] *Supra* fn. 7.

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 Regulation Committee

BILL:	SB 1456
INTRODUCER:	Senator Garcia
SUBJECT:	Public Records/Florida Health Choices Program
DATE:	March 17, 2011 REVISED: 3/21/2011

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Brown	Stovall	HR	**Pre-meeting**
2.			CF	
3.			GO	
4.				
5.				
6.				

I. Summary:

The bill creates confidentiality and an exemption from the public records requirements of s. 119.07(1), F.S., and s. 24(a), Article I of the Florida Constitution, for any personal, identifying information of an applicant, enrollee, or participant in the Florida Health Choices program (FHC). The bill provides exceptions under which the information may be disclosed. The bill provides retroactivity for the information to which the confidentiality and exemption apply. The bill provides that the confidentiality and exemption are subject to the Open Government Sunset Review Act and will be repealed on October 2, 2016, unless reviewed and saved from repeal through reenactment by the Legislature. The bill provides a Legislative finding of public necessity for the confidentiality and exemption.

The bill has an effective date of October 1, 2011.

This bill substantially amends the following sections of the Florida Statutes: 408.910.

II. Present Situation:

Florida's Public Records Laws

Florida has a long history of providing public access to the records of governmental and other public entities. The Legislature enacted its first law affording access to public records in 1892.[1] In 1992, Florida voters approved an amendment to the State Constitution which raised the statutory right of access to public records to a constitutional level.

[1] Section 1390, 1391 F.S. (Rev. 1892).

Section 24(a), Art. I, of the Florida Constitution, provides that:

> Every person has the right to inspect or copy any public record made or received in connection with the official business of any public body, officer, or employee of the state, or persons acting on their behalf, except with respect to records exempted pursuant to this section or specifically made confidential by this Constitution. This section specifically includes the legislative, executive, and judicial branches of government and each agency or department created thereunder; counties, municipalities, and districts; and each constitutional officer, board, and commission, or entity created pursuant to law or this Constitution.

The Public Records Act is contained in ch. 119, F.S., and specifies conditions under which the public must be given access to governmental records. Section 119.07(1)(a), F.S., provides that every person who has custody of a public record[2] must permit the record to be inspected and examined by any person, at any reasonable time, under reasonable conditions, and under supervision by the custodian of the public record. Unless specifically exempted, all agency[3] records are to be available for public inspection.

The Florida Supreme Court has interpreted the definition of "public record" to encompass all materials made or received by an agency in connection with official business which are "intended to perpetuate, communicate, or formalize knowledge."[4] All such materials, regardless of whether they are in final form, are open for public inspection unless made exempt.[5]

Only the Legislature is authorized to create exemptions from open government requirements.[6] Exemptions must be created by general law and such law must specifically state the public necessity justifying the exemption. Further, the exemption must be no broader than necessary to accomplish the stated purpose of the law.[7] A bill enacting an exemption may not contain other substantive provisions, although it may contain multiple exemptions relating to one subject.[8]

There is a difference between records that the Legislature exempts from public inspection and those that the Legislature makes confidential and exempt from public inspection. If a record is made confidential with no provision for its release so that its confidential status will be

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[2] Section 119.011(12), F.S., defines "public records" to include "all documents, papers, letters, maps, books, tapes, photographs, film, sound recordings, data processing software, or other material, regardless of the physical form, characteristics, or means of transmission, made or received pursuant to law or ordinance or in connection with the transaction of official business by any agency."

[3] Section 119.011(2), F.S., defines "agency" as "any state, county, district, authority, or municipal officer, department, division, board, bureau, commission, or other separate unit of government created or established by law including, for the purposes of this chapter, the Commission on Ethics, the Public Service Commission, and the Office of Public Counsel, and any other public or private agency, person, partnership, corporation, or business entity acting on behalf of any public agency."

[4] *Shevin v. Byron, Harless, Schaffer, Reid, and Assocs., Inc.*, 379 So. 2d 633, 640 (Fla. 1980).

[5] *Wait v. Florida Power & Light Co.*, 372 So. 2d 420 (Fla. 1979).

[6] FLA. CONST. art. I, s. 24(c) (1992).

[7] *Memorial Hospital-West Volusia, Inc. v. News-Journal Corporation*, 729 So. 2d 373, 380 (Fla. 1999); *Halifax Hospital Medical Center v. News-Journal Corporation*, 724 So. 2d 567 (Fla. 1999).

[8] *Supra* fn. 6.

maintained, such record may not be released by an agency to anyone other than the person or entities designated in the statute.[9] If a record is simply exempt from mandatory disclosure requirements, an agency is not prohibited from disclosing the record in all circumstances.[10]

Access to public records is a substantive right; therefore, a statute affecting that right is presumptively prospective in its application.[11] There must be a clear legislative intent for a statute affecting substantive rights to apply retroactively.[12]

Open Government Sunset Review Act

The Open Government Sunset Review Act[13] provides for the systematic review of an exemption from the Public Records Act in the fifth year after its enactment.[14] The act states that an exemption may be created, revised, or maintained only if it serves an identifiable public purpose and if the exemption is no broader than necessary to meet the public purpose it serves.[15] An identifiable public purpose is served if the exemption meets one of three specified criteria and if the Legislature finds that the purpose is sufficiently compelling to override the strong public policy of open government and cannot be accomplished without the exemption.[16] An exemption meets the statutory criteria if it:

- Allows the state or its political subdivisions to effectively and efficiently administer a governmental program, which administration would be significantly impaired without the exemption;
- Protects information of a sensitive personal nature concerning individuals, the release of which would be defamatory or cause unwarranted damage to the good name or reputation of such individuals or would jeopardize the safety of such individuals; or
- Protects information of a confidential nature concerning entities, including, but not limited to, a formula, pattern, device, combination of devices, or compilation of information which is used to protect or further a business advantage over those who do not know or use it, the disclosure of which would injure the affected entity in the marketplace.[17]

The act also requires the Legislature to consider the following six questions that go to the scope, public purpose, and necessity of the exemption:[18]

- What specific records or meetings are affected by the exemption?
- Whom does the exemption uniquely affect, as opposed to the general public?
- What is the identifiable public purpose or goal of the exemption?
- Can the information contained in the records or discussed in the meeting be readily obtained by alternative means? If so, how?

[9] Attorney General Opinion 85-62, August 1, 1985.
[10] *Williams v. City of Minneola*, 575 So. 2d 683, 687 (Fla. 5th DCA), *review denied*, 589 So. 2d 289 (Fla. 1991).
[11] *Memorial Hospital-West Volusia, Inc. v. News-Journal Corporation*, 784 So. 2d 438 (Fla. 2001).
[12] *Id.*
[13] Section 119.15, F.S.
[14] Section 119.15(4)(b), F.S., provides that an existing exemption may be considered a substantially amended exemption if the exemption is expanded to cover additional records. As with a new exemption, a substantially amended exemption is also subject to the 5-year review.
[15] Section 119.15(6)(b), F.S.
[16] *Id.*
[17] *Id.*
[18] Section 119.15(6)(a), F.S.

- Is the record or meeting protected by another exemption?
- Are there multiple exemptions for the same type of record or meeting that it would be appropriate to merge?

If, and only if, in reenacting an exemption that will repeal, the exemption is expanded (essentially creating a new exemption), then a public necessity statement and a two-thirds vote for passage are required.[19] If the exemption is reenacted with grammatical or stylistic changes that do not expand the exemption, if the exemption is narrowed, or if an exception to the exemption is created,[20] then a public necessity statement and a two-thirds vote for passage are not required.[21]

The Florida Health Choices Program

In 2008, the Legislature created the FHC program in s. 408.910, F.S., as a single, centralized "marketplace" for the sale and purchase of various products that enable individuals to pay for health care coverage. The Florida Health Choices Corporation (the Corporation) was created to administer the program.[22]

The FHC program defines "marketplace" as follows: "Florida's Insurance Marketplace is a web-based shopping experience that allows easy access and side-by-side comparison of health care options for individuals, families, and businesses."[23]

The following types of employers are eligible to use FHC for choosing their employer-sponsored health plan:

- Employers with 1-50 employees
- Fiscally constrained counties
- Municipalities with populations less than 50,000
- School districts in fiscally constrained counties.

The Corporation is charged with establishing procedures for employer participation, including compliance with Section 125 of the Internal Revenue Code regarding cafeteria plans and enabling the employers' contributions and the employees' contributions to be made using pre-tax dollars.[24] Employers must also designate the Corporation as the third-party administrator for the employer's health plan, establish payroll deduction, and arrange for employer contribution payments.

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[19] *Supra* fn. 6.
[20] An example of an exception to a public records exemption would be allowing another agency access to confidential or exempt records.
[21] *Cf., State v. Knight*, 661 So. 2d 344 (Fla. 4th DCA 1995).
[22] See s. 4, ch. 2008-32, Laws of Florida.
[23] *Florida Health Choices: How Does the Marketplace Work?*, available at http://myfloridachoices.org/faq/ (last visited March 18, 2011).
[24] Section 125 allows employers to offer employees a choice between cash salary and a variety of nontaxable (qualified) benefits. A qualified benefit is one that does not defer compensation and is excludable from an employee's gross income under a specific provision of the IRS Code, without being subject to the principles of constructive receipt. Qualified benefits include health care, vision and dental care, group-term life insurance, disability, adoption assistance and certain other benefits.

The following types of individuals are eligible to purchase FHC health care products and coverage:

- Employees of employers choosing FHC as the employer-sponsored health plan
- State government employees not eligible for state employee health benefits
- State government retirees
- Medicaid Reform participants who select the opt-out provision of Reform[25]
- Employees of statutory rural hospitals.

The FHC program establishes portability of products by allowing individuals to voluntarily continue participation in the program regardless of changes in job status. The program establishes procedures for portable participation by individuals, who must make arrangement for payment (such as changing payroll deduction with a change in employer, or arranging for the contribution formerly made by an employer to be made by the individual).

The FHC model encourages diversity of price and benefit packages and allows for many types of products provided by many types of vendors:

- Licensed insurers may sell health insurance policies, limited benefit policies, other risk-bearing coverage, and other products or services.
- Licensed health maintenance organizations (HMOs) may sell health coverage policies, limited benefit policies, other risk-bearing products, and other products or services.
- Licensed prepaid clinic service providers may sell prepaid service contracts and other arrangements for a specified amount and type of health services or treatments.
- Out-of-state insurers may sell health insurance policies, limited benefit policies, other risk-bearing products, and other products or services.
- Health care providers, including hospitals and other licensed health facilities, health care clinics, licensed health professionals, pharmacies, and other licensed health care providers, may sell non-risk-bearing service contracts and other arrangements for a specified amount and type of health services or treatments.
- Provider organizations including provider service networks, group practices, professional associations, and other incorporated organizations of providers, may sell non-risk-bearing service contracts and arrangements for a specified amount and type of health services or treatments.
- Corporate entities providing specific health services in accordance with applicable state laws may sell service contracts and arrangements for a specified amount and type of health services or treatments.

These products within the FHC program are not subject to the licensing requirements or mandated coverage or offering requirements of ch. 641 or part VI of ch. 627. However, only licensed vendors may offer risk-bearing products.

The program provides for the exclusion of vendors for deceptive or predatory practices, financial insolvency, and failure to comply with program standards set by the Corporation. The program establishes procedures for participation by vendors, which must submit complete descriptions of

[25] The "Medicaid Reform" pilot program authorized under s. 409.91211, F.S., allows Medicaid recipients to "opt-out" of the state-run Medicaid program and use a Medicaid-funded subsidy to pay their share of the premium for employer-sponsored health coverage, if available.

the products offered, including information on the provider network, set product prices based on the basic risk-adjustment factors of age, gender, and location of the individual participant, participate in ongoing reporting as required by the Corporation, and establish grievance procedures. In addition, vendors must agree to make all the products they offer available to all individual participants in the program.

The program provides that licensed health insurance agents may voluntarily participate as buyers' representatives to act on behalf of individual purchasers and provide information about the products and services sold. Such agents would receive compensation from the Corporation for performing this function. The program requires such agents to receive training and disclose relationships with vendors. As additional tools for helping consumers make informed decisions, the program is required to enable purchasing through an interactive website and make information about the products and services available on the website and through other means. The program requires that consumers are made aware of any benefit limitations and can make informed choices.

The Corporation is charged with establishing the marketplace and performing several functions to administer it. The Corporation is required to establish procedures to determine the eligibility of employers, vendors, individuals and agents, and develop criteria for the exclusion of vendors. The Corporation must collect individual and employer contributions and pay them out to vendors. The Corporation must establish procedures for application, enrollment, risk assessment, risk adjustment, plan administration, performance monitoring, and consumer education. The Corporation has authority to establish qualifying criteria and certification procedures for vendors, including requiring performance bonds, monitoring vendor performance, and enforcing the terms of agreements with vendors.

To avoid selection bias in the distribution of consumers among available products, the Corporation must employ a variety of risk-pooling techniques. Most notably, these measures include the ability to re-allocate a portion of the premium paid for risk-bearing products through a post-enrollment risk adjustment. This adjustment process will be applied monthly based on data reported by the vendors about their enrollees.

The Corporation is charged with coordinating with the Department of Revenue to develop a plan to establish tax credits or refunds for employers that participate in the program.

Launching Florida Health Choices

The FHC program has scheduled a phased-in launch of the marketplace for 2011 and 2012.[26] Phase One, known as "Quick Start," will support the application and enrollment of eligible employers, employees, and insurance agents in the summer of 2011. The initial web-based portal will support up to nine medical coverage plans and permit side-by-side comparison of benefits and costs.

[26] *Florida Health Choices 2010 Annual Report,* February 1, 2011, p. 3, available at http://myfloridachoices.org/wp-content/uploads/2011/02/FHC-AnnualReport_v2a.pdf

An online calculator will display member premium costs after taking into account any employer contributions. A statewide customer contact center will open in St. Petersburg, Florida, and the ability to accept payroll deducted premiums will also be included.

The Mid-Term phase is designed to expand the portal functionality for both employers and insurance agents. Supporting up to 20 vendors, the Mid-Term portal offerings can include dental, vision, and prepaid plans.

With the Long-Term phase expected in 2012, the marketplace is expected to offer life insurance and other non-medical products to enrolled participants and employers.

Information Collected and Utilized in the Florida Health Choices Program

In the administration of the program and the execution of the functions described above, the FHC program may collect and utilize various pieces of personal, indentifying information about applicants, enrollees, and participants. When applying for the program, insurance agents, employers, and eligible employees will provide a variety of personal and financial information. Information could include a participating insurance agent's client list, an employer's business and accounting records, human resource records, or other proprietary business or personal identification information.[27]

III. Effect of Proposed Changes:

Section 1 creates section (14) of s. 408.910, F.S., to provide that any personal, identifying information of an applicant, enrollee, or participant in the FHC program is confidential and exempt from s. 119.07(1), F.S., and s. 24(a), Article I of the State Constitution.

The bill creates the following exceptions by requiring that such information must be disclosed to:
- Another governmental entity in the performance of its official duties and responsibilities;
- Any person who has the written consent of the program applicant; and
- The Florida Kidcare program for the purpose of administering the program.[28]

The bill provides that the confidentiality and exemption do not prohibit an enrollee's legal guardian from obtaining confirmation of coverage, dates of coverage, the name of the enrollee's health plan, and the amount of premium being paid.

The bill provides that the confidentiality and exemption apply to any pertinent information in the FHC program before, on, or after the bill's effective date.

[27] Email from Florida Health Choices to staff in the Florida Senate Committee on Health Regulation, March 18, 2011, 1:40 pm EDT (on file with committee staff).

[28] Under certain circumstances in federal law, health insurance exchanges similar to the marketplace created under the FHC program could be required to exchange information with the state Medicaid program. In Florida, the state Medicaid program also exchanges data with the Florida Kidcare program. The bill provides these exceptions to the FHC program's public records exemption to allow FHC data to be exchanged with those programs as necessary.

The bill provides that a person who knowingly and willfully violates the confidentiality or exemption commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083, F.S.

The bill provides that the confidentiality and exemption are subject to the Open Government Sunset Review Act and are repealed on October 2, 2016, unless reviewed and saved from repeal through reenactment by the Legislature.

Section 2 provides a Legislative finding of public necessity for the confidentiality and exemption.

Section 3 provides an effective date for the bill of October 1, 2011.

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 bill creates a new public records exemption in s. 408.910, F.S. and contains a constitutionally required statement of public necessity for the exemption. This bill is subject to a two-thirds vote of each house of the Legislature for enactment as required by s. 24(c), Art. I, 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:

None.

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.)

None.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Norman) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Section 790.338, Florida Statutes, is created to read:

790.338 Medical privacy concerning firearms; prohibitions; penalties; exceptions.—

(1)(a) A verbal or written inquiry by any public or private physician, nurse, or other medical staff person regarding the ownership of a firearm by a patient or the family of a patient or the presence of a firearm in a patient's home or other

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domicile violates the privacy of the patient or the patient's family, respectively, and is prohibited.

(b) Any public or private physician, nurse, or other medical staff person may not condition receipt of medical treatment or medical care on a person's willingness or refusal to disclose personal and private information unrelated to medical treatment in violation of an individual's privacy as specified in this section.

(c) Any public or private physician, nurse, or other medical staff person may not intentionally, accidentally, or inadvertently enter any disclosed information concerning firearms into any record, whether written or electronic, or disclose such information to any other source.

(2)(a) A person who violates a provision of this section commits a noncriminal violation as defined in s. 775.08, punishable as provided in s. 775.082 or s. 775.083.

(b) If the court determines that the violation was knowing and willful or that the person committing the prohibited act, in the exercise of ordinary care, should have known the act was a violation, the court shall assess a fine of not less than $10,000 for the first offense, not less than $25,000 for the second offense, and not less than $100,000 for the third and subsequent offenses. The person found to have committed the violation shall be personally liable for the payment of all fines, costs, and fees assessed by the court for the noncriminal violation.

(3) The state attorney in the circuit where the violation is alleged to have occurred shall investigate complaints of noncriminal violations of this section and, where the state

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attorney determines probable cause that a violation exists, shall prosecute violators in the circuit court where the violation is alleged to have occurred. Any state attorney who fails to execute his or her duties under this section may be held accountable under the appropriate Florida rules of professional conduct.

(4) The state attorney shall notify the Attorney General of any fines assessed under this section, notwithstanding s. 28.246(6), and if a fine for a violation of this section remains unpaid after 90 days, the Attorney General shall bring a civil action to enforce the fine.

(5) Except as required by s. 16, Art. I of the State Constitution or the Sixth Amendment to the United States Constitution, public funds may not be used to defend the unlawful conduct of any person charged with a knowing and willful violation of this section.

(6) Notwithstanding any other provision of this section, it is not a violation for:

(a) Any psychiatrist as defined in s. 394.455, psychologist as defined in s. 490.003, school psychologist as defined in s. 490.003, clinical social worker as defined in s. 491.003, or public or private physician, nurse, or other medical personnel to make an inquiry prohibited by paragraph (1)(a) if the person making the inquiry in good faith believes that the possession or control of a firearm or ammunition by the patient or another member of the patient’s household would pose an imminent danger or threat to the patient or others.

(b) Any public or private physician, nurse, or other medical personnel to make an inquiry prohibited by paragraph

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(1)(a) if such inquiry is necessary to treat a patient during the course and scope of a medical emergency which specifically includes, but is not limited to, a mental health or psychotic episode where the patient's conduct or symptoms reasonably indicate that the patient has the capacity of causing harm to himself, herself, or others.

(c) Any public or private physician, nurse, or other medical personnel to enter any of the information disclosed pursuant to paragraphs (a) and (b) into any record, whether written or electronic.

However, a patient's response to any inquiry permissible under this subsection shall be private and may not be disclosed to any third party not participating in the treatment of the patient other than a law enforcement officer conducting an active investigation involving the patient or the events giving rise to a medical emergency. The exceptions provided by this subsection do not apply to inquiries made due to a person's general belief that firearms or ammunition are harmful to health or safety.

(7) Medical records created on or before the effective date of this act do not violate this section, nor is it a violation of this section to transfer such records to another health care provider.

Section 2. This act shall take effect upon becoming a law.

================ T I T L E A M E N D M E N T ================

And the title is amended as follows:

Delete everything before the enacting clause

and insert:

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A bill to be entitled

An act relating to the privacy of firearms owners; creating s. 790.338, F.S.; prohibiting physicians or other medical personnel from inquiring, either verbally or in writing, about the ownership of a firearm by a patient or the family of a patient or the presence of a firearm in a patient's private home or other domicile; prohibiting conditioning the receipt of medical treatment or care on a person's willingness or refusal to disclose personal and private information unrelated to medical treatment in violation of an individual's privacy contrary to specified provisions; prohibiting entry of certain information concerning firearms into medical records or disclosure of such information by specified individuals; providing noncriminal penalties; providing for prosecution of violations; requiring informing the Attorney General of prosecution of violations; providing for collection of fines by the Attorney General in certain circumstances; providing exemptions; providing an effective date.

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Gaetz and Latvala) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Paragraph (b) of subsection (4) of section 381.026, Florida Statutes, is amended to read:

381.026 Florida Patient's Bill of Rights and Responsibilities.—

(4) RIGHTS OF PATIENTS.—Each health care facility or provider shall observe the following standards:

(b) *Information.*—

1. A patient has the right to know the name, function, and

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qualifications of each health care provider who is providing medical services to the patient. A patient may request such information from his or her responsible provider or the health care facility in which he or she is receiving medical services.

2. A patient in a health care facility has the right to know what patient support services are available in the facility.

3. A patient has the right to be given by his or her health care provider information concerning diagnosis, planned course of treatment, alternatives, risks, and prognosis, unless it is medically inadvisable or impossible to give this information to the patient, in which case the information must be given to the patient's guardian or a person designated as the patient's representative. A patient has the right to refuse this information.

4. A patient has the right to refuse any treatment based on information required by this paragraph, except as otherwise provided by law. The responsible provider shall document any such refusal.

5. A patient in a health care facility has the right to know what facility rules and regulations apply to patient conduct.

6. A patient has the right to express grievances to a health care provider, a health care facility, or the appropriate state licensing agency regarding alleged violations of patients' rights. A patient has the right to know the health care provider's or health care facility's procedures for expressing a grievance.

7. A patient in a health care facility who does not speak

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English has the right to be provided an interpreter when receiving medical services if the facility has a person readily available who can interpret on behalf of the patient.

8. A patient may decline to answer or provide any information regarding the ownership of a firearm by the patient or by a family member of the patient or the presence of a firearm in a private home or other domicile of the patient or a family member of the patient. A patient's decision to decline to answer does not alter existing law regarding a physician's authorization to choose his or her patients.

9. A health care provider or health care facility shall respect a patient's legal right to own or possess a firearm and shall refrain from unnecessarily harassing a patient about firearm ownership during an examination.

Section 2. Paragraph (mm) is added to subsection (1) of section 456.072, Florida Statutes, to read:

456.072 Grounds for discipline; penalties; enforcement.—

(1) The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken:

(mm) Creating any type of list or database, without a patient's consent, relating to the lawful:

1. Ownership or possession of a firearm or ammunition;

2. Use of a firearm or ammunition; or

3. Storage of a firearm or ammunition.

For purposes of this paragraph, a list or database does not include an entry in a patient's individual medical record.

Section 3. Section 790.338, Florida Statutes, is created to

read:

790.338 Medical privacy concerning firearms; prohibitions; penalties; exceptions.—

(1) A health care provider licensed under chapter 456 or a health care facility licensed under chapter 395 may not intentionally enter any disclosed information concerning firearm ownership in a patient's medical record when the provider knows that such information is not relevant to the patient's medical care.

(2)(a) A person who violates this section commits a noncriminal violation as defined in s. 775.08, punishable as provided in s. 775.082 or s. 775.083.

(b) If the trial court determines that the violation was committed knowingly and willfully, the court shall assess a fine of not more than $5,000. The person who committed the violation is liable for the payment of all fines, costs, and fees assessed by the court for the noncriminal violation.

(c) The state attorney in the circuit where the violation is alleged to have occurred may investigate complaints of noncriminal violations of this section. If the state attorney determines probable cause that a violation exists, the state attorney may prosecute the violator in the circuit where the violation is alleged to have occurred.

Section 4. An insurer that issues any type of insurance policy or contract under chapter 627, Florida Statutes, may not deny coverage or increase any premium, or otherwise discriminate against any insured or applicant for insurance on the basis of, or upon reliance upon, the applicant's or insured's lawful:

(1) Ownership or possession of a firearm or ammunition; or

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(2) Use or storage of a firearm or ammunition.

Section 5. This act shall take effect July 1, 2011.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to privacy of firearm owners; amending s. 381.026, F.S.; providing that a patient may decline to answer or provide information to a health care facility or provider regarding firearm ownership; prohibiting a health care provider or facility from unnecessarily harassing a patient about firearm ownership; amending s. 456.072, F.S.; revising the list of grounds for which a health care practitioner may be disciplined to prohibit the creation of a list or database concerning the ownership, possession, use, or storage of a firearm by a patient; creating s. 790.338, F.S.; prohibiting certain health care providers and health care facilities from intentionally entering any disclosed information concerning firearm ownership in a patient's medical record under certain circumstances; providing a penalty; requiring the trial court to assess a fine if the health care provider or health care facility knowingly and willfully violates such prohibition; providing for payment of fines, costs, and fees that are assessed; authorizing the state attorney to

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investigate complaints of any violations and to prosecute any violators if there is probable cause; prohibiting certain insurers from denying insurance coverage or increasing their premiums based upon an applicant’s or insured’s lawful ownership or possession of a firearm or ammunition or the lawful use or storage of a firearm or ammunition; providing an effective date.

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 Criminal Justice Committee

BILL:	CS/SB 432
INTRODUCER:	Criminal Justice Committee and Senator Evers
SUBJECT:	Privacy of Firearm Owners
DATE:	February 22, 2011 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Cellon	Cannon	CJ	**Fav/CS**
2.			HR	
3.			JU	
4.			BC	
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	X	Statement of Substantial Changes
B. AMENDMENTS.....		Technical amendments were recommended
		Amendments were recommended
		Significant amendments were recommended

I. Summary:

The bill creates a noncriminal violation in circumstances where a public or private physician, nurse, or other medical staff person conditions receipt of medical treatment or care on a person's willingness or refusal to disclose "personal and private information unrelated to medical treatment" in violation of the privacy right created by the bill regarding ownership or possession of firearms.

The bill also creates a noncriminal violation where a public or private physician, nurse, or other medical staff person enters information concerning firearms into any record or otherwise discloses such information to any other source, whether intentionally, inadvertently, or accidentally.

The bill states that an inquiry of a patient or his or her family regarding the ownership or possession of firearms in the home by a public or private physician, nurse, or other medical staff person constitutes an invasion of privacy.

The state attorney is given responsibility for investigating and prosecuting the noncriminal violations.

The defendant may be assessed up to a $100,000 fine, on a third offense, if the court finds the violation is knowing and willful. The Attorney General is charged with filing suit to collect any fine that remains unpaid after 90 days.

Certain mental health care professionals as statutorily defined, and physicians, nurses, and other medical personnel are exempted from the provisions in the bill in cases where inquiries are reasonably necessary under emergency circumstances such as where the patient is exhibiting conduct that indicates the patient could pose an imminent threat to himself, herself, or others. The patient's response is private and shall not be disclosed to a third party, other than law enforcement conducting an active investigation, under the provisions of the bill.

The bill further exempts medical records created on or before the effective date of the bill from the prohibitions created by the bill.

This bill creates a new section of the Florida Statutes: 790.338.

II. Present Situation:

Physicians Inquiring About Firearms

In recent months, there has been media attention surrounding an incident in Ocala, Florida, where, during a routine doctor's visit, an Ocala pediatrician asked a patient's mother whether there were firearms in the home. When the mother refused to answer, the doctor advised her that she had 30 days to find a new pediatrician.[1] The doctor stated that he asked all of his patients the same question in an effort to provide safety advice in the event there was a firearm in the home.[2] He further stated that he asked similar questions about whether there was a pool at the home, and whether teenage drivers use their cell phone while driving for similar reasons – to give safety advice to patients. The mother, however, felt that the question invaded her privacy.[3] This incident has led many to question whether it should be an accepted practice for a doctor to inquire about a patient's firearm ownership.

Various professional medical groups have adopted policies that encourage or recommend that physicians ask patients about the presence of a firearm in the home. For example, the American Medical Association (AMA) encourages its members to inquire as to the presence of household firearms as a part of childproofing the home and to educate patients to the dangers of firearms to children.[4]

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[1] Family and pediatrician tangle over gun question, http://www.ocala.com/article/20100723/news/100729867/1402/news?p=1&tc=pg (last accessed January 27, 2011).
[2] *Id*.
[3] *Id*.
[4] H-145.990 Prevention of Firearm Accidents in Children https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fama1%2fpub%2fupload%2fmm%2fPolicyFinder%2fpolicyfiles%2fHnE%2fH-145.990.HTM (last accessed January 28, 2011).

Additionally, the American Academy of Pediatrics (AAP) recommends that pediatricians incorporate questions about guns into their patient history taking.[5]

Florida law contains numerous provisions relating to the regulation of the medical profession, regulation of medical professionals, and the sale, purchase, possession, and carrying of firearms.[6] However, Florida law does not contain any provision that prohibits physicians or other medical staff from asking a patient whether he or she owns a firearm or whether there is a firearm in the patient's home.

Terminating the Doctor - Patient Relationship

The relationship between a physician and a patient is generally considered a private relationship and contractual in nature. According to the AMA, both the patient and the physician are free to enter into or decline the relationship.[7] Once a physician-patient relationship has been established, patients are free to terminate the relationship at any time.[8] Generally, doctors can only terminate existing relationships after giving the patient notice and a reasonable opportunity to obtain the services of another physician.[9] Florida's statutes do not currently contain any provisions that dictate when physicians and patients can terminate a doctor-patient relationship.

III. Effect of Proposed Changes:

The bill creates s. 790.338, F.S., entitled "Medical privacy concerning firearms." The bill specifies that a verbal or written inquiry by a public or private physician, nurse, or other medical staff person regarding the ownership of a firearm by a patient or the family of a patient or the presence of a firearm in a private home or other domicile of a patient or the family of a patient violates the privacy of the patient or the patient's family members.[10]

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[5] American Academy of Pediatrics: Firearm-Related Injuries Affecting the Pediatric Population. Pediatrics Vol. 105 No. 4 April 2000, pp. 888-895. http://aappolicy.aappublications.org/cgi/content/full/pediatrics;105/4/888 (last accessed January 28, 2011). See also American Academy of Pediatrics, Committee on Injury, Violence, and Poison Prevention, "TIIP (The Injury Prevention Program), A Guide to Safety Counseling in Office Practice", 1994.

[6] *See, e.g.*, Chapters 456, 458, 790, F.S.

[7] AMA Code of Medical Ethics, Opinion 9.12, *Patient-Physician Relationship: Respect for Law and Human Rights*, http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion912.shtml (last accessed February 7, 2011). Doctors who offer their services to the public may not decline to accept patients because of race, color, religion, national origin, sexual orientation, gender identity, or any other basis that would constitute invidious discrimination.

[8] AMA's Code of Medical Ethics, Opinion 9.06 *Free Choice. http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion906.shtml* (last accessed February 7, 2011).

[9] A health care provider owes a duty to the patient to provide the necessary and appropriate medical care to the patient with due diligence and to continue providing those services until: 1) they are no longer needed by the patient; 2) the relationship is ended with the consent of or at the request of the patient; or 3) the health care provider withdraws from the relationship after giving the patient notice and a reasonable opportunity to obtain the services of another health care provider. The relationship typically terminates when the patient's medical condition is cured or resolved, and this often occurs at the last visit when the health care provider notes in his records that the patient is to return as needed. *See Saunders v. Lischkoff*, 188 So. 815 (Fla. 1939). *See also, Ending the Patient-Physician Relationship*, AMA White Paper http://www.ama-assn.org/ama/pub/physician-resources/legal-topics/patient-physician-relationship-topics/ending-patient-physician-relationship.shtml (last accessed February 7, 2011); AMA's Code of Medical Ethics, Opinion 8.115 *Termination of the Physician-Patient Relationship. http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8115.shtml* (last accessed February 7, 2011).

[10] Invading someone's privacy is not a criminal act. However, there is a common law tort claim of invasion of privacy. *See Allstate Insurance Company v. Ginsberg*, 863 So.2d 156 (Fla. 2003) where the Florida Supreme Court reaffirms the four types of claims of invasion of privacy recognized by Florida courts: "As recognized in *Agency for Health Care*

The bill creates a noncriminal violation if a public or private physician, nurse, or other medical staff:

- Conditions receipt of medical treatment or care on a person's willingness or refusal to disclose personal and private information unrelated to medical treatment in violation of an individual's privacy, as specified in the bill.
- Enters any intentionally, accidentally, or inadvertently disclosed information concerning firearms into any record, whether written or electronic, or discloses such information to any other source.

The bill also provides that a person who violates s. 790.338, F.S., may be assessed a fine of no less than $10,000 for a first violation, $25,000 for a second violation, and $100,000 for a third violation if the court determines that the violation was knowing and willful.

The bill requires the state attorney with jurisdiction to investigate complaints of criminal violations of s. 790.338, F.S., and, if there is probable cause to indicate that a person may have committed a violation, to prosecute the violator and notify the Attorney General of the prosecution. The bill requires the Attorney General to bring a civil action to enforce any fine assessed if such fine is not paid after 90 days.

Certain mental health care professionals as statutorily defined, and physicians, nurses, and other medical personnel are exempted from the provisions in the bill in cases where inquiries are reasonably necessary under emergency circumstances such as where the patient is exhibiting conduct that indicates the patient could pose an imminent threat to himself, herself, or others. The patient's response is private and shall not be disclosed to a third party, other than law enforcement conducting an active investigation, under the provisions of the bill.

The bill further exempts medical records created on or before the effective date of the bill from the prohibitions created by the bill.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

Administration v. Associated Industries of Florida, Inc., 678 So.2d 1239, 1252 n. 20 (Fla.1996) (hereinafter *AHCA*), the four categories are: (1) appropriation-the unauthorized use of a person's name or likeness to obtain some benefit; (2) intrusion-physically or electronically intruding into one's private quarters; (3) public disclosure of private facts-the dissemination of truthful private information which a reasonable person would find objectionable; and (4) false light in the public eye-publication of facts which place a person in a false light even though the facts themselves may not be defamatory." As the dissenting opinion notes, the common law tort of invasion of privacy, or any common law tort is an area of the law that is subject to evolution. It would appear that SB 432 creates a new statutory category in the area of invasion of privacy torts.

C. Trust Funds Restrictions:

None.

D. Other Constitutional Issues:

Although this bill states that inquiries by certain medical professionals about the ownership of a firearm or presence of a firearm in the home of a patient or his or her family violates the patient's or the family's privacy, it should not be forgotten that the individual's right to exercise free speech is only regulated in the most egregious of circumstances.

It should also be noted that any civil action that might ensue will likely raise issues surrounding personal, professional, and contractual obligations between the parties, and the weight given to a constitutionally-protected right (free speech) versus a right to privacy created by general law, as between the two parties.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

A public or private physician, nurse, or other medical staff person who is found to have violated the law created by the bill could be assessed up to a $100,000 fine for a third violation.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

The bill creates s. 790.338, F.S., to make it a noncriminal violation for a *public or private physician, nurse, or other medical staff* to do certain acts. The bill does not define these terms, nor are they defined in ch. 790, F.S. Defining these terms, or using a term already defined in Florida law such as "healthcare practitioner," would clarify to whom the penalties apply.

Also, the term "unrelated to medical treatment" on line 39 of the bill may create a loophole to prosecution in that the term invites challenge and argument as to what is or is not "unrelated."

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 Criminal Justice on February 22, 2011:

- Removes the criminal penalties from the bill and instead provides for noncriminal violations which could result in graduated fines for each successive violation of the prohibitions in the bill.
- Provides limited exemptions from the prohibitions in the bill in the course of emergency treatment, including mental health emergencies, and where certain mental health professionals believe it is necessary to inquire about firearm possession. The patient's response is only to be disclosed to others participating in the patient's treatment or to law enforcement conducting an active investigation of the events giving rise to a medical emergency.
- Provides an exemption for medical records created on or before the effective date of the bill.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Altman) recommended the following:

Senate Amendment (with title amendment)

Delete lines 56 - 130
and insert:

(4)(b). Any sale or lease of a tax-supported hospital is subject to approval by the Attorney General. For the purposes of this section, the term "tax-supported hospital" means a county, district, or municipal hospital that has received ad valorem or other tax revenues directly from a county, district, or municipal taxing authority to support the hospital at any time


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within the 5 years prior to the effective date of any proposed lease or sale.

(2) Any ~~such~~ lease, contract, or agreement made pursuant hereto shall:

(a) Provide that the articles of incorporation of the ~~such~~ for-profit or not-for-profit corporation be subject to the approval of the board of directors or board of trustees of the ~~such~~ hospital;

(b) Require that any not-for-profit corporation become qualified under s. 501(c)(3) of the United States Internal Revenue Code;

(c) Provide for the orderly transition of the operation and management of the ~~such~~ facilities;

(d) Provide for the return of the ~~such~~ facility to the county, municipality, or district upon the termination of the ~~such~~ lease, contract, or agreement; and

(e) Provide for the continued treatment of indigent patients pursuant to the Florida Health Care Responsibility Act and pursuant to chapter 87-92, Laws of Florida.

(3) Any sale, lease, or contract entered into pursuant to this section prior to the effective date of this act must have complied with the requirements of subsection (2) in effect at the time of the sale, lease, or contract. It is the intent of the Legislature that this section does not impose any further requirements with respect to the formation of any for-profit or not-for-profit Florida corporation, the composition of the board of directors of any Florida corporation, or the manner in which control of the hospital is transferred to the Florida corporation.

(4) If ~~In the event~~ the governing board of a county, district, or municipal hospital determines it is no longer in the public interest to own or operate the hospital and elects to consider a sale or lease of the hospital, the board shall first determine whether there are any qualified purchasers or lessees of the hospital. In the process of evaluating any potential purchasers or lessees ~~elects to sell or lease the hospital~~, the board shall:

(a) ~~Negotiate the terms of the sale or lease with a for-profit or not-for-profit Florida corporation and~~ Publicly advertise the meeting at which the proposed sale or lease will be considered by the governing board of the hospital in accordance with s. 286.0105; or

(b) Publicly advertise the offer to accept proposals in accordance with s. 255.0525 and receive proposals from all interested and qualified purchasers.

Any sale or lease must be for fair market value, and any sale or lease must comply with all applicable state and federal antitrust laws. As used in this section, the term "fair market value" means the most likely price that the assets would bring in a sale or lease in a competitive and open market under all conditions requisite to a fair sale or lease, with the buyer or lessee, and seller or lessor, each acting prudently, knowledgeably, and in their own best interest, and with a reasonable time being allowed for exposure in the open market.

(5) If the governing board decides to accept a proposal to purchase or lease the hospital, the board's decision must be in writing and clearly state the facts and findings that support

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its decision to sell or lease the hospital. The facts and findings must include, but are not limited to, whether the proposal:

(a) Represents the fair market value of the hospital;

(b) Constitutes the best use of the hospital and its attendant facilities;

(c) Will have a positive effect on the reduction or elimination of ad valorem or other tax revenues if any are used to support the hospital; and

(d) Ensures that quality health care will continue to be provided to all residents of the affected community, and in particular the indigent, the uninsured, and the underinsured.

(6) A governing board of a tax-supported hospital may not enter into any sale or lease of a hospital and its attendant facilities without first having received approval of the sale or lease from the Attorney General pursuant to this section.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete lines 4 - 26

and insert:

sale or lease of a tax-supported hospital to a for-profit or not-for-profit Florida corporation receive prior approval by the Attorney General; defining the term "tax-supported hospital;" requiring the governing board of a tax-supported hospital to first determine whether there are any qualified purchasers or lessees


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of the hospital before considering whether to sell or lease the hospital; defining the term "fair market value"; requiring the governing board to put in writing the facts and findings to justify the governing board's decision to sell or lease the public hospital to a third party; detailing the issues that the governing board must address in order to sell or lease the hospital; setting forth the procedures that must be followed by the governing board to gain the approval of the Attorney General to sell or lease a tax-supported hospital; authorizing the Attorney General to employ independent consultants to determine the fair market value of the proposed sale or lease of a tax-supported hospital; authorizing interested persons to file a statement in opposition to the sale or lease of the hospital; specifying the criteria the Attorney General must consider when deciding whether to approve or deny the proposed sale or lease of a tax-supported hospital; requiring the Attorney

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 Regulation Committee

BILL:	SB 1448
INTRODUCER:	Senator Garcia
SUBJECT:	Sale or Lease of a Public Hospital
DATE:	March 17, 2011 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	O'Callaghan	Stovall	HR	**Pre-meeting**
2.			CA	
3.			JU	
4.			BC	
5.			RC	
6.				

I. Summary:

This bill amends s. 155.40, F.S., to require any sale or lease of a public hospital (owned by a county, district, or municipality) to be approved by the Attorney General (AG) prior to the sale or lease. Also, prior to the sale or lease, the governing board of the public hospital must publicly notice meetings earlier in the process. If the governing board decides to accept a proposal to purchase or lease the hospital, the sale or lease of the public hospital must be for a "fair market value," which is defined in the bill, and the board's decision must be in writing and clearly state certain facts and findings that support its decision to sell or lease the hospital.

After the AG receives a request for approval of the sale or lease of a public hospital, the AG must publish notice of the request and allow time for public comment about the proposed sale or lease. The bill delineates specific information that the request must include and gives the AG authority to demand additional information and testimony regarding the proposed sale or lease through the authority of a subpoena and to contract with experts or consultants in order to review the proposed sale or lease.

The AG must issue a report of his or her findings by making certain determinations and must report his or her decision to approve, with or without modification, or deny the sale or lease of the public hospital. The AG's decision must be published in the Florida Administrative Weekly.

This bill substantially amends the following sections of the Florida Statutes: 155.40 and 395.3036.

II. Present Situation:

Sale or Lease of Public Hospitals

County, district, and municipal hospitals are created by special enabling acts, rather than by general acts under Florida law.[1] The special act sets out the hospital authority's ability or inability to levy taxes to support the maintenance of the hospital, the framework for the governing board and whether or not the governing board has the ability to issue bonds. There are currently 31 hospital districts in Florida under which public hospitals operate.[2]

The process for the sale of a public hospital is established by s. 155.40, F.S. Currently, the governing board of a public hospital has the authority to negotiate the sale or lease of the hospital. The hospital can be sold or leased to a for-profit or not-for-profit Florida corporation and such sale or lease must be in the best interest of the public. The board is required to publicly advertise the meeting at which the proposed sale or lease will be discussed in accordance with s. 286.0105, F.S., and the offer to accept proposals from all interested and qualified purchasers in accordance with s. 255.0525, F.S.

Section 155.40(2), F.S., requires any lease, contract, or agreement to:

- Provide that the articles of incorporation of the corporation are subject to approval of the board of directors or board of trustees of the hospital.
- Require that any not-for-profit corporation become qualified under s. 501(c)(3) of the U.S. Internal Revenue Code.
- Provide for the orderly transition of the operation and management of the facilities.
- Provide for the return of the facility to the county, municipality, or district upon the termination of the lease, contract, or agreement.
- Provide for the continued treatment of indigent patients pursuant to the Florida Health Care Responsibility Act[3] and ch. 87-92, Laws of Florida.

For the sale or lease to be considered "a complete sale of the public agency's interest in the hospital" under s. 155.40(8)(a), F.S., the purchasing entity must:

- Acquire 100 percent ownership of the hospital enterprise.
- Purchase the physical plant of the hospital facility and have complete responsibility for the operation and maintenance of the facility, regardless of the underlying ownership of the real property.
- Not allow the public agency to retain control over decision-making or policymaking for the hospital.
- Not receive public funding, other than by contract for services rendered to patients for whom the public agency seller has the responsibility to pay for hospital or medical care.
- Not receive substantial investment or loans from the seller.

[1] Section 155.04, F.S., allows a county, upon receipt of a petition signed by at least 5 percent of resident freeholders, to levy an ad valorem tax or issue bonds to pay for the establishment and maintenance of a hospital. Section 155.05, F.S., gives a county the ability to establish a hospital without raising bonds or an ad valorem tax, utilizing available discretionary funds. However, an ad valorem tax can be levied for the ongoing maintenance of the hospital.
[2] Information provided by the Agency for Health Care Administration via email on March 17, 2011.
[3] Sections 154.301-154.316, F.S.

- Not be created by the public agency seller.
- Primarily operate for its own interests and not those of the public agency seller.

A complete sale of the public agency's interest shall not be construed as:

- A transfer of governmental function from the county, district, or municipality to the private corporation or entity.
- A financial interest of the public agency in the private corporation or other private entity purchaser.
- Making the private corporation or other private entity purchaser an "agency" as that term is used in statute.
- Making the private entity an integral part of the public agency's decision-making process.
- Indicating that the private entity is "acting on behalf of a public agency," as that term is used in statute.

If the corporation that operates a public hospital receives more than $100,000 in revenues from the county, district, or municipality, it must account for the manner in which the funds are expended. The funds are to be expended by being subject to annual appropriations by the county, district, or municipality or if there is a contract for 12 months or longer to provide revenues to the hospital, then the governing board of the county, district, or municipality must be able to modify the contract upon 12 months notice to the hospital.

Office of the Attorney General (Department of Legal Affairs)

The AG is the statewide elected official directed by the Florida Constitution[4] to serve as the chief legal officer for the State of Florida. The AG is the agency head of the Office of the Attorney General (OAG), within the Department of Legal Affairs, and is responsible for protecting Florida consumers from various types of fraud and enforcing the state's antitrust laws. Additionally, the AG protects constituents in cases of Medicaid fraud, defends the state in civil litigation cases, and represents the people of Florida when criminals appeal their convictions in state and federal courts.[5] Within the OAG, there is an Office of Statewide Prosecution that investigates and prosecutes criminal offenses that extend across multiple jurisdictions.

Within the OAG, there exists an Antitrust Division (division), which is responsible for enforcing state and federal antitrust laws. The division works to stop violations that harm competition and adversely impact the citizens of Florida. Under ch. 542, F.S., the AG has the authority to bring actions against individuals or entities that commit state or federal antitrust violations, including bid-rigging, price-fixing, market or contract allocation, and monopoly-related actions.[6]

Several recent trends have emphasized the importance of this division in the OAG. In the antitrust area, there has been a dramatic increase over the last five years in the number of proposed mergers, acquisitions, and joint ventures. Along with the increase in these types of

[4] *See* FLA. CONST. art. IV., s. 4.
[5] Office of the Attorney General of Florida, *The Role and Function of the Attorney General*, available at: http://myfloridalegal.com/pages.nsf/Main/F06F66DA272F37C885256CCB0051916F (Last visited on March 18, 2011).
[6] Department of Legal Affairs, Office of the Attorney General, *Long Range Program Plan FY 2011-12 through FY 2015-16*, available at: http://floridafiscalportal.state.fl.us/PDFDoc.aspx?ID=3463 (Last visited on March 18, 2011).

transactions, the economy has become unstable and consequently, companies and individuals may be more likely to collude with competitors to fix prices, rig bids on public entity procurement contracts, unlawfully fix prices, or illegally monopolize or attempt to monopolize a particular market or industry. In addition, the federal antitrust enforcement agencies have not been as aggressive in years past in enforcing the federal antitrust laws and therefore, the division has had to compensate for such lack of enforcement.[7]

The General Civil Litigation Division (litigation division) also exists within the OAG. The litigation division discharges the AG's responsibilities under s. 16.01, F.S., by providing statewide representation on behalf of the state, its agencies, officers, employees, and agents at the trial and appellate level. The AG has common law authority to protect the public's interest, which the Legislature declared to be in force pursuant to s. 2.01, F.S., and under which the litigation division serves to protect the public's interest. The Ethics Bureau within the litigation division prosecutes complaints before the Florida Commission on Ethics. Once the Commission on Ethics has received and investigated a sworn complaint alleging that a public officer or employee has breached the public trust, the commission's prosecutor (Advocate) recommends as to whether the case should go forward. If the case goes forward the prosecutor conducts the prosecution under ch. 120, F.S., Administrative Procedure Act.[8]

The Department of Legal Affairs budget for Fiscal Year 2010-11 includes the following: for the Florida Elections Commission, $1,398,762; for the Office of Attorney General, $183,502,762; and for the Office of Statewide Prosecution, $6,281,871.[9]

Recent Leases or Sales of Public Hospitals

The public hospital Bert Fish Medical Center entered into a controversial $80 million lease agreement with Adventist Health System, which was nullified by Circuit Court Judge Richard Graham because of 21 closed-door meetings that occurred during the negotiation process and violated Florida's Sunshine laws under s. 286.011, F.S.[10]

Other recent leases or sales or proposed leases or sales of public hospitals have been scrutinized, especially for the effect such sales or leases would have on taxpayers. For example, Helen Ellis Hospital was merged with Adventist Health in 2010 and currently there are proposals that would turn public hospital systems in Miami and Broward County into private hospitals.[11]

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[7] *Id.*
[8] *Id.*
[9] The Florida Legislature's Office of Program Policy Analysis & Government Accountability, *Office of the Attorney General (Department of Legal Affairs)*, available at: http://www.oppaga.state.fl.us/profiles/1026/ (Last visited on March 18, 2011).
[10] Linda Shrieves, Orlando Sentinel, *Judge rules Bert Fish must cut ties with Florida Hospital*, February 24, 2011, available at: http://articles.orlandosentinel.com/2011-02-24/health/os-bert-fish-decision-20110224_1_sunshine-laws-open-meetings-hospital-board (Last visited on March 19, 2011).
[11] Anne Geggis, Daytona Beach News-Journal, *Bills reflect problems at Bert Fish*, March 8, 2011, available at: http://www.news-journalonline.com/news/local/southeast-volusia/2011/03/08/bills-reflect-problems-at-bert-fish.html (Last visited on March 19, 2011).

III. Effect of Proposed Changes:

This bill amends s. 155.40, F.S., to require any sale or lease of a public hospital (owned by a county, district, or municipality) to be approved by the AG prior to the sale or lease. Also, prior to the sale or lease, the governing board of the public hospital must determine whether there are qualified purchasers or lessees of the hospital by publicly advertising the meeting at which the proposed sale or lease will be considered by the governing board or publicly advertise the offer to accept proposals. However, the bill amends s. 155.40, F.S., to no longer allow the board to make such a determination by negotiation of the terms of the sale or lease with a for-profit or not-for-profit Florida corporation.

If the governing board decides to accept a proposal to purchase or lease the hospital, the sale or lease of the public hospital must be for a "fair market value," which is defined in the bill as the most likely price that the assets would bring in a sale or lease in a competitive and open market under all conditions requisite to a fair sale or lease, with the buyer or lessee, and seller or lessor, each acting prudently, knowledgeably, and in their own best interest, and with a reasonable time being allowed for exposure in the open market.

The board's decision to accept a proposal to purchase or lease the hospital must be in writing and clearly state facts and findings that support its decision to sell or lease the hospital. The facts and findings must state whether the proposal:

- Represents the fair market value of the hospital;
- Constitutes the best use of the hospital and its attendant facilities;
- Will have a positive effect on the reduction or elimination of certain tax revenues to support the hospital; and
- Ensures that the quality of health care will continue to be provided to residents of the affected community, especially the indigent, the uninsured, and the underinsured.

In order for the governing board of the public hospital to receive approval from the AG to sell or lease the hospital, it must file a request for approval with the AG not less than 120 days before the anticipated closing date of the sale or lease. The request for approval must contain the following information:

- The name and address of all parties to the transaction;
- The location of the hospital and all related facilities;
- A description of the terms of all proposed agreements;
- A copy of the proposed sale or lease agreement and related agreements, including leases, management contracts, service contracts, and memoranda of understanding;
- The estimated total value associated with the proposed agreement, the proposed acquisition price, and other consideration;
- Any valuations of the hospital's assets prepared 3 years immediately preceding the proposed transaction date;
- An analysis of the financial or economic status of the hospital and a report from any financial expert or consultant retained by the governing board;
- A fairness evaluation by an independent expert in such transactions;
- Copies of all other proposals and bids; and
- Any other information requested by the AG.

Within 30 days after the AG receives this request along with the information required above, the AG must publish notice of the proposed sale or lease in one or more newspapers of general circulation in the county where the main campus of the hospital is located and must also publish such notice in the Florida Administrative Weekly. The notice must provide the names of the parties in the transaction and provide the means by which persons may submit written comments about the proposed transaction. A person must submit written comments in support or in opposition of the sale or lease of the hospital within 20 days after the public notice of such sale or lease is published by the AG in the Florida Administrative Weekly. The governing board, the proposed purchaser or lessee, or any other interested person may submit a written response to such comments no later than 10 days after the general comment period to the public notice ends.

The bill gives the AG authority to demand additional information and testimony regarding the proposed sale or lease through the authority of a subpoena.

The bill authorizes the AG to contract with experts or consultants in order to review the proposed sale or lease and determine the fair market value of the proposed transaction and such contracts must be paid for by the acquiring entity. The acquiring entity, when billed for the contract services, has 30 days to pay the bill.

Sixty days after the date the public notice of sale or lease is published, the AG must issue a report of his or her findings and must report his or her decision to approve, with or without modification, or deny the sale or lease of the public hospital. In making his or her decision, the AG must determine whether:

- The proposed sale or lease is permitted by law;
- The proposed sale or lease would result in the best use of the hospital facilities and assets;
- The proposed sale or lease discriminates among potential purchasers or lessees depending on whether the entity is a for-profit or not-for-profit Florida corporation;
- The governing board of the hospital publicly advertised the meeting at which the proposed transaction was considered by the board in compliance with s. 286.0105, F.S.;
- The governing board of the hospital publicly advertised the offer to accept proposals in compliance with s. 255.0525, F.S.;
- The governing board of the hospital exercised due diligence in deciding to dispose of hospital assets, selecting the transacting entity, and negotiating the terms and conditions of the disposition;
- The procedures used by the governing board of the hospital in making its decision to dispose of its assets were fair and reasonable;
- Any conflict of interest was disclosed;
- The seller or lessor will receive fair market value of the assets;
- Charitable assets are placed at an unreasonable risk if the transaction is financed in part by the seller or lessor;
- The terms of any management or services contract negotiated in conjunction with the transaction are fair and reasonable;
- The acquiring entity made an enforceable commitment to provide health care to the indigent, the uninsured, and the underinsured and to provide benefits to the affected community to promote improved health care; and

- The proposed transaction will result in a reduction or elimination of ad valorem or other taxes used to support the hospital.

The AG's decision must be published in the Florida Administrative Weekly.

The bill provides an effective date of July 1, 2011.

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:

This bill will provide more disclosure of the sale or lease process of a public hospital by requiring the hospital to make available to the public its facts and findings that support its decision to sell or lease the hospital and requiring publication of a notice of the sale or lease by the AG. Additionally, the bill ensures more oversight over the sale or lease process by requiring the AG to determine whether the public has been put on notice as to any meetings at which the proposed sale or lease is to be considered or as to any offer to accept the proposal for sale or lease prior to the AG's approval of the sale.

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:

There would be an indeterminate negative fiscal impact on those entities seeking to purchase or lease a public hospital because of the requirements in the bill. For example, the acquiring entity must pay a bill for contract services obtained by the AG to review the proposed sale or lease agreement, including contract services to determine the fair market value of the proposed transaction.

C. Government Sector Impact:

The OAG has estimated that it will have to expend approximately $250,129 to comply with the requirements of the bill.[12]

VI. Technical Deficiencies:

On line 218 of the bill, the word "whether" should be deleted as it is redundant.

VII. Related Issues:

Because this bill requires the AG to take an "agency action" by requiring the AG to approve or deny the sale or lease of a public hospital, a person would have recourse to challenge the AG's decision under ch. 120, F.S.

Many of the terms or standards provided for in the bill may be subject to judicial interpretation. For example see, "reasonable time being allowed for exposure in the open market,"[13] "fairness evaluation,"[14] "best use of the hospital facilities and assets,"[15] the procedures used by the board "were fair and reasonable."[16]

VIII. Additional Information:

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

None.

B. Amendments:

None.

[12] OAG, *FY 2011-2012 Fiscal Impact of HB 619* (companion bill to SB 1448), on file with the Senate Health Regulation Committee.
[13] Line 110, SB 1448.
[14] Line 152, SB 1448.
[15] Lines 118-119, SB 1448.
[16] Lines 225-227, SB 1448.

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LEGISLATIVE ACTION

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The Committee on Health Regulation (Garcia) recommended the following:

Senate Amendment (with title amendment)

Delete line 94

and insert:

defined in s. 381.986, for at least one visit per policy

Delete line 196

and insert:

defined in s. 381.986, for at least one visit per policy

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete line 14

466022

and insert:

to provide at least one visit per year for

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 Regulation Committee

BILL:	SB 100
INTRODUCER:	Senator Ring
SUBJECT:	Autism
DATE:	March 18, 2011
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Fernandez/Brown	Stovall	HR	**Pre-meeting**
2.			BI	
3.			BC	
4.				
5.				
6.				

I. Summary:

The bill requires a licensed physician, other than one providing emergency services and care, to screen a minor for autism spectrum disorder (ASD) when the parent or legal guardian of that minor believes the minor exhibits symptoms of ASD and notifies the physician. Based on a determination by the physician of medical necessity or lack thereof, the physician must refer the minor for additional ASD screening or inform the parent or legal guardian of other available ASD screening options.

The bill requires health insurers and health maintenance organizations (HMOs) to provide coverage for "direct patient access," as defined in the bill, to an appropriate specialist for screening for or evaluation or diagnosis of ASD. The bill mandates that health insurance policies and HMO contracts provide coverage for a minimum of three visits per policy year for that purpose.

The bill substantially amends the following sections of the Florida Statutes: 627.6686 and 641.31098.

The bill creates the following section of the Florida Statutes: 381.986.

II. Present Situation:

What is Autism?

Autism is a term used to describe a group of complex developmental disabilities that many researchers believe are the result of a neurological disorder that affects the functioning of the

brain. Individuals with autism often have problems communicating with others through spoken language and nonverbal communication. The early signs of autism usually appear in the form of developmental delays before a child turns 3 years old.[1]

Section 393.063(3), F.S., defines autism to mean: ". . . a pervasive, neurologically based developmental disability of extended duration which causes severe learning, communication, and behavior disorders with age of onset during infancy or childhood. Individuals with autism exhibit impairment in reciprocal social interaction, impairment in verbal and nonverbal communication and imaginative ability, and a markedly restricted repertoire of activities and interests."

The various forms of autism are referred to as the autism spectrum disorders, meaning that autism can be manifested in a wide variety of combinations, from mild to severe. Thus, many different behaviors can indicate that a person should be diagnosed as autistic.

According to the National Institute of Mental Health (NIMH),[2] the pervasive developmental disorders, or ASDs, range from a severe form, called autistic disorder, to a milder form, Asperger's syndrome.[3] If a child has symptoms of either of these disorders, but does not meet the specific criteria for either, the diagnosis is called pervasive developmental disorder not otherwise specified (PDD-NOS). Other rare, severe disorders that are included in the autism spectrum are Rett syndrome[4] and childhood disintegrative disorder.[5]

The NIMH states that all children with an ASD demonstrate deficits in:

- *Social Interaction* – Most children with an ASD have difficulty learning to engage in everyday human interaction. Children with an ASD are also slower in understanding subtle social cues (nonverbal communication) and thus struggle to interpret what others are thinking

[1] Centers for Disease Control and Prevention website, Found at: <http://www.cdc.gov/ncbddd/autism/signs.html> (Last visited on March 17, 2011).
[2] Department of Health and Human Services, National Institute of Mental Health. *Autism Spectrum Disorders: Pervasive Developmental Disorders.* Printed 2004 Reprinted 2008. Found at: <http://www.nimh.nih.gov/health/publications/autism/nimhautismspectrum.pdf> (Last visited on March 17, 2011).
[3] The NIMH states that children with Asperger's syndrome are similar to high-functioning children with autism in that their language and intelligence remain intact. Like autistic children, persons with Asperger's syndrome have repetitive behaviors, severe social problems, and clumsy movements. The symptoms of Asperger's syndrome usually appear later in childhood than those of autism.
[4] The NIMH provides the following explanation of Rett syndrome: Rett syndrome is relatively rare, affecting almost exclusively females, one out of 10,000 to 15,000. After a period of normal development, sometime between 6 and 18 months, autism-like symptoms begin to appear. The little girl's mental and social development regresses—she no longer responds to her parents and pulls away from any social contact. If she has been talking, she stops; she cannot control her feet; she wrings her hands. Some of the problems associated with Rett syndrome can be treated. Physical, occupational, and speech therapy can help with problems of coordination, movement, and speech.
[5] The NIMH provides the following explanation of childhood disintegrative disorder: Very few children who have an ASD diagnosis meet the criteria for childhood disintegrative disorder (CDD). An estimate based on four surveys of ASD found fewer than two children per 100,000 with an ASD could be classified as having CDD. This suggests that CDD is a very rare form of ASD. It has a strong male preponderance. Symptoms may appear by age 2, but the average age of onset is between 3 and 4 years. Until this time, the child has age-appropriate skills in communication and social relationships. The long period of normal development before regression helps differentiate CDD from Rett syndrome. The loss of such skills as vocabulary is more dramatic in CDD than they are in classical autism. The diagnosis requires extensive and pronounced losses involving motor, language, and social skills. CDD is also accompanied by loss of bowel and bladder control and oftentimes seizures and a very low IQ.

and feeling. This causes them to often find social interaction confusing and frustrating. It is also common for people with an ASD to have difficulty controlling their emotions. Examples include episodes of disruptive behavior such as crying or verbal outbursts at inappropriate times or physical aggression. Autistics often can lose self control when exposed to a strange or overwhelming environment or when angry or frustrated.

- *Verbal and nonverbal communication* – Autistics have difficulty developing standard communication skills. Some children with an ASD remain mute, while others do not develop language until ages 5 to 9. Others use language in unusual ways or utilize sign language or pictures to communicate. The body language of autistics can be difficult to understand because it is not always consistent with the words they are saying. As they grow older, persons with an ASD often become more aware of their difficulties in communication, which can lead to anxiety or depression.
- *Repetitive behaviors or interests* – Children with an ASD often perform odd repetitive motions that set them apart from their peers. For example, some children and adults repeatedly flap their arms or walk on their toes while others freeze in position. Children with an ASD exhibit the need for consistency in their environment. Changes in daily routines—such as mealtimes, dressing, bathing, going to school at a certain time and by the same route—can cause autistics to become extremely disturbed. As children, they might spend hours lining up their toys in a certain way and if the toys are moved, they become upset. Additionally, autistics often form intense, obsessive preoccupations with certain objects or topics on which they focus much of their energy.

Another common difficulty is that children with an ASD often have unusual responses to sensory experiences, such as certain sounds or the way objects look.

The Diagnostic and Statistical Manual of Mental Disorders (DSM), published by the American Psychiatric Association, is the primary system used to classify and diagnose mental disorders. The 4th edition of the DSM was released in 1994. On February 10, 2010, the American Psychiatric Association released its draft criteria for the fifth edition of the DSM on its website.[6] The draft DSM-5 includes collapsing all autism related diagnoses into one single category, "autism spectrum disorder" that would incorporate autistic disorder, Asperger's syndrome, childhood disintegrative disorder, and pervasive developmental disorder not otherwise specified. The final DSM-5 is not scheduled for release until May 2013.

Sections 627.6686(2)(b) and 641.31098(2)(b), F.S., define the term "autism spectrum disorder" as any of the following disorders as defined in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders of the American Psychiatric Association:

- Autistic disorder.
- Asperger's syndrome.
- Pervasive developmental disorder not otherwise specified.

The law requires certain insurance coverage for diagnostic screening, intervention, and treatment of autism spectrum disorder for eligible individuals and defines an eligible individual as:

[6] Proposed Draft Revisions to DSM Disorders and Criteria. Found at: <http://www.dsm5.org/Pages/Default.aspx> (Last visited on March 17, 2011).

> . . .an individual under 18 years of age or an individual 18 years of age or older who is in high school who has been diagnosed as having a developmental disability at 8 years of age or younger.[7]

Diagnosis of Autism Spectrum Disorders

There is no medical test for ASDs. Instead, doctors look at behavioral symptoms to make a diagnosis. These symptoms may show up within the first few months of life or may appear at any time before the age of 3.[8]

According to the Centers for Disease Control and Prevention (CDC), research shows that the diagnosis of autism at age 2 can be reliable, valid, and stable. However, many children do not receive final diagnosis until they are much older. This delay in diagnosis may result in lost opportunities for specialized early intervention.[9]

The diagnosis of an ASD is a two-stage process. The first stage involves developmental screening during "well child" check-ups. These screening tests are used solely for identifying children with developmental disabilities. Additional screening may be needed if a child is at high risk[10] for an ASD or if the symptoms warrant it.[11]

The second stage of diagnosis is a comprehensive evaluation. If the initial screening tests indicate the possibility of an ASD, then further comprehensive testing is performed. Comprehensive testing is done by health care practitioners from multiple disciplines (psychologists, psychiatrists, neurologists, speech therapists, and other professions with experience in diagnosing children with an ASD) who evaluate the child in depth and determine if there is a developmental disorder, and if so, render a diagnosis. This may include:[12]

- Clinical observations;
- Parent interviews;
- Developmental histories;
- Psychological testing;
- Speech and language assessments;
- The possibility of the use of one or more autism diagnostic scales; and
- The possibility of physical, neurological, and genetic testing.

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[7] ss. 627.6686(2)(c) and 641.31098(2)(c), F.S.
[8] Centers for Disease Control and Prevention website. Found at: <http://www.cdc.gov/ncbddd/autism/screening.html> (Last visited on March 17, 2011).
[9] Centers for Disease Control and Prevention website. Found at <http://www.cdc.gov/ncbddd/autism/screening.html> (Last visited on March 17, 2011).
[10] The CDC considers a child with a sibling or parent with an ASD to be at high risk.
[11] Centers for Disease Control and Prevention website, Found at <http://www.cdc.gov/ncbddd/autism/screening.html> (Last visited on March 17, 2011).
[12] Centers for Disease Control and Prevention website, Found at <http://www.cdc.gov/ncbddd/autism/screening.html> (Last visited on March 17, 2011).

Treatment Approaches

Much of the scientific and clinical evidence indicates that early treatment of autism during preschool years (ages 3 to 5) often yields positive results in mitigating the effects of ASDs. According to the National Institute of Neurological Disorders and Stroke (NINDS), therapies for autism are designed to remedy specific symptoms.[13] Educational and behavioral interventions are highly-structured and usually aimed at the development of skills such as language and social skills. Medication may be prescribed to reduce self-injurious behavior or other behavioral symptoms of autism. Early intervention is important for children because children learn most rapidly when they are very young. If begun early enough, such intervention has a chance of favorably influencing brain development. In a 2001 report, the Commission on Behavioral and Social Sciences and Education recommended that treatment "services begin as soon as a child is suspected of having an autistic spectrum disorder. Those services should include a minimum of 25 hours a week, 12 months a year, in which the child is engaged in systematically planned, and developmentally appropriate educational activity toward identified objectives."[14]

The Center for Autism and Related Disabilities provided the following information concerning the application of speech-language therapy, occupational therapy, and physical therapy for individuals with autism:

- *Speech-Language Therapy:* People with autism usually have delays in communication. Speech therapists look for a system of communication that will work for an individual with autism and may consider alternatives to the spoken word such as signing, typing, or a picture board with words.
- *Occupational Therapy:* Commonly, this therapy focuses on improving fine motor skills, such as brushing teeth, feeding, and writing, or sensory motor skills that include balance, awareness of body position, and touch.
- *Physical Therapy:* This therapy specializes in developing strength, coordination, and movement.

According to the NIMH, a number of treatment approaches have evolved in the decades since autism was first identified. These approaches include developmental, behaviorist, and nonstandard. Developmental approaches provide consistency and structure along with appropriate levels of stimulation.

Behaviorist training approaches are based on rewarding individuals for a certain type of behavior. Dr. Ivar Lovaas pioneered the use of behaviorist methods for children with autism more than 25 years ago. Lovaas therapy involves time-intensive, highly structured, repetitive sequences in which a child is given a command and rewarded each time he responds correctly. Using this approach for up to 40 hours a week, some children may be brought to the point of near-normal behavior. Others are much less responsive to the treatment. However, some researchers and therapists believe that less intensive treatments, particularly those begun early in a child's life, may provide the same level of efficacy.

[13] National Institutes of Health, National Institute of Neurological Disorders and Stroke, Autism Information Page. Found at: <http://www.ninds.nih.gov/disorders/autism/autism.htm#Is_there_any_treatment> (Last visited on March 18, 2011).
[14] Commission on Behavioral and Social Sciences and Education, *Educating Children with Autism* 6, 2001. Found at: <http://www.nap.edu/openbook.php?record_id=10017&page=66> (Last visited on March 18, 2011).

Health Insurance Coverage for Autism Spectrum Disorders in Florida

In 2008, the Legislature passed CS/CS/SB 2654, which included the *Steven A. Geller Autism Coverage Act* and the *Window of Opportunity Act*.[15]

The Window of Opportunity Act required the Office of Insurance Regulation (OIR) to convene a workgroup of stakeholders by August 31, 2008, to negotiate a compact for a binding agreement among the participants relating to insurance coverage and access to services for persons with developmental disabilities. The law required the compact to include coverage for behavioral analysis and behavior assistant services, speech therapy, physical therapy, and occupational therapy when medically necessary; policies and procedures for notifying policy holders of the amount, scope, and developmental disability conditions covered; penalties for documented cases of denial of claims for medically necessary services due to the presence of a developmental disability; and proposals for new product lines that may be offered in conjunction with traditional health insurance to provide a more appropriate means of spreading risk, financing costs, and accessing favorable prices.

In September 2008, the OIR convened the Developmental Disabilities Compact Workgroup to develop the compact required in law. A compact was developed by the workgroup and adopted on December 17, 2008.[16] Insurers and HMOs that sign onto the compact agreement must provide coverage for developmental disabilities as specified in the compact for all plans issued or renewed after January 1, 2010. The OIR reports that Total Health Choice is the only health insurer that has signed onto the autism compact.[17]

All insurers and HMOs that did not sign the Developmental Disabilities Compact Workgroup by April 1, 2009, are subject to the requirements of the Steven A. Gellar Autism Act. The Act requires insurers, including the state group insurance plan, to provide coverage for well-baby and child screening for diagnosing the presence of autism and to cover the treatment of autism through applied behavioral analysis and assistant services, physical therapy, speech therapy, and occupational therapy.[18] The autism disorders covered in the law are: autistic disorder, Asperger's syndrome, and pervasive developmental disorder not otherwise specified. The insurance coverage is limited to $36,000 annually with a $200,000 total lifetime benefit. Beginning January 1, 2011, the coverage maximum will increase with inflation.

State Group Health Insurance Program

Florida law provides for the State Group Health Insurance Program for the purpose of offering health insurance benefits for state and political subdivision employees in a cost-efficient and

[15] *See* ch. 2008-30, L.O.F.
[16] Developmental Disabilities Compact. Found at: <http://www.floir.com/pdf/DDCProposal-A.pdf> (Last visited on March 18, 2011).
[17] Florida Department of Financial Services Library. Found at: http://www.myfloridacfo.com/consumers/insurancelibrary/index.htm#insurance/l_and_h/health_coverages/health_coverage_-_autism_and_developmental_disabilities.htm (last visited on March 18, 2011).
[18] ss. 627.6686 and 641.31098, F.S.

prudent manner.[19] On January 1, 2010, the State Group Health Insurance Program implemented the requirements of the Steven A. Geller Autism Coverage Act, which requires comprehensive coverage for the screening, diagnosis and treatment of autism spectrum disorder. The State Group Insurance Plan is required to cover well-baby and child screening for diagnosing the presence of autism and to cover the treatment of autism through applied behavior analysis and assistant services, physical therapy, speech therapy and occupational therapy. The disorders covered are autistic disorder, Asperger's syndrome and pervasive developmental disorder not otherwise specified. Children under age 18 or in high school are covered.

III. Effect of Proposed Changes:

Section 1 creates s. 381.986, F.S., to require a licensed physician to screen a minor for ASD, in accordance with the American Academy of Pediatrics' guidelines,[20] when the parent or legal guardian of that minor believes the minor exhibits symptoms of ASD and notifies the physician. If the physician determines that a referral to a specialist is medically necessary, he or she must refer the minor to an appropriate specialist to determine whether the minor meets diagnostic criteria for ASD. If the physician determines that a referral to a specialist is not medically necessary, the physician must inform the parent or guardian that he or she can self-refer to the Early Steps Program[21] or other specialist in autism. The bill exempts physicians providing emergency services and care[22] from this requirement.

An "appropriate specialist" is defined in the bill as a qualified professional who is experienced in the evaluation of autism spectrum disorder, is licensed in this state, and has training in validated diagnostic tools. The term includes, but is not limited to:

- A psychologist;
- A psychiatrist;
- A neurologist;
- A developmental or behavioral pediatrician; or
- A professional whose licensure is deemed appropriate by the Children's Medical Services Early Steps Program within the Department of Health.

Sections 2 and 3 amend the Steven A. Geller Autism Coverage Act, under ss. 627.6686 and 641.31098, F.S., to mandate that health insurance plans and health maintenance contracts provide coverage for direct patient access to an appropriate specialist, as defined by the bill in s. 381.986, F.S, (see above) for a minimum of three visits per policy year for screening for or evaluation or diagnosis of ASD.

The bill defines "direct patient access" as the ability of an insured to obtain services from an in-network provider without a referral or other authorization before receiving services.

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[19] *See* s. 110.123(3)(b), F.S.

[20] Greenspan et. al., "Guidelines for Early Identification, Screening, and Clinical Management of Children With Autism Spectrum Disorders," *Pediatrics: Official Journal of the American Academy of Pediatrics,* April 2008, vol. 121, no. 4, p. 828.

[21] Early Steps is Florida's early intervention system that offers services to eligible infants and toddlers (birth to thirty-six months) with significant delays or a condition likely to result in a developmental delay. Early intervention is provided to support families and caregivers in developing the competence and confidence to help their child learn and develop. *See* http://www.doh.state.fl.us/alternatesites/cms-kids/families/early_steps/early_steps.html

[22] *See* s. 395.1041, F.S.

Section 4 provides an effective date for the bill of July 1, 2011.

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 the 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:

The bill may increase the total number and cost of claims incurred by insurers and HMOs for evaluations because more minors may be referred for ASD screening or visit specialists under the direct patient access provision. If so, the bill may cause health insurance costs to increase by an indeterminate amount.

C. Government Sector Impact:

The Division of State Group Insurance within the Department of Management Services (DMS) examined the bill for fiscal impact on the State Group Health Insurance Program. DMS advises that because the bill requires coverage for direct patient access and a minimum of three visits per policy year for autism spectrum screenings (in addition to the non-specialist opinion of the primary care physician), the bill could result in marginally higher cost if medically unnecessary repetition of valid screenings occurs. The fiscal impact is indeterminate but is not expected by DMS to be significant.

The Department of Health has provided the following fiscal analysis:

- The bill could result in additional families seeking ASD screening from the Early Steps Program, which would increase the program's screening costs.
- The bill could increase the number children in the program who need early intervention services, which could result in further increased costs and in the inability

of the Early Steps Program to ensure that appropriate early intervention services are available to eligible children.

- The exact fiscal impact is indeterminate.

VI. Technical Deficiencies:

Section 1 refers to "a physician licensed in this state." It may be more appropriate to specify a physician licensed under ch. 458 or ch. 459, F.S.

Section 1 defines the term "appropriate specialist," in part, with the phrase "has training in validated diagnostic tools." However, the term "validated diagnostic tools" is defined neither in the bill nor in existing Florida law, leaving ambiguous the standard(s) by which a diagnostic tool may be considered "validated."

Section 2, which amends s. 627.6686, F.S., defines "direct patient access" using the term "in-network" provider. The OIR advises that not all health plans governed by this statute have "networks" or "in-network" providers. A more appropriate term would be "contracted" provider.

VII. Related Issues:

Section 624.215, F.S., requires every person or organization seeking consideration of a legislative proposal mandating health coverage to submit to the Agency for Health Care Administration and the appropriate legislative committees having jurisdiction a report assessing the social and financial impacts of the proposed coverage. The Senate Committee on Health Regulation has not received a report analyzing the mandated coverage for direct patient access to an appropriate specialist for a minimum of three visits per policy year as created by the bill.

VIII. Additional Information:

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

B. Amendments:

None.

187478

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment (with title amendment)

Before line 268

insert:

Section 1. Subsection (1) of section 83.42, Florida Statutes, is amended to read:

83.42 Exclusions from application of part.—This part does not apply to:

(1) Residency or detention in a facility, whether public or private, when residence or detention is incidental to the provision of medical, geriatric, educational, counseling, religious, or similar services. The procedures for all transfers

187478

and discharges as provided in s. 400.0255 apply only to residents of a facility licensed under part II of chapter 400.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete line 2

and insert:

An act relating to health care; amending s. 83.42, F.S., relating to exclusions from part II of ch. 83, F.S., the Florida Residential Landlord and Tenant Act; clarifying that the procedures in s. 400.0255, F.S., for transfers and discharges are exclusive to residents of a nursing home licensed under part II of ch. 400, F.S.; amending s. 112.0455,

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment (with title amendment)

Between lines 481 and 482
insert:

Section 8. Subsection (3) of section 395.0161, Florida Statutes, is amended to read:

395.0161 Licensure inspection.—

(3) In accordance with s. 408.805, an applicant or licensee shall pay a fee for each license application submitted under this part, part II of chapter 408, and applicable rules. With the exception of state-operated licensed facilities, each facility licensed under this part shall pay to the agency~~, at~~

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~~the time of inspection,~~ the following fees:

(a) *Inspection for licensure.*—A fee shall be paid which is not less than $8 per hospital bed, nor more than $12 per hospital bed, except that the minimum fee shall be $400 per facility.

(b) *Inspection for lifesafety only.*—A fee shall be paid which is not less than 75 cents per hospital bed, nor more than $1.50 per hospital bed, except that the minimum fee shall be $40 per facility.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete line 15

and insert:

provision; conforming a cross-reference; amending s. 395.0161, F.S.; deleting a requirement that facilities licensed under part I of ch. 395, F.S., pay licensing fees at the time of inspection; amending s.

149114

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment

Delete lines 1040 - 1041

and insert:

programming and staff. At the time of inspection ~~and in the semiannual report required pursuant to paragraph (o)~~, a

522758

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment (with directory and title amendments)

Between lines 1129 and 1130
insert:
(3) A facility may charge a reasonable fee for copying a resident's records. Such fee may not exceed $1 per page for the first 25 pages and 25 cents per page for each page in excess of 25 pages.

====== D I R E C T O R Y C L A U S E A M E N D M E N T ======
And the directory clause is amended as follows:
Delete lines 934 - 938

522758

and insert:

Section 27. Paragraphs (o) through (w) of subsection (1) of section 400.141, Florida Statutes, are redesignated as paragraphs (n) through (u), respectively, present paragraphs (f), (g), (j), (n), (o), and (r) of that subsection are amended, and subsection (3) is added to that section to read:

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete line 88

and insert:

by the act; authorizing a facility to charge a fee to copy a resident’s records; amending s. 400.142, F.S.; deleting

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment (with title amendment)

Between lines 1145 and 1146
insert:

Section 29. Section 400.145, Florida Statutes, is repealed.

Section 30. Subsection (1) of section 400.0234, Florida Statutes, is amended to read:

400.0234 Availability of facility records for investigation of resident's rights violations and defenses; penalty.—

(1) Failure to provide complete copies of a resident's records, including, but not limited to, all medical records and the resident's chart, within the control or possession of the

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facility constitutes ~~in accordance with s. 400.145 shall constitute~~ evidence of failure of that party to comply with good faith discovery requirements and waives ~~shall waive~~ the good faith certificate and presuit notice requirements under this part by the requesting party.

Section 31. Subsection (1) of section 429.294, Florida Statutes, is amended to read:

429.294 Availability of facility records for investigation of resident's rights violations and defenses; penalty.—

(1) Failure to provide complete copies of a resident's records, including, but not limited to, all medical records and the resident's chart, within the control or possession of the facility within 10 days, constitutes ~~in accordance with the provisions of s. 400.145, shall constitute~~ evidence of failure of that party to comply with good faith discovery requirements and waives ~~shall waive~~ the good faith certificate and presuit notice requirements under this part by the requesting party.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete line 90

and insert:

repealing s. 400.145, F.S., relating requirements for furnishing the records of residents in a licensed nursing home to certain specified parties; amending ss. 400.0234 and 429.294, F.S.; conforming provisions to changes made by the act; amending s. 400.147, F.S.; revising reporting

252278

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment (with title amendment)

Between lines 1305 and 1306
insert:

Section 35. Subsection (27) of section 400.462, Florida Statutes, is amended to read:

400.462 Definitions.—As used in this part, the term:

(27) "Remuneration" means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind. However, when the term is used in any provision of law relating to health care providers, such term does not mean an item that has an individual value of up to $10, including, but not limited

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to, a plaque, a certificate, a trophy, or a novelty item that is intended solely for presentation or is customarily given away solely for promotional, recognition, or advertising purposes.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete line 107

and insert:

members; amending s. 400.462, F.S.; redefining the term "remuneration" as it relates to the Home Health Services Act; amending s. 400.484, F.S.; revising the

357892

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Bennett) recommended the following:

Senate Amendment (with title amendment)

Between lines 1344 and 1345
insert:

Section 36. Paragraph (a) of section (15) of section 400.506, Florida Statutes, is amended, and subsection (18) is added to that section, to read:

400.506 Licensure of nurse registries; requirements; penalties.—

(15)(a) The agency may deny, suspend, or revoke the license of a nurse registry and shall impose a fine of $5,000 against a nurse registry that:

357892

1. Provides services to residents in an assisted living facility for which the nurse registry does not receive fair market value remuneration.

2. Provides staffing to an assisted living facility for which the nurse registry does not receive fair market value remuneration.

3. Fails to provide the agency, upon request, with copies of all contracts with assisted living facilities which were executed within the last 5 years.

4. Gives remuneration to a case manager, discharge planner, facility-based staff member, or third-party vendor who is involved in the discharge planning process of a facility licensed under chapter 395 or this chapter and from whom the nurse registry receives referrals. A nurse registry is exempt from this subparagraph if it does not bill the ~~Florida Medicaid program or~~ the Medicare program or share a controlling interest with any entity licensed, registered, or certified under part II of chapter 408 that bills ~~the Florida Medicaid program~~ or the Medicare program.

5. Gives remuneration to a physician, a member of the physician's office staff, or an immediate family member of the physician, and the nurse registry received a patient referral in the last 12 months from that physician or the physician's office staff. A nurse registry is exempt from this subparagraph if it does not bill ~~the Florida Medicaid program or~~ the Medicare program or share a controlling interest with any entity licensed, registered, or certified under part II of chapter 408 that bills ~~the Florida Medicaid program or~~ the Medicare program.

(18) An administrator may manage only one nurse registry,

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except that an administrator may manage up to five registries if all five registries have identical controlling interests as defined in s. 408.803 and are located within one agency geographic service area or within an immediately contiguous county. An administrator shall designate, in writing, for each licensed entity, a qualified alternate administrator to serve during the administrator's absence.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Between lines 108 and 109

insert:

amending s. 400.506, F.S.; revising the circumstances in which a nurse registry is exempt from the denial, suspension, or revocation of its license; authorizing an administrator to manage only one nurse registry; providing exceptions; requiring an administrator to designate a qualified alternative administrator to serve during the administrator's absence;

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment (with title amendment)

Between lines 1344 and 1345
insert:

Section 36. Subsection (15) of section 400.506, Florida Statutes, is amended, present subsection (17) of that section is renumbered as subsection (18), and a new subsection (17) is added to that section, to read:

400.506 Licensure of nurse registries; requirements; penalties.—

(15)(a) The agency may deny, suspend, or revoke the license of a nurse registry and shall impose a fine of $5,000 against a

nurse registry that:

1. Provides services to residents in an assisted living facility for which the nurse registry does not receive fair market value remuneration.

2. Provides staffing to an assisted living facility for which the nurse registry does not receive fair market value remuneration.

3. Fails to provide the agency, upon request, with copies of all contracts with assisted living facilities which were executed within the last 5 years.

4. Gives remuneration to a case manager, discharge planner, facility-based staff member, or third-party vendor who is involved in the discharge planning process of a facility licensed under chapter 395 or this chapter and from whom the nurse registry receives referrals. A nurse registry is exempt from this subparagraph if it does not bill the Florida Medicaid program or the Medicare program or share a controlling interest with any entity licensed, registered, or certified under part II of chapter 408 that bills the Florida Medicaid program or the Medicare program.

5. Gives remuneration to a physician, a member of the physician’s office staff, or an immediate family member of the physician, and the nurse registry received a patient referral in the last 12 months from that physician or the physician’s office staff. A nurse registry is exempt from this subparagraph if it does not bill the ~~Florida Medicaid program or the~~ Medicare program or share a controlling interest with any entity licensed, registered, or certified under part II of chapter 408 that bills the ~~Florida Medicaid program or the~~ Medicare program.

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(b) The agency shall also impose an administrative fine of $15,000 if the nurse registry refers nurses, certified nursing assistants, home health aides, or other staff without charge to a facility licensed under chapter 429 in return for patient referrals from the facility.

(c) The proceeds of all fines collected under this subsection shall be deposited into the Health Care Trust Fund.

(17) An administrator may manage only one nurse registry. However, an administrator may manage up to five nurse registries if all five registries have identical controlling interests, as defined in s. 408.803, and are located within one agency geographic service area or within an immediately contiguous county. An administrator shall designate, in writing, for each licensed entity, a qualified alternate administrator to serve during the administrator's absence.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete line 108

and insert:

schedule of home health agency inspection violations; amending s. 400.506, F.S.; providing that a nurse registry is exempt from certain license penalties and fines otherwise imposed by the Agency for Health Care Administration on a nurse registry under certain circumstances; authorizing an administrator to manage up to five nurse registries under certain

circumstances; requiring an administrator to designate, in writing, for each licensed entity, a qualified alternate administrator to serve during the administrator's absence;

570218

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment (with title amendment)

Between lines 1344 and 1345
insert:

Section 36. Subsection (1) of section 400.509, Florida Statutes, is amended to read:

400.509 Registration of particular service providers exempt from licensure; certificate of registration; regulation of registrants.—

(1) Any organization that provides companion services or homemaker services and does not provide a home health service to a person is exempt from licensure under this part. However, any

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organization that provides companion services or homemaker services must register with the agency. Organizations that provide companion services only for persons with developmental disabilities, as defined in s. 393.063, under contract with the Agency for Persons with Disabilities, are exempt from registration with the agency.

Section 37. For the purpose of incorporating the amendment made by this act to section 400.509, Florida Statutes, in a reference thereto, paragraph (b) of subsection (5) of section 400.464, Florida Statutes, is reenacted to read:

400.464 Home health agencies to be licensed; expiration of license; exemptions; unlawful acts; penalties.—

(5) The following are exempt from the licensure requirements of this part:

(b) Home health services provided by a state agency, either directly or through a contractor with:

1. The Department of Elderly Affairs.

2. The Department of Health, a community health center, or a rural health network that furnishes home visits for the purpose of providing environmental assessments, case management, health education, personal care services, family planning, or followup treatment, or for the purpose of monitoring and tracking disease.

3. Services provided to persons with developmental disabilities, as defined in s. 393.063.

4. Companion and sitter organizations that were registered under s. 400.509(1) on January 1, 1999, and were authorized to provide personal services under a developmental services provider certificate on January 1, 1999, may continue to provide

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such services to past, present, and future clients of the organization who need such services, notwithstanding the provisions of this act.

5. The Department of Children and Family Services.

Section 38. For the purpose of incorporating the amendment made by this act to section 400.509, Florida Statutes, in a reference thereto, paragraph (a) of subsection (6) of section 400.506, Florida Statutes, is reenacted to read:

400.506 Licensure of nurse registries; requirements; penalties.—

(6)(a) A nurse registry may refer for contract in private residences registered nurses and licensed practical nurses registered and licensed under part I of chapter 464, certified nursing assistants certified under part II of chapter 464, home health aides who present documented proof of successful completion of the training required by rule of the agency, and companions or homemakers for the purposes of providing those services authorized under s. 400.509(1). A licensed nurse registry shall ensure that each certified nursing assistant referred for contract by the nurse registry and each home health aide referred for contract by the nurse registry is adequately trained to perform the tasks of a home health aide in the home setting. Each person referred by a nurse registry must provide current documentation that he or she is free from communicable diseases.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete line 108

and insert:

schedule of home health agency inspection violations; amending s. 400.509, F.S.; providing that organizations that provide companion services only to persons with developmental disabilities, under contract with the Agency for Persons with Disabilities, are exempt from registration with the Agency for Health Care Administration; reenacting ss. 400.464(5)(b) and 400.506(6)(a), F.S., relating to home health agencies and licensure of nurse registries, respectively, to incorporate the amendment made to s. 400.509, F.S., in references thereto;

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment (with title amendment)

Delete lines 1403 - 1411
and insert:

Section 40. Section 400.931, Florida Statutes, is amended to read:

400.931 Application for license; documentation of accreditation; fee~~; provisional license; temporary permit~~.—

(1) In addition to the requirements of part II of chapter 408, the applicant must file with the application satisfactory

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proof that the home medical equipment provider is in compliance with this part and applicable rules, including:

(a) A report, by category, of the equipment to be provided, indicating those offered either directly by the applicant or through contractual arrangements with existing providers. Categories of equipment include:

1. Respiratory modalities.
2. Ambulation aids.
3. Mobility aids.
4. Sickroom setup.
5. Disposables.

(b) A report, by category, of the services to be provided, indicating those offered either directly by the applicant or through contractual arrangements with existing providers. Categories of services include:

1. Intake.
2. Equipment selection.
3. Delivery.
4. Setup and installation.
5. Patient training.
6. Ongoing service and maintenance.
7. Retrieval.

(c) A listing of those with whom the applicant contracts, both the providers the applicant uses to provide equipment or services to its consumers and the providers for whom the applicant provides services or equipment.

(2) An applicant for initial licensure, change of ownership, or renewal to operate a licensed home medical equipment provider at a location outside the state of Florida


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must submit documentation of accreditation, or an application for accreditation, from an accrediting organization that is recognized by the agency. An applicant that has applied for accreditation must provide proof of accreditation that is not conditional or provisional within 120 days after the date of the agency's receipt of the application for licensure or the application shall be withdrawn from further consideration. Such accreditation must be maintained by the home medical equipment provider in order to maintain licensure. ~~As an alternative to submitting proof of financial ability to operate as required in s. 408.810(8), the applicant may submit a $50,000 surety bond to the agency.~~

(3) As specified in part II of chapter 408, the home medical equipment provider must also obtain and maintain professional and commercial liability insurance. Proof of liability insurance, as defined in s. 624.605, must be submitted with the application. The agency shall set the required amounts of liability insurance by rule, but the required amount must not be less than $250,000 per claim. In the case of contracted services, it is required that the contractor have liability insurance not less than $250,000 per claim.

(4) When a change of the general manager of a home medical equipment provider occurs, the licensee must notify the agency of the change within 45 days.

(5) In accordance with s. 408.805, an applicant or a licensee shall pay a fee for each license application submitted under this part, part II of chapter 408, and applicable rules. The amount of the fee shall be established by rule and may not exceed $300 per biennium. The agency shall set the fees in an

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amount that is sufficient to cover its costs in carrying out its responsibilities under this part. However, state, county, or municipal governments applying for licenses under this part are exempt from the payment of license fees.

(6) An applicant for initial licensure, renewal, or change of ownership shall also pay an inspection fee not to exceed $400, which shall be paid by all applicants except those not subject to licensure inspection by the agency as described in s. 400.933.

================ T I T L E A M E N D M E N T ================

And the title is amended as follows:

Delete line 118

and insert:

requiring each applicant for initial licensure, change of ownership, or renewal to operate a licensed home medical equipment provider at a location outside the state to submit documentation of accreditation, or an application for accreditation, from an accrediting organization that is recognized by the Agency for Health Care Administration; requiring an applicant that has applied for accreditation to provide proof of accreditation within a specified time; deleting a requirement that an applicant for a home

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment

Between lines 1613 and 1614
insert:

(o) Entities that employ 50 or more health care practitioners who are licensed under chapter 458 or chapter 459 if the billing for medical services is under a single corporate tax identification number. The application for exemption under this paragraph must contain information that includes the name, residence address, business address, and telephone number of the entity that owns the practice; a complete list of the names and contact information of all the officers and directors of the

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entity; the name, residence address, business address, and medical license number of each health care practitioner who is licensed to practice in this state and employed by the entity; the corporate tax identification number of the entity seeking an exemption; a listing of health care services to be provided by the entity at the health care clinics owned or operated by the entity; and a certified statement prepared by an independent certified public accountant which states that the entity and the health care clinics owned or operated by the entity have not received payment for health care services under insurance coverage for personal injury protection for the preceding year. If the agency determines that an entity that is exempt under this paragraph has received payments for medical services for insurance coverage for personal injury protection, the agency may deny or revoke the exemption from licensure under this paragraph.

837388

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment (with title amendment)

Between lines 1697 and 1698
insert:

Section 46. Paragraph (a) of subsection (2) of section 408.033, Florida Statutes, is amended to read:

408.033 Local and state health planning.—

(2) FUNDING.—

(a) The Legislature intends that the cost of local health councils be borne by assessments on selected health care facilities subject to facility licensure by the Agency for Health Care Administration, including abortion clinics, assisted

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living facilities, ambulatory surgical centers, birthing centers, clinical laboratories except community nonprofit blood banks and clinical laboratories operated by practitioners for exclusive use regulated under s. 483.035, home health agencies, hospices, hospitals, intermediate care facilities for the developmentally disabled, nursing homes, health care clinics, and multiphasic testing centers and by assessments on organizations subject to certification by the agency pursuant to chapter 641, part III, including health maintenance organizations and prepaid health clinics. Any fee that is assessed may be collected prospectively at the time a facility's license is renewed and prorated for the licensing period.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete line 139

and insert:

operate a mobile clinic; amending s. 408.033, F.S.; providing that fees assessed on selected health care facilities and organizations may be collected prospectively at the time of licensure renewal and prorated for the licensing period; amending s. 408.034, F.S.;

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment (with title amendment)

Delete lines 1708 - 1718
and insert:
Section 47. Paragraph (d) of subsection (1) and paragraph (m) of subsection (3) of section 408.036, Florida Statutes, are amended to read:
408.036 Projects subject to review; exemptions.—
(1) APPLICABILITY.—Unless exempt under subsection (3), all health-care-related projects, as described in paragraphs (a)-(g), are subject to review and must file an application for a certificate of need with the agency. The agency is exclusively

responsible for determining whether a health-care-related project is subject to review under ss. 408.031-408.045.

(d) The establishment of a hospice or hospice inpatient facility~~, except as provided in s. 408.043~~.

(3) EXEMPTIONS.—Upon request, the following projects are subject to exemption from the provisions of subsection (1):

(m)1. For the provision of adult open-heart services in a hospital located within the boundaries of a health service planning district, as defined in s. 408.032(5), which has experienced an annual net out-migration of at least 600 open-heart-surgery cases for 3 consecutive years according to the most recent data reported to the agency, and the district's population per licensed and operational open-heart programs exceeds the state average of population per licensed and operational open-heart programs by at least 25 percent. All hospitals within a health service planning district which meet the criteria reference in sub-subparagraphs 2.a.-h. shall be eligible for this exemption on July 1, 2004, and shall receive the exemption upon filing for it and subject to the following:

a. A hospital that has received a notice of intent to grant a certificate of need or a final order of the agency granting a certificate of need for the establishment of an open-heart-surgery program is entitled to receive a letter of exemption for the establishment of an adult open-heart-surgery program upon filing a request for exemption and complying with the criteria enumerated in sub-subparagraphs 2.a.-h., and is entitled to immediately commence operation of the program.

b. An otherwise eligible hospital that has not received a notice of intent to grant a certificate of need or a final order

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of the agency granting a certificate of need for the establishment of an open-heart-surgery program is entitled to immediately receive a letter of exemption for the establishment of an adult open-heart-surgery program upon filing a request for exemption and complying with the criteria enumerated in sub-subparagraphs 2.a.-h., but is not entitled to commence operation of its program until December 31, 2006.

2. A hospital shall be exempt from the certificate-of-need review for the establishment of an open-heart-surgery program when the application for exemption submitted under this paragraph complies with the following criteria:

a. The applicant must certify that it will meet and continuously maintain the minimum licensure requirements adopted by the agency governing adult open-heart programs, including the most current guidelines of the American College of Cardiology and American Heart Association Guidelines for Adult Open Heart Programs.

b. The applicant must certify that it will maintain sufficient appropriate equipment and health personnel to ensure quality and safety.

c. The applicant must certify that it will maintain appropriate times of operation and protocols to ensure availability and appropriate referrals in the event of emergencies.

d. The applicant can demonstrate that it has discharged at least 300 inpatients with a principal diagnosis of ischemic heart disease for the most recent 12-month period as reported to the agency.

e. The applicant is a general acute care hospital that is

863564

in operation for 3 years or more.

f. The applicant is performing more than 300 diagnostic cardiac catheterization procedures per year, combined inpatient and outpatient.

g. The applicant's payor mix at a minimum reflects the community average for Medicaid, charity care, and self-pay patients or the applicant must certify that it will provide a minimum of 5 percent of Medicaid, charity care, and self-pay to open-heart-surgery patients.

h. If the applicant fails to meet the established criteria for open-heart programs or fails to reach 300 surgeries per year by the end of its third year of operation, it must show cause why its exemption should not be revoked.

~~3. By December 31, 2004, and annually thereafter, the agency shall submit a report to the Legislature providing information concerning the number of requests for exemption it has received under this paragraph during the calendar year and the number of exemptions it has granted or denied during the calendar year.~~

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete line 145

and insert:

facility; deleting a requirement that the agency submit a report to the Legislature providing information concerning the number of requests it receives for an exemption from certificate-of-need review; amending s. 408.043, F.S.; revising

130558

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment (with title amendment)

Between lines 1718 and 1719
insert:

Section 48. Paragraph (c) of subsection (1) of section 408.037, Florida Statutes, is amended to read:

408.037 Application content.—

(1) Except as provided in subsection (2) for a general hospital, an application for a certificate of need must contain:

(c) An audited financial statement of the applicant or of the applicant's parent corporation if audited financial statements of the applicant do not exist. In an application

130558

submitted by an existing health care facility, health maintenance organization, or hospice, financial condition documentation must include, but need not be limited to, a balance sheet and a profit-and-loss statement of the 2 previous fiscal years' operation.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete line 145

and insert:

facility; amending s. 408.037, F.S.; revising requirements for the financial information to be included in an application for a certificate of need; amending s. 408.043, F.S.; revising

885012

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment

Delete lines 1962 - 1963
and insert:
licensee of the expiration of the license. If the licensee does not receive

585110

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment (with title amendment)

Between lines 1973 and 1974
insert:

Section 56. Paragraph (b) of subsection (1) of section 408.8065, Florida Statutes, is amended to read:

408.8065 Additional licensure requirements for home health agencies, home medical equipment providers, and health care clinics.—

(1) An applicant for initial licensure, or initial licensure due to a change of ownership, as a home health agency, home medical equipment provider, or health care clinic shall:

585110

(b) Submit projected ~~pro forma~~ financial statements, including a balance sheet, income and expense statement, and a statement of cash flows for the first 2 years of operation which provide evidence that the applicant has sufficient assets, credit, and projected revenues to cover liabilities and expenses.

All documents required under this subsection must be prepared in accordance with generally accepted accounting principles and may be in a compilation form. The financial statements must be signed by a certified public accountant.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete line 162

and insert:

considered complete under certain circumstances; amending s. 408.8065, F.S.; revising the requirements for becoming licensed as a home health agency, home medical equipment provider, or health care clinic;

914908

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment (with title amendment)

Between lines 1973 and 1974
insert:

Section 56. Subsections (4) through (8) of section 408.809, Florida Statutes, are amended to read:

408.809 Background screening; prohibited offenses.—

(4) In addition to the offenses listed in s. 435.04, all persons required to undergo background screening pursuant to this part or authorizing statutes must not have an arrest awaiting final disposition for, must not have been found guilty of, regardless of adjudication, or entered a plea of nolo

914908

contendere or guilty to, and must not have been adjudicated delinquent and the record not have been sealed or expunged for any of the following offenses or any similar offense of another jurisdiction:

(a) Any authorizing statutes, if the offense was a felony.

(b) This chapter, if the offense was a felony.

(c) Section 409.920, relating to Medicaid provider fraud.

(d) Section 409.9201, relating to Medicaid fraud.

(e) Section 741.28, relating to domestic violence.

(f) Section 817.034, relating to fraudulent acts through mail, wire, radio, electromagnetic, photoelectronic, or photooptical systems.

(g) Section 817.234, relating to false and fraudulent insurance claims.

(h) Section 817.505, relating to patient brokering.

(i) Section 817.568, relating to criminal use of personal identification information.

(j) Section 817.60, relating to obtaining a credit card through fraudulent means.

(k) Section 817.61, relating to fraudulent use of credit cards, if the offense was a felony.

(l) Section 831.01, relating to forgery.

(m) Section 831.02, relating to uttering forged instruments.

(n) Section 831.07, relating to forging bank bills, checks, drafts, or promissory notes.

(o) Section 831.09, relating to uttering forged bank bills, checks, drafts, or promissory notes.

(p) Section 831.30, relating to fraud in obtaining

914908

medicinal drugs.

(q) Section 831.31, relating to the sale, manufacture, delivery, or possession with the intent to sell, manufacture, or deliver any counterfeit controlled substance, if the offense was a felony.

(5) A person who serves as a controlling interest of, is employed by, or contracts with a licensee on July 31, 2010, who has been screened and qualified according to standards specified in s. 435.03 or s. 435.04 must be rescreened by July 31, 2015, in accordance with the schedule provided in this subsection. ~~The agency may adopt rules to establish a schedule to stagger the implementation of the required rescreening over the 5-year period, beginning July 31, 2010, through July 31, 2015.~~ If, upon rescreening, such person has a disqualifying offense that was not a disqualifying offense at the time of the last screening, but is a current disqualifying offense and was committed before the last screening, he or she may apply for an exemption from the appropriate licensing agency and, if agreed to by the employer, may continue to perform his or her duties until the licensing agency renders a decision on the application for exemption if the person is eligible to apply for an exemption and the exemption request is received by the agency within 30 days after receipt of the rescreening results by the person. The rescreening schedule is as follows:

(a) An individual whose last screening was conducted before December 31, 2003, must be rescreened by July 31, 2013;

(b) An individual whose last screening was conducted between January 1, 2004, and December 31, 2007, must be rescreened by July 31, 2014; and

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(c) An individual whose last screening was conducted between January 1, 2008, and July 31, 2010, must be rescreened by July 31, 2015.

(6) ~~(5)~~ The costs associated with obtaining the required screening must be borne by the licensee or the person subject to screening. Licensees may reimburse persons for these costs. The Department of Law Enforcement shall charge the agency for screening pursuant to s. 943.053(3). The agency shall establish a schedule of fees to cover the costs of screening.

(7) ~~(6)~~ (a) As provided in chapter 435, the agency may grant an exemption from disqualification to a person who is subject to this section and who:

1. Does not have an active professional license or certification from the Department of Health; or

2. Has an active professional license or certification from the Department of Health but is not providing a service within the scope of that license or certification.

(b) As provided in chapter 435, the appropriate regulatory board within the Department of Health, or the department itself if there is no board, may grant an exemption from disqualification to a person who is subject to this section and who has received a professional license or certification from the Department of Health or a regulatory board within that department and that person is providing a service within the scope of his or her licensed or certified practice.

(8) ~~(7)~~ The agency and the Department of Health may adopt rules pursuant to ss. 120.536(1) and 120.54 to implement this section, chapter 435, and authorizing statutes requiring background screening and to implement and adopt criteria

914908

relating to retaining fingerprints pursuant to s. 943.05(2).

(9) ~~(8)~~ There is no unemployment compensation or other monetary liability on the part of, and no cause of action for damages arising against, an employer that, upon notice of a disqualifying offense listed under chapter 435 or this section, terminates the person against whom the report was issued, whether or not that person has filed for an exemption with the Department of Health or the agency.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Between lines 162 and 163

insert:

amending s. 408.809, F.S.; revising provisions to include a schedule for background rescreenings of certain employees;

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Fasano) recommended the following:

Senate Amendment

Delete lines 2332 - 2335

and insert:

for the use of a drug. The agency shall accept from prescribers or pharmacists electronic requests for any drug requiring prior authorization and ~~may~~ post prior authorization criteria and protocol and updates to the list of drugs that are subject to prior authorization on an Internet website without amending its rule or engaging in additional rulemaking.

283102

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment (with title amendment)

Delete lines 2391 - 2502.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete lines 171 - 177

and insert:

amending

495712

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment (with title amendment)

Delete lines 2684 - 2685
and insert:
(a) The biennial license fee required of a facility is $300 per license, with an additional fee of $71 ~~$50~~ per resident
Delete line 2690
and insert:
exceed $10,000.
Delete line 2695
and insert:
biennial fee shall be $400 per license, with an additional

495712

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14 ================ T I T L E A M E N D M E N T ================
15 And the title is amended as follows:
16 Delete lines 189 - 193
17 and insert:
18 services; increasing the additional licensing fee per
19 resident based on the total licensed resident capacity
20 of the facility; eliminating the license fee for the
21 limited nursing services license; transferring

920702

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment

Delete lines 2707 - 2708
and insert:
429.28, the agency's standard license survey shall include private informal conversations with a sample

658290

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment (with title amendment)

Delete lines 2776 - 2788.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete lines 213 - 215

and insert:

the issuance of conditional licenses;

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment (with title amendment)

Delete lines 2867 - 2881.

================ T I T L E A M E N D M E N T ================

And the title is amended as follows:

Delete lines 230 - 233

and insert:

429.41,

731102

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment (with title amendment)

Delete lines 2882 - 2908
and insert:
Section 70. Paragraphs (i) and (j) of subsection (1) and subsection (3) of section 429.41, Florida Statutes, are amended, and present subsections (4) and (5) of that section are renumbered subsections (3) and (4), respectively, to read:
429.41 Rules establishing standards.—
(1) It is the intent of the Legislature that rules published and enforced pursuant to this section shall include criteria by which a reasonable and consistent quality of

731102

resident care and quality of life may be ensured and the results of such resident care may be demonstrated. Such rules shall also ensure a safe and sanitary environment that is residential and noninstitutional in design or nature. It is further intended that reasonable efforts be made to accommodate the needs and preferences of residents to enhance the quality of life in a facility. The agency, in consultation with the department, may adopt rules to administer the requirements of part II of chapter 408. In order to provide safe and sanitary facilities and the highest quality of resident care accommodating the needs and preferences of residents, the department, in consultation with the agency, the Department of Children and Family Services, and the Department of Health, shall adopt rules, policies, and procedures to administer this part, which must include reasonable and fair minimum standards in relation to:

(i) Facilities holding an ~~a limited nursing,~~ extended congregate care, or limited mental health license.

(j) The establishment of specific criteria to define appropriateness of resident admission and continued residency in a facility holding a standard, ~~limited nursing,~~ extended congregate care, and limited mental health license.

~~(3) The department shall submit a copy of proposed rules to the Speaker of the House of Representatives, the President of the Senate, and appropriate committees of substance for review and comment prior to the promulgation thereof. Rules promulgated by the department shall encourage the development of homelike facilities which promote the dignity, individuality, personal strengths, and decisionmaking ability of residents.~~

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========== T I T L E A M E N D M E N T ==========
And the title is amended as follows:
Delete line 235
and insert:
changes made by the act; deleting the requirement for the Department of Elderly Affairs to submit to the Legislature a copy of proposed rules regarding the quality of resident care in an assisted living facility; amending s. 429.53, F.S.;

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment (with title amendment)

Between lines 3085 and 3086
insert:

Section 78. Subsection (1) of section 483.035, Florida Statutes, is amended to read:

483.035 Clinical laboratories operated by practitioners for exclusive use; licensure and regulation.—

(1) A clinical laboratory operated by one or more practitioners licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, part I of chapter 464, or chapter 466, exclusively in connection with the diagnosis and treatment

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of their own patients, must be licensed under this part and must comply with the provisions of this part, except that the agency shall adopt rules for staffing, for personnel, including education and training of personnel, for proficiency testing, and for construction standards relating to the licensure and operation of the laboratory based upon and not exceeding the same standards contained in the federal Clinical Laboratory Improvement Amendments of 1988 and the federal regulations adopted thereunder.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete line 249

and insert:

testing of employees and job applicants; amending s. 483.035, F.S.; providing for a clinical laboratory to be operated by certain nurses; amending s.

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment (with title amendment)

Between lines 3085 and 3086
insert:

Section 78. Subsections (1) and (9) of section 483.051, Florida Statutes, are amended to read:

483.051 Powers and duties of the agency.—The agency shall adopt rules to implement this part, which rules must include, but are not limited to, the following:

(1) LICENSING; QUALIFICATIONS.—The agency shall provide for biennial licensure of all nonwaived clinical laboratories meeting the requirements of this part and shall prescribe the

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qualifications necessary for such licensure, including, but not limited to, an application for or proof of a certificate under Clinical Laboratory Improvement Amendments of 1988. A nonwaived laboratory is a laboratory that has not been granted a certificate of waiver by the Centers for Medicare and Medicaid Services under the Clinical Laboratory Improvement Amendments of 1988 and the federal rules adopted thereunder.

(9) ALTERNATE-SITE TESTING.—The agency, in consultation with the Board of Clinical Laboratory Personnel, shall adopt, by rule, the criteria for alternate-site testing to be performed under the supervision of a clinical laboratory director. The elements to be addressed in the rule include, but are not limited to: a hospital internal needs assessment; a protocol of implementation including tests to be performed and who will perform the tests; criteria to be used in selecting the method of testing to be used for alternate-site testing; minimum training and education requirements for those who will perform alternate-site testing, such as documented training, licensure, certification, or other medical professional background not limited to laboratory professionals; documented inservice training as well as initial and ongoing competency validation; an appropriate internal and external quality control protocol; an internal mechanism for identifying and tracking alternate-site testing by the central laboratory; and recordkeeping requirements. ~~Alternate-site testing locations must register when the clinical laboratory applies to renew its license.~~ For purposes of this subsection, the term "alternate-site testing" means any laboratory testing done under the administrative control of a hospital, but performed out of the physical or

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administrative confines of the central laboratory.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete line 249

and insert:

testing of employees and job applicants; amending s. 483.051, F.S.; requiring the Agency for Health Care Administration to provide for biennial licensure of all nonwaived laboratories that meet certain requirements; requiring the agency to prescribe qualifications for such licensure; defining nonwaived laboratories as laboratories that do not have a certificate of waiver from the Centers for Medicare and Medicaid Services; deleting requirements for the registration of an alternate site testing location when the clinical laboratory applies to renew its license; amending s.

951376

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment

Delete line 3281

and insert:

400.141(n)1.~~(o)1.d.~~

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment (with title amendment)

Between lines 3310 and 3311
insert:

Section 88. Section 429.195, Florida Statutes, is amended to read:

429.195 Rebates prohibited; penalties.—

(1) It is unlawful for any assisted living facility licensed under this part to contract or promise to pay or receive any commission, bonus, kickback, or rebate or engage in any split-fee arrangement in any form whatsoever with any health care provider or health care facility under s. 817.505

553056

~~physician, surgeon, organization, agency, or person, either directly or indirectly, for residents referred to an assisted living facility licensed under this part.~~ ~~A facility may employ or contract with persons to market the facility, provided the employee or contract provider clearly indicates that he or she represents the facility. A person or agency independent of the facility may provide placement or referral services for a fee to individuals seeking assistance in finding a suitable facility; however, any fee paid for placement or referral services must be paid by the individual looking for a facility, not by the facility.~~

(2) A violation of this section shall be considered patient brokering and is punishable as provided in s. 817.505.

(3) This section does not apply to:

(a) An individual with whom the facility employs or contracts with to market the facility if the individual clearly indicates that he or she works with or for the facility.

(b) A referral service that provides information, consultation, or referrals to consumers to assist them in finding appropriate care or housing options for senior citizens or disabled adults if such referred consumers are not Medicaid recipients.

(c) A resident of an assisted living facility who refers to the assisted living facility a friend, family member, or other individual with whom the resident has a personal relationship, and the assisted living facility is not prohibited from providing a monetary reward to the resident for making such a referral.

Section 89. Paragraph (j) is added to subsection (3) of

553056

section 817.505, Florida Statutes, to read:

817.505 Patient brokering prohibited; exceptions; penalties.—

(3) This section shall not apply to:

(j) Any payment by an assisted living facility, as defined in s. 429.02, which is permitted under s. 429.195(3).

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete line 260

and insert:

the definition of "health care provider"; amending s. 429.195, F.S.; prohibiting an assisted living facility from contracting or promising to pay or receive any commission, bonus, kickback, or rebate or engage in any split-fee arrangement with any health care provider or health care facility; providing exceptions; amending s. 817.505, F.S.; providing that it is not patient brokering for an assisted living facility to offer payment under certain circumstances; amending ss.

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Gaetz) recommended the following:

Senate Amendment (with title amendment)

Between lines 3310 and 3311
insert:

Section 88. Section 381.06014, Florida Statutes, is amended to read:

381.06014 Blood establishments.—

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

(a) "Blood establishment" means any person, entity, or organization, operating within the state, which examines an individual for the purpose of blood donation or which collects, processes, stores, tests, or distributes blood or blood


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components collected from the human body for the purpose of transfusion, for any other medical purpose, or for the production of any biological product. A person, entity, or organization that uses a mobile unit to conduct such activities within the state is also a blood establishment.

(b) "Volunteer donor" means a person who does not receive remuneration, other than an incentive, for a blood donation intended for transfusion, and the product container of the donation from the person qualifies for labeling with the statement "volunteer donor" under 21 C.F.R. s. 606.121.

(2) Any blood establishment operating in the state may not conduct any activity defined in paragraph (1)(a) ~~subsection (1)~~ unless that blood establishment is operated in a manner consistent with the provisions of Title 21 C.F.R. parts 211 and 600-640~~, Code of Federal Regulations~~.

(3) Any blood establishment determined to be operating in the state in a manner not consistent with the provisions of Title 21 C.F.R. parts 211 and 600-640~~, Code of Federal Regulations,~~ and in a manner that constitutes a danger to the health or well-being of donors or recipients as evidenced by the federal Food and Drug Administration's inspection reports and the revocation of the blood establishment's license or registration is ~~shall be~~ in violation of this chapter and must ~~shall~~ immediately cease all operations in the state.

(4) The operation of a blood establishment in a manner not consistent with the provisions of Title 21 C.F.R. parts 211 and 600-640~~, Code of Federal Regulations,~~ and in a manner that constitutes a danger to the health or well-being of blood donors or recipients as evidenced by the federal Food and Drug

Administration's inspection process is declared a nuisance and inimical to the public health, welfare, and safety. The Agency for Health Care Administration or any state attorney may bring an action for an injunction to restrain such operations or enjoin the future operation of the blood establishment.

(5) A local government may not restrict the access to or use of any public facility or infrastructure for the collection of blood or blood components from volunteer donors based on whether the blood establishment is operating as a for-profit organization or not-for-profit organization.

(6) In determining the service fee of blood or blood components received from volunteer donors and sold to hospitals or other health care providers, a blood establishment may not base the service fee of the blood or blood component solely on whether the purchasing entity is a for-profit organization or not-for-profit organization.

(7) A blood establishment that collects blood or blood components from volunteer donors must disclose on the Internet the information required under this subsection to educate and inform donors and the public about the blood establishment's activities. A hospital that collects blood or blood components to be used only by that hospital's licensed facilities or by a health care provider that is a part of the hospital's business entity is exempt from the disclosure requirements in this subsection. The information required to be disclosed under this subsection may be cumulative for all blood establishments within a business entity. A blood establishment must disclose on its website all of the following information:

(a) A description of the steps involved in collecting,

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processing, and distributing volunteer donations.

(b) By March 1 of each year, the number of units of blood components which were:

1. Produced by the blood establishment during the preceding calendar year;

2. Obtained from other sources during the preceding calendar year;

3. Distributed during the preceding calendar year to health care providers located outside this state. However, if the blood establishment collects donations in a county outside this state, distributions to health care providers in that county shall be excluded. Such information shall be reported in the aggregate for health care providers located within the United States and its territories or outside the United States and its territories; and

4. Distributed during the preceding calendar year to entities that are not health care providers. Such information shall be reported in the aggregate for purchasers located within the United States and its territories or outside the United States and its territories.

(c) The blood establishment’s conflict-of-interest policy, policy concerning related-party transactions, whistleblower policy, and policy for determining executive compensation. If a change occurs to any of these documents, the revised document must be available on the blood establishment’s website by the following March 1.

(d) Except for a hospital that collects blood or blood components from volunteer donors:

1. The most recent 3 years of the Return of Organization


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Exempt from Income Tax, Internal Revenue Service Form 990, if the business entity for the blood establishment is eligible to file such return. The Form 990 must be available on the blood establishment's website within 60 calendar days after it is filed with the Internal Revenue Service; or

2. If the business entity for the blood establishment is not eligible to file the Form 990 return, a balance sheet, income statement, and statement of changes in cash flow, along with the expression of an opinion thereon by an independent certified public accountant who audited or reviewed such financial statements. Such documents must be available on the blood establishment's website within 120 days after the end of the blood establishment's fiscal year and must remain on the blood establishment's website for at least 36 months.

(8) A blood establishment is liable for a civil penalty for failing to make the disclosures required under subsection (7). The Department of Legal Affairs may assess the civil penalty against the blood establishment for each day that it fails to make such required disclosures, but the penalty may not exceed $10,000 per year. If multiple blood establishments operated by a single business entity fail to meet such disclosure requirements, the civil penalty may be assessed against only one of the business entity's blood establishments. The Department of Legal Affairs may terminate an action if the blood establishment agrees to pay a stipulated civil penalty. A civil penalty so collected accrues to the state and shall be deposited as received into the General Revenue Fund unallocated. The Department of Legal Affairs may terminate the action and waive the civil penalty upon a showing of good cause by the blood

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establishment as to why the required disclosures were not made.

Section 89. Subsection (23) of section 499.003, Florida Statutes, is amended to read:

499.003 Definitions of terms used in this part.—As used in this part, the term:

(23) "Health care entity" means a closed pharmacy or any person, organization, or business entity that provides diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care, but does not include any wholesale distributor or retail pharmacy licensed under state law to deal in prescription drugs. However, a blood establishment is a health care entity that may engage in the wholesale distribution of prescription drugs under s. 499.01(2)(g)1.c.

Section 90. Subsection (21) of section 499.005, Florida Statutes, is amended to read:

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

(21) The wholesale distribution of any prescription drug that was:

(a) Purchased by a public or private hospital or other health care entity; or

(b) Donated or supplied at a reduced price to a charitable organization,

unless the wholesale distribution of the prescription drug is authorized in s. 499.01(2)(g)1.c.

Section 91. Paragraphs (a) and (g) of subsection (2) of

section 499.01, Florida Statutes, are amended to read:

499.01 Permits.—

(2) The following permits are established:

(a) *Prescription drug manufacturer permit.*—A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.

1. A person that operates an establishment permitted as a prescription drug manufacturer may engage in wholesale distribution of prescription drugs manufactured at that establishment and must comply with all of the provisions of this part, except s. 499.01212, and the rules adopted under this part, except s. 499.01212, which ~~that~~ apply to a wholesale distributor.

2. A prescription drug manufacturer must comply with all appropriate state and federal good manufacturing practices.

3. A blood establishment, as defined in s. 381.06014, operating in a manner consistent with the provisions of Title 21 C.F.R. parts 211 and 600-640, and manufacturing only the prescription drugs described in s. 499.003(54)(d) is not required to be permitted as a prescription drug manufacturer under this paragraph or to register products under s. 499.015.

(g) *Restricted prescription drug distributor permit.*—

1. A restricted prescription drug distributor permit is required for:

a. Any person located in this state that engages in the distribution of a prescription drug, which distribution is not considered "wholesale distribution" under s. 499.003(54)(a).

b.~~1.~~ Any ~~A~~ person located in this state who engages in the

receipt or distribution of a prescription drug in this state for the purpose of processing its return or its destruction ~~must obtain a permit as a restricted prescription drug distributor~~ if such person is not the person initiating the return, the prescription drug wholesale supplier of the person initiating the return, or the manufacturer of the drug.

c. A blood establishment located in this state which collects blood and blood components only from volunteer donors as defined in s. 381.06014 or pursuant to an authorized practitioner's order for medical treatment or therapy and engages in the wholesale distribution of a prescription drug not described in s. 499.003(54)(d) to a health care entity. The health care entity receiving a prescription drug distributed under this sub-subparagraph must be licensed as a closed pharmacy or provide health care services at that establishment. The blood establishment must operate in accordance with s. 381.06014 and may distribute only:

(I) Prescription drugs indicated for a bleeding or clotting disorder or anemia;

(II) Blood-collection containers approved under s. 505 of the federal act;

(III) Drugs that are blood derivatives, or a recombinant or synthetic form of a blood derivative;

(IV) Prescription drugs that are identified in rules adopted by the department and that are essential to services performed or provided by blood establishments and authorized for distribution by blood establishments under federal law; or

(V) To the extent authorized by federal law, drugs necessary to collect blood or blood components from volunteer

blood donors; for blood establishment personnel to perform therapeutic procedures under the direction and supervision of a licensed physician; and to diagnose, treat, manage, and prevent any reaction of either a volunteer blood donor or a patient undergoing a therapeutic procedure performed under the direction and supervision of a licensed physician,

as long as all of the health care services provided by the blood establishment are related to its activities as a registered blood establishment or the health care services consist of collecting, processing, storing, or administering human hematopoietic stem cells or progenitor cells or performing diagnostic testing of specimens if such specimens are tested together with specimens undergoing routine donor testing.

2. Storage, handling, and recordkeeping of these distributions by a person required to be permitted as a restricted prescription drug distributor must comply with the requirements for wholesale distributors under s. 499.0121, but not those set forth in s. 499.01212 if the distribution occurs pursuant to sub-subparagraph 1.a. or sub-subparagraph 1.b.

3. A person who applies for a permit as a restricted prescription drug distributor, or for the renewal of such a permit, must provide to the department the information required under s. 499.012.

4. The department may adopt rules regarding the distribution of prescription drugs by hospitals, health care entities, charitable organizations, ~~or~~ other persons not involved in wholesale distribution, and blood establishments, which rules are necessary for the protection of the public

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health, safety, and welfare.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete lines 263 - 264

and insert:

by the act; revising a reference; amending s. 381.06014, F.S.; redefining the term "blood establishment" and defining the term "volunteer donor"; prohibiting local governments from restricting access to public facilities or infrastructure for certain activities based on whether a blood establishment is operating as a for-profit organization or not-for-profit organization; prohibiting a blood establishment from considering whether certain customers are operating as for-profit organizations or not-for-profit organizations when determining service fees for selling blood or blood components; requiring that certain blood establishments disclose specified information on the Internet; authorizing the Department of Legal Affairs to assess a civil penalty against a blood establishment that fails to disclose specified information on the Internet; providing that the civil penalty accrues to the state and requiring that it be deposited as received into the General Revenue Fund; amending s. 499.003, F.S.; redefining the term "health care entity" to clarify that a blood establishment is a health care entity that may engage in certain


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activities; amending s. 499.005, F.S.; clarifying provisions that prohibit the unauthorized wholesale distribution of a prescription drug that was purchased by a hospital or other health care entity or donated or supplied at a reduced price to a charitable organization, to conform to changes made by the act; amending s. 499.01, F.S.; exempting certain blood establishments from the requirements to be permitted as a prescription drug manufacturer and register products; requiring that certain blood establishments obtain a restricted prescription drug distributor permit under specified conditions; limiting the prescription drugs that a blood establishment may distribute under a restricted prescription drug distributor permit; authorizing the Department of Health to adopt rules regarding the distribution of prescription drugs by blood establishments; providing an effective date.

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 Regulation Committee

BILL:	SB 1736
INTRODUCER:	Senator Latvala
SUBJECT:	Health Care
DATE:	March 19, 2011
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Stovall	HR	**Pre-meeting**
2.			BC	
3.				
4.				
5.				
6.				

I. Summary:

This bill repeals obsolete and redundant provisions, defines and corrects references to the Joint Commission, updates references to a variety of organizations and state agencies to reflect current titles or responsibilities related to facilities regulated by the Agency for Health Care Administration (AHCA), and streamlines reporting by licensed facilities and state agencies.

The bill makes the following substantive changes:

- Revises provisions affecting nursing homes as follows:
  - Expands the authorized staffing of a geriatric outpatient clinic in a nursing home to include a licensed practical nurse under the direct supervision of a registered nurse, advanced registered nurse practitioner, or physician;
  - Eliminates the requirement for a resident care plan to be signed by certain persons;
  - Authorizes a $1,000 fine per day if a nursing home fails to impose a moratorium on new admissions when the facility has not complied with the minimum-staffing requirements;
  - Eliminates the requirement for a newly hired nursing home surveyor to observe a facility's operations as a part of basic training;
  - Removes the one-year exception for the annual assessment related to Medicaid overpayments for leased nursing homes since the provision has expired;
  - Eliminates the requirement that an "incident" be reported within one-day and only requires reporting if the investigation, which must be completed within 15 days, indicates the incident qualifies as an adverse incident;
  - Requires the AHCA to adopt rules for minimum staffing requirements for nursing homes that serve persons under 21 years of age;
  - Eliminates the reporting of staffing ratios, staff turnover, and staff stability; and

  - Eliminates the monthly reporting of any notice of claims or liability claims filed against the facility;
- Revises provisions affecting assisted living facilities (ALFs) as follows:
  - Repeals the limited nursing services (LNS) specialty license and authorizes LNS to be provided by appropriately licensed persons in an ALF with a standard license;
  - Increases the per-bed fee for a standard-licensed ALF for beds that are not designated for recipients of optional state supplementation payments (OSS), to offset the loss of revenue that is currently generated from the fees associated with the LNS specialty license. The maximum amount that an ALF is required to pay for the standard license fee is increased;
  - Requires additional monitoring, either onsite or by a desk review, for an ALF that has been cited with a class I or class II deficiency. The bill repeals the requirement for additional monitoring inspections of an ALF licensed with an extended congregate care (ECC) specialty license;
  - Requires all ALFs to report electronically to the AHCA, at least semiannually, certain aggregated data related to the residents and staff of the facility;
  - Modifies the AHCA's consultation responsibilities; and
  - Eliminates the monthly reporting of any notice of claims or liability claims filed against the facility;
- Expands the definition of a portable equipment provider within the requirements for a health care clinic license to include a portable *health service* or equipment provider;
- Provides additional exemptions for licensure and regulation as a health care clinic for the following:
  - Pediatric cardiology or perinatology clinic facilities;
  - Certain corporate entities with $250 million or more in annual sales of health care services provided by licensed health care practitioners; and
  - Certain publicly traded entities;
- Enhances the general licensing provisions of part II of ch. 408, F.S., to:
  - Provide that the license renewal notice that the AHCA sends is a *courtesy* notice;
  - Authorize the AHCA to impose an administrative fine, not to exceed $500 per violation, for violations that do not qualify within the classification scheme of class I – class IV violations;
  - Authorize the AHCA to extend the license expiration date for up to 30 days and impose other conditions during that extension period in order to accomplish the safe and orderly discharge of clients or residents; and
  - Prohibit activities related to altering, defacing, or falsifying a license certificate;
- Authorizes the AHCA to impose an administrative fine for class IV violations that are uncorrected or repeated by a licensed intermediate care facility for developmentally disabled persons;
- Requires a Medicaid claim for a prescription drug billed as a 340B prescribed medication to meet certain requirements;
- Transfers responsibilities for Federally Qualified Health Centers from the Department of Health (DOH) to the AHCA;
- Authorizes group or individual health plans to offer rewards and incentives for persons participating in voluntary wellness or health improvement programs; and
- Includes licensed orthotists and prosthetists in the definition of a health care provider under ch. 766, F.S., related to medical malpractice.

This bill amends the following sections of the Florida Statutes: 154.11, 394.4787, 394.741, 395.002, 395.003, 395.0193, 395.1023, 395.1041, 395.1055, 395.10972, 395.2050, 395.3036, 395.3038, 395.602, 400.021, 400.0239, 400.0255, 400.063, 400.071, 400.0712, 400.111, 400.1183, 400.141, 400.142, 400.147, 400.162, 400.19, 400.23, 400.275, 400.484, 400.606, 400.607, 400.915, 400.925, 400.931, 400.932, 400.967, 400.9905, 400.991, 400.9935, 408.034, 408.036, 408.043, 408.05, 408.061, 408.07, 408.10, 408.804, 408.806, 408.810, 408.813, 408.815, 409.91196, 409.912, 409.91255, 429.07, 429.11, 429.17, 429.19, 429.255, 429.35, 429.41, 429.53, 429.54, 429.71, 429.915, 430.80, 440.13, 483.294, 626.9541, 627.645, 627.668, 627.669, 627.736, 641.495, 651.118, 766.1015, and 766.202.

The bill repeals the following sections of the Florida Statutes: 112.0455(10)(e) and (12)(d), 383.325, 395.1046, 395.3037, 400.148, 400.179(2)(e), 400.195, 408.802(11), 429.12(2), 429.23(5), 429.28(3), and 440.102(9)(d).

II. Present Situation:

Health Care Licensing

The AHCA regulates over 41,000 health care providers under several regulatory programs based upon individual licensing statutes and the general licensing provisions in part II of ch. 408, F.S. The health care providers include:

- Laboratories authorized to perform testing under the Drug-Free Workplace Act, as provided under ss. 112.0455 and 440.102, F.S.;
- Birth centers, as provided under ch. 383, F.S.;
- Abortion clinics, as provided under ch. 390, F.S.;
- Crisis stabilization units, as provided under parts I and IV of ch. 394, F.S.;
- Short-term residential treatment facilities, as provided under parts I and IV of ch. 394, F.S.;
- Residential treatment facilities, as provided under part IV of ch. 394, F.S.;
- Residential treatment centers for children and adolescents, as provided under part IV of ch. 394, F.S.;
- Hospitals, as provided under part I of ch. 395, F.S.;
- Ambulatory surgical centers, as provided under part I of ch. 395, F.S.;
- Mobile surgical facilities, as provided under part I of ch. 395, F.S.;
- Health care risk managers, as provided under part I of ch. 395, F.S.;
- Nursing homes, as provided under part II of ch. 400, F.S.;
- Assisted living facilities, as provided under part I of ch. 429, F.S.;
- Home health agencies, as provided under part III of ch. 400, F.S.;
- Nurse registries, as provided under part III of ch. 400, F.S.;
- Companion services or homemaker services providers, as provided under part III of ch. 400, F.S.;
- Adult day care centers, as provided under part III of ch. 429, F.S.;
- Hospices, as provided under part IV of ch. 400, F.S.;
- Adult family-care homes, as provided under part II of ch. 429, F.S.;
- Homes for special services, as provided under part V of ch. 400, F.S.;
- Transitional living facilities, as provided under part V of ch. 400, F.S.;

- Prescribed pediatric extended care centers, as provided under part VI of ch. 400, F.S.;
- Home medical equipment providers, as provided under part VII of ch. 400, F.S.;
- Intermediate care facilities for persons with developmental disabilities, as provided under part VIII of ch. 400, F.S.;
- Health care services pools, as provided under part IX of ch. 400, F.S.;
- Health care clinics, as provided under part X of ch. 400, F.S.;
- Clinical laboratories, as provided under part I of ch. 483, F.S.;
- Multiphasic health testing centers, as provided under part II of ch. 483, F.S.; and
- Organ, tissue, and eye procurement organizations, as provided under part V of ch. 765, F.S.

The general licensing provisions contain standards for licensure application requirements, ownership disclosure, staff background screening, inspections, and administrative sanctions. Each provider type has an authorizing statute (as listed above) that includes unique provisions for licensure beyond the general licensing provisions. If a conflict exists between the general licensing provisions and the authorizing statute, s. 408.832, F.S., provides that the general licensing provisions prevail.

There are several references in the authorizing statutes that conflict or duplicate regulations in the general licensing provisions, including references to the classification of deficiencies, penalties for an intentional or negligent act by a provider, provisional licenses, proof of financial ability to operate, inspection requirements, and plans of corrections from providers.

Nursing Homes

Nursing homes provide long-term and sub-acute care to persons in need of 24-hour nursing services or significant supportive services. Nursing home residents are generally frail, physically and psychosocially compromised, heavily dependent upon others for basic care and sustenance, and in some cases near the end of their lives. When residents live in an environment where they are totally dependent on others, they are especially vulnerable to abuse, neglect, and exploitation.

The quality of care and quality of life for residents of nursing homes have been a concern for decades. Nursing home regulation has evolved over the past 20 years at the state and federal levels. In February 2001, the Committee on Health, Aging and Long-Term Care in the Florida Senate published Interim Project Report 2001-025, *Long-Term Care Affordability and Availability*.[1] This report lays out the historical landscape and challenges of long-term care in Florida as it existed in the early part of this decade. Generally, the nursing home system in Florida was near crisis with increasing litigation and adverse judgments, spiraling liability insurance premiums or the inability to obtain liability coverage from regulated carriers, financial instability of nursing homes, and concerns regarding the quality of care that patients were receiving and prospective care based on increasingly more complex resident needs. Chapter 2001-45, Laws of Florida (L.O.F.), stemming in part from the Interim Project Report 2001-025, represented a significant overhaul of the long-term care system in Florida. Among other things, this law established a monthly reporting requirement of liability claims filed against

[1] The Florida Senate Interim Project Report 2001-025, *Long-Term Care Affordability and Availability*, may be found at <http://www.flsenate.gov/data/Publications/2001/Senate/reports/interim_reports/pdf/2001-025hc.pdf> (Last visited on March 19, 2011).

nursing homes. This data, as well as other data related to nursing homes was included in a Semi-annual Report on Nursing Homes that the AHCA was required to submit to the Governor and Legislature. This statutory reporting obligation in s. 400.195, F.S., expired on June 30, 2005. Cumulative data is reported on the AHCA's website that reflects trending information on the number of claims filed statewide monthly and quarterly.[2]

Assisted Living Facilities

An assisted living facility (ALF) provides housing, meals, personal care services, and supportive services to older persons and disabled adults who are unable to live independently. ALFs are intended to be an alternative to more restrictive, institutional settings for individuals who need housing and supportive services, but who do not need 24-hour nursing supervision. Generally, an ALF provides supervision, assistance with personal care services, such as bathing, dressing, eating, and assistance with or administration of medications.

As of December 2009, there were 2,830 ALFs licensed with a standard license by the AHCA in this state, for a total of 80,539 beds.[3] In addition to a standard license, an ALF may have specialty licenses that authorize an ALF to provide LNS, limited mental health services,[4] and ECC services. As of September 2009, there were 475 ALFs licensed with a standard license only, for a total of 32,356 beds.[5]

LNS Specialty License
An LNS license enables an ALF to provide, directly or through contract, a select number of nursing services in addition to the personal services that are authorized under the standard license. As of December 2009, there were 977 ALFs licensed with an LNS specialty license.[6]

The nursing services authorized to be provided with this license are limited to acts specified in administrative rules,[7] may only be provided as authorized by a health care provider's order, and

[2] *See:* <http://www.fdhc.state.fl.us/MCHQ/Long_Term_Care/FDAU/docs/LiabilityClaims/NH_Chart.pdf> (Last visited on March 19, 2011).
[3] Source: The AHCA 2010 Bill Analysis & Economic Impact Statement for SPB 7018, on file with the Senate Health Regulation Committee.
[4] An ALF that serves three or more mental health residents must obtain a limited mental health specialty license. A mental health resident is an individual who receives social security disability income (SSDI) due to a mental disorder or supplemental security income (SSI) due to a mental disorder, and receives OSS.
[5] Source: The AHCA in an email to committee professional staff dated September 23, 2009.
[6] *Id*, fn 5. The AHCA does not track the number of LNS beds.
[7] Rule 58A-5.031, F.A.C. The additional nursing services that might be performed pursuant to the LNS license include: conducting passive range of motion exercises; applying ice caps or collars; applying heat, including dry heat, hot water bottle, heating pad, aquathermia, moist heat, hot compresses, sitz bath and hot soaks; cutting the toenails of diabetic residents or residents with a documented circulatory problem if the written approval of the resident's health care provider has been obtained; performing ear and eye irrigations; conducting a urine dipstick test; replacing an established self-maintained indwelling urinary catheter, or performing an intermittent urinary catheterization; performing digital stool removal therapies; applying and changing routine dressings that do not require packing or irrigation, but are for abrasions, skin tears and closed surgical wounds; caring for stage 2 pressure sores, (care for stage 3 or 4 pressure sores are not permitted); caring for casts, braces and splints, (care for head braces, such as a halo, is not permitted); assisting, applying, caring for, and monitoring the application of anti-embolism stockings or hosiery; administering and regulating portable oxygen; applying, caring for, and monitoring a transcutaneous electric nerve stimulator (TENS); performing catheter, colostomy, and ileostomy care and maintenance; conducting nursing assessments; and, for hospice patients, providing any nursing service permitted within the scope of the nurse's license, including 24-hour nursing supervision.

must be conducted and supervised in accordance with ch. 464, F.S., relating to nursing, and the prevailing standard of practice in the nursing community. A nursing assessment, that describes the type, amount, duration, scope, and outcomes or services that are rendered and the general status of the resident's health, is required to be conducted at least monthly on each resident who receives a limited nursing service.

An LNS licensee is subject to monitoring inspections by the AHCA or its agents at least twice a year. At least one registered nurse must be included in the inspection team to monitor residents receiving LNS and to determine if the facility is complying with applicable regulatory requirements.[8]

The biennial fee for an LNS license is $296 per license with an additional fee of $10 per resident based on the total licensed resident capacity of the facility.[9] Ostensibly, this fee covers the additional monitoring inspections currently required of facilities with an LNS license.

Licensure Fees

The biennial licensure fees for the ALF standard license and specialty licenses are found in s. 429.07(4), F.S. This section refers to the general health care licensure provisions in part II of ch. 408, F.S. Section 408.805, F.S., provides for licensure fees to be adjusted annually by not more than the change in the Consumer Price Index (CPI) based on the 12 months immediately preceding the increase. The following chart reflects the licensure fees contained in s. 429.07(4), F.S., and the adjusted licensure fees based on the CPI that are currently in effect, for licenses expiring on or after August 1, 2010.[10]

Fee Description	Per s. 429.07(4), F.S.	CPI adjusted (current fee)
Standard ALF Application Fee	$300	$366
Standard ALF Per-Bed Fee (non-OSS)	$50	$61
Total Licensure fee for Standard ALF	$10,000	$13,443
ECC Application Fee	$400	$515
ECC Per-Bed Fee (licensed capacity)	$10	$10
LNS Application Fee	$250	$304
LNS Per-Bed Fee (licensed capacity)	$10	$10

Senate Interim Project Report 2010-118

During the 2009-2010 interim, professional staff of the Senate Committee on Health Regulation reviewed the licensure structure for ALFs. The recommendations in the resulting report are to repeal the LNS specialty license and authorize a standard-licensed ALF to provide the nursing services currently authorized under the LNS license; require an additional inspection fee, adjusted for inflation, for a facility that indicates that it intends to provide LNS; require each ALF to periodically report electronically information, as determined by rule, related to resident

[8] s. 429.07(3)(c), F.S.
[9] s. 429.07(4)(c), F.S., as adjusted per s. 408.805(2), F.S.
[10] Found on the AHCA website at:
<http://ahca.myflorida.com/MCHQ/LONG_TERM_CARE/Assisted_living/alf/ALF_fee_increase.pdf>, (Last visited on March 19, 2010).

population, characteristics, and attributes; authorize the AHCA to determine the number of additional monitoring inspections required for an ALF that provides LNS based on the type of nursing services provided and the number of residents who received LNS as reported by the ALF; and repeal the requirement for the AHCA to inspect *all* the ECC licensees quarterly, instead targeting monitoring inspections for those facilities with residents receiving ECC services.

Liability Claims Reporting
Chapter 2001-45, L.O.F.,[11] also established a monthly reporting requirement of liability claims filed against assisted living facilities. Cumulative data is reported on the AHCA's website that reflects trending information on the number of claims filed statewide monthly and quarterly.[12]

Adult Family-Care Homes

An adult family-care home is a full-time family-type living arrangement, in a private home, under which a person who owns or rents the home provides room, board, and personal care, on a 24-hour basis, for no more than five disabled adults or frail elders who are not relatives. The adult family-care home provider must live in the home. Adult family-care homes are licensed and regulated under part II of ch. 429, F.S., part II of ch. 408, F.S., and Chapter 58A-14, F.A.C., unless the person who owns or rents the home provides room, board, and personal services for not more than two adults who do not receive optional state supplementation, or for only his or her relatives. A frail elder is a functionally impaired person who is 60 years of age or older and who has physical or mental limitations that restrict the person's ability to perform the normal activities of daily living and impede the person's capacity to live independently.

Federally Qualified Health Centers

Federally Qualified Health Centers (FQHCs)[13] are also referred to as rural health clinics. They are certified by the CMS to participate in the Medicare and Medicaid programs and receive federal grant funding. They primarily operate in areas designated as rural areas, having a shortage of personal health services, and having medically underserved populations.

Since 1981, the Florida Association of Community Health Centers, Inc. (FACHC) has been the leading state advocate for community-based health care programs. Focusing on Florida's Federally Qualified Community Health Centers, the Association plays a vital role in educating federal, state and local policymakers about issues relating to health care and the role of the health centers. The primary mission of FACHC is to improve access to quality health services by bringing together agencies, legislators and key persons able to affect health care services.[14]

[11] s. 36, ch. 2001-45, L.O.F., creating s. 400.423, F.S.
[12] *See*: <http://www.fdhc.state.fl.us/MCHQ/Long_Term_Care/FDAU/docs/LiabilityClaims/ALF_Chart.pdf> (Last visited on March 19, 2011).
[13] *See:* 42 C.F.R. 491.
[14] For additional information *see:* <http://www.fachc.org/about-welcome.php>, (Last visited on March 19, 2011).

Wellness or Health Improvement Programs

Chapter 626, F.S., governs the practices of insurance agents and the operations of insurance companies.[15] Section 626.9541, F.S., defines unfair methods of competition and unfair or deceptive acts or practices. The section specifies 32 different acts that qualify under the definition.[16] Among the prohibited acts relating to rates that may be charged to policyholders are: "unfair discrimination," which is defined as knowingly making an unfair discrimination between individuals of the same actuarially supportable class in the amount of premium charged for a policy, or in the benefits payable under the contract, or in the terms and conditions of the contract;[17] and "unlawful rebates," which prohibits paying, directly or indirectly, any valuable consideration or inducement not specified in the contract.[18]

III. Effect of Proposed Changes:

Sections 1, 3, 11, 16, 30, 31, 53, 63, 66, 68, and 76 repeal the following sections of the Florida Statutes:

- s. 112.0455(10)(e) and (12)d), F.S., to remove an obsolete provision concerning drug testing within the Drug-Free Workplace Act. The Division of Statutory Revision requested clarification of this provision. Also this bill repeals a monthly reporting requirement for a laboratory to notify the AHCA of statistical information regarding drug testing;
- s. 383.325, F.S., related to public access to governmental inspection reports for birth centers, since this is required in the general licensing provisions in part II of ch. 408, F.S.;
- s. 395.1046, F.S., related to the AHCA's investigation procedures for complaints against a hospital for violations of the access to emergency services and care provisions under s. 395.1041, F.S. Complaint procedures exist in the general licensing provisions in part II of ch. 408, F.S. The federal process for emergency access complaints dictates that access to emergency services and care complaints be handled similarly to routine complaints;
- s. 395.3037, F.S., related to definitions of Department and Agency as they pertain to stroke centers. These terms are already defined in s. 395.002, F.S., which provides definitions for all of ch. 395, F.S.;
- s. 400.148, F.S., related to the obsolete Medicaid "Up-or-Out" Quality of Care Contract Management Program;
- s. 400.179(2)(e), F.S., related to a one-year exemption to nursing home leasehold bond payments;
- s. 400.195, F.S., related to an obsolete requirement for the AHCA to report on lawsuits against and deficiencies in nursing homes. The statutory reporting requirement was for the period June 30, 2001 through June 30, 2005;
- s. 408.802(11), F.S., related to the general licensure provisions, to delete reference to private review agents. The regulation of private review agents was repealed by the Legislature in 2009;
- s. 429.12(2), F.S., related to change of ownership for assisted living facilities, since this is addressed under the general licensing provisions in part II of ch. 408, F.S.;

[15] *See* ss. 626.011 through 626.99296, F.S.
[16] *See* s. 626.9541(1)(a) through (ff), F.S.
[17] *See* s. 626.9541(1)(g), F.S.
[18] *See* s. 626.9541(1)(h), F.S.

- s. 429.23(5), F.S., to repeal the requirement for an assisted living facility to report monthly to the AHCA any liability claim filed against it, which is currently published in the aggregate on the AHCA's website;
- s. 429.28(3), F.S., to eliminate duplicative provisions related to inspections and monitoring facilities that have been cited with violations. The provision requiring the AHCA to determine whether an ALF licensee is adequately protecting residents' rights in its biennial survey is transferred to s. 429.07, in section 68 of this bill; and
- s. 440.102(9)(d), F.S., to remove a monthly reporting requirement for a laboratory to notify the AHCA of statistical information regarding drug testing under workers' compensation provisions.

Sections 2, 5, 17, 39, 45, 49, 75, 77, 80, 81, 82, 83, 84, and 86 amend the following sections of the Florida Statutes to update the name of certain accrediting organizations, including the Joint Commission:

- s. 154.11, F.S., related to facilities owned and operated by the board of trustees of each public health trust;
- s. 394.741, F.S., related to providers of behavioral health care services;
- s. 395.3038, F.S., related to stroke centers;
- s. 400.925, F.S., related to home medical equipment providers;
- s. 400.9935, F.S., related to health care clinics;
- s. 408.05, F.S., related to health care quality measures that are reported by the AHCA;
- s. 430.80, F.S., related to the teaching nursing home pilot project;
- s. 440.13, F.S., related to workers' compensation;
- s. 627.645, F.S., related to health insurance;
- s. 627.668, F.S., related to insurance coverage for mental and nervous disorders;
- s. 627.669, F.S., related to insurance for substance abuse impaired persons;
- s. 627.736, F.S., related to personal injury protection automobile insurance;
- s. 641.495, F.S., related to health maintenance organizations and prepaid health clinics; and
- s. 766.1015, F.S., related to boards or other groups established for quality improvement purposes.

Section 4 amends s. 394.4787, F.S., to correct a cross-reference concerning licensure of a specialty psychiatric hospital.

Section 6 amends s. 395.002, F.S., to redefine the term "accrediting organizations" as it relates to hospitals and other licensed facilities to delete the list of four organizations that are identified in statute. The term is redefined to mean nationally recognized or approved accrediting organizations whose standards incorporate comparable licensure requirements as determined by the AHCA. In addition, the following obsolete definitions are repealed: "initial denial determination," "private review agent," "utilization review," and "utilization review plan."

Section 7 amends s. 395.003, F.S., to remove obsolete language concerning emergency departments located off-site from a licensed hospital.

Section 8 amends s. 395.0193, F.S., related to peer review of physicians within hospitals and licensed facilities, to correct references to the Division of Medical Quality Assurance of the DOH.

Section 9 amends s. 395.1023, F.S., related to reporting actual or suspected cases of child abuse, abandonment, or neglect by hospitals and licensed facilities, to clarify that references to the Department mean the Department of Children and Family Services (DCF).

Section 10 amends s. 395.1041, F.S., to remove obsolete language pertaining to services within a hospital's service capability. The Division of Statutory Revision requested clarification of this provision.

Section 12 amends s. 395.1055, F.S., to require that the AHCA's rulemaking concerning licensed facility beds conform to standards specified by the AHCA, the Florida Building Code, and the Florida Fire Prevention Code.

Section 13 amends s. 395.10972, F.S., to update the reference to the current name of the Florida Society for Healthcare Risk Management and Patient Safety.

Section 14 amends s. 395.2050, F.S., to update the reference to the current name of the Centers for Medicare and Medicaid Services.

Section 15 amends s. 395.3036, F.S., to correct a cross-reference concerning the confidentiality of records and meetings of corporations that lease public health care facilities. The Division of Statutory Revision requested clarification of this provision.

Section 18 amends s. 395.602, F.S., to eliminate one of the conditions that qualifies a hospital as a rural hospital. This condition is a hospital in a constitutional charter county with a population of over 1 million persons that has imposed a local option health service tax, in an area that was directly impacted by a catastrophic event on August 24, 1992, for which the Governor of Florida declared a state of emergency, has 120 beds or less that serves an agricultural community with an emergency room utilization of no less than 20,000 visits, and a Medicaid inpatient utilization rate greater than 15 percent. No hospitals meet this condition.

Section 19 amends s. 400.021, F.S., to expand the definition of a geriatric outpatient clinic in a nursing home, to add that it may be staffed by a licensed practical nurse under the direct supervision of a registered nurse, advanced registered nurse practitioner, or physician. Currently, the definition of a geriatric outpatient clinic provides that it is to be staffed by a registered nurse or a physician assistant.

The bill also amends the definition of a resident care plan to remove the requirement that the resident care plan be signed by the director of nursing or alternate and the resident or the resident's designee or legal representative.

Section 20 amends s. 400.0239, F.S., to delete an obsolete reference to the Medicaid "Up or Out" Quality of Care Contract Management Program.

Section 21 amends s. 400.0255, F.S., to correct an obsolete cross-reference to an administrative rule concerning fair hearings requested by nursing home residents. This correction was requested by the Joint Administrative Procedures Committee.

Section 22 amends s. 400.063, F.S., to eliminate a cross-reference in the procedures for resident protection and relocation accounts, since the section of law that is referenced was repealed. The Division of Statutory Revision requested clarification of this provision.

Section 23 amends s. 400.071, F.S., to repeal disclosure of certain information related to the closure of other licensed facilities in which the nursing home licensure applicant held a controlling interest. The bill amends s. 400.111, F.S., to require certain disclosures to replace these requirements. This section also repeals the requirement for a nursing home licensure applicant to identify the number of beds and number of Medicare and Medicaid certified beds since this is required in the general licensing provisions in s. 408.806(1)(d), F.S.

Section 24 amends s. 400.0712, F.S., to make technical changes to move into another subsection the authority for a nursing home to request an inactive license for a portion of its beds and to provide a cross-reference to the general licensure provisions in part II of ch. 408, F.S.

Section 25 amends. s. 400.111, F.S., to require disclosure of certain information concerning other licenses that a controlling interest has held when requested by the AHCA instead of a mandatory submission for all nursing home licensure applications.

Section 26 amends s. 400.1183, F.S., to repeal the requirement for a nursing home to report to the AHCA upon relicensure information concerning grievances received by the facility; instead, requiring the nursing home to maintain a log of the grievances for the AHCA's inspection.

Section 27 amends s. 400.141, F.S., to authorize a nursing home with a standard licensure status or one that has been awarded a Gold Seal, to provide respite care for a maximum of 14 days per stay pursuant to an abbreviated plan of care. The abbreviated plan of care must, at a minimum, include nutritional requirements, medication orders, physician orders, nursing assessments, and dietary preferences. A contract must be executed for each person admitted under the respite care program that specifies the services to be provided and the charges for those services. This contract may be used for subsequent admissions for that person within one year after the date of execution. A respite resident may receive a total of 60 days of respite care within a 12-month period. A prospective respite resident must provide medical information from one of the specified practitioners along with an order for respite care. Provisions are made for the respite resident to use his or her personal medications and the nursing home must arrange for transportation to certain health care services to ensure continuity of care and services while the resident is receiving the respite care. A person admitted to the nursing home under the respite care program is exempt from requirements related to discharge planning and is covered by certain residents' rights.

A nursing home is required to maintain complete clinical records on each resident that are readily accessible and systematically organized.

The bill eliminates the nursing home reporting requirements pertaining to staffing ratios, staff turnover, and staff stability.

The bill eliminates the requirement for a licensed nursing facility to disclose, within 30 days after the nursing home executes an agreement with a company to manage the nursing home, certain information related to the closure of other licensed facilities in which the management company held a controlling interest.

The bill requires the AHCA to fine a nursing facility $1,000 if it fails to impose a moratorium on new admissions when the facility has not complied with the minimum-staffing requirements.

The bill repeals the requirement for a licensed nursing home to report to the AHCA information concerning filing for bankruptcy, divestiture of assets, or corporate reorganization. A similar provision is amended into the general licensing provisions in s. 408.810, F.S., in this bill.

Section 28 amends s. 400.142, F.S., to eliminate the requirement for the AHCA to adopt rules related to nursing facility staff implementing an order to withhold or withdraw cardiopulmonary resuscitation inasmuch as statutory provisions exist in s. 401.45, F.S., for emergency medical responders.

Section 29 amends s. 400.147, F.S., to remove the 1-day notification requirement to the AHCA when a risk manager in a nursing home receives an incident report. The risk manager for the nursing home is only required to report to the AHCA if, after the investigation, it is determined that the incident was an adverse incident. The investigation must be completed within 15 days.

This section also repeals the requirement for a licensed nursing home to report to the AHCA, monthly, any notice of claims against the facility for violation of a resident's rights or negligence. This information has been required to be submitted since 2001. It was included in the AHCA's Semi-Annual Report on Nursing Homes, which is repealed in another section of this bill. Currently this information is published in the aggregate on the AHCA's website;

Section 32 amends s. 400.19, F.S., to authorize the AHCA to certify correction of a class III or class IV deficiency related to resident rights or resident care based on written documentation from the facility.

Section 33 amends s. 400.23, F.S., to update the reference to the current name of the Division of Children's Medical Services Network of the DOH. The Division of Statutory Revision requested clarification of this provision.

In addition, the bill requires the AHCA to adopt rules for minimum staffing requirements for nursing homes that serve persons under 21 years of age. These rules are to be adopted in collaboration with the DOH Division of Children's Medical Services Network and must require, at a minimum, 3.9 hours of direct care per resident per day for residents requiring skilled care and 5 hours of direct care per resident per day for residents who are fragile.

Section 34 amends s. 400.275, F.S., to eliminate the requirement for the AHCA to assign each newly hired nursing home surveyor to observe a facility's operations as a part of basic training.

The AHCA nursing home staff must be qualified under the federal requirements for the Surveyor Minimum Qualifications Test.

Section 35 amends s. 400.484, F.S., related to violations by home health agencies, to cross-reference the definitions of the classes of violations in the general licensing provisions in part II of ch. 408, F.S., thereby eliminating redundant definitions for deficiencies in this section.

Section 36 amends s. 400.606, F.S., to eliminate the requirement for an applicant for a hospice license to submit the projected annual operating cost of the hospice. Under the general licensing provisions, in part II of ch. 408, F.S., an applicant for licensure must submit information pertaining to the applicant's financial ability to operate.

Section 37 amends s. 400.607, F.S., to clarify the grounds for administrative action by the AHCA against a hospice and eliminate duplicative provisions found in the general licensing provisions in part II of ch. 408, F.S.

Section 38 amends s. 400.915, F.S., to correct an obsolete cross-reference to an administrative rule concerning the construction or renovation of a prescribed pediatric extended care center. This correction was requested by the Joint Administrative Procedures Committee.

Section 40 amends s. 400.931, F.S., to repeal the option for an applicant for a home medical equipment provider license to submit a $50,000 surety bond in lieu of proof of financial ability to operate.

Section 41 amends s. 400.932, F.S., to clarify the grounds for administrative action by the AHCA against a home medical equipment provider.

Section 42 amends s. 400.967, F.S., related to violations by intermediate care facilities for developmentally disabled persons, to cross-reference the definitions of the classes of violations in the general licensing provisions in part II of ch. 408, F.S., thereby eliminating redundant definitions for deficiencies in this section. In addition, the bill requires the AHCA to impose an administrative fine not to exceed $500 for each occurrence and each day that an uncorrected or repeated class IV violation exists.

Section 43 amends s. 400.9905, F.S., to revise the definitions related to the health care clinic act. This includes an entity that contracts with or employs a person to provide portable *health care services or* equipment to multiple locations, which bills third-party payors for those services, and that otherwise, meets the definition of a clinic.

The bill also exempts the following entities from the definition and regulation as a health care clinic:

- A pediatric cardiology or perinatology clinic facility that is a publicly traded corporation or that is wholly owned by a publicly traded corporation;
- Entities that are owned by a corporation that has $250 million or more in total annual sales of health care services provided by licensed health care practitioners if at least one of the owners is a Florida-licensed health care practitioner who is responsible for supervising the

business activities and legally responsible for compliance with state law for purposes of this section of law; and

- Entities that are owned or controlled, directly or indirectly, by a publicly traded entity with $100 million or more in total annual revenues derived from providing health care services by licensed health care practitioners who are employed with or contracted by the entity.

Section 44 amends s. 400.991, F.S., to repeal the option for an applicant for a health care clinic license to submit a $500,000 surety bond in lieu of proof of financial ability to operate. Another cross-reference is added to reflect an existing provision concerning proof of financial ability to operate for an applicant for a health care clinic license.

Section 46 amends s. 408.034, F.S., to correct a reference to the AHCA's authority to issue licenses to intermediate care facilities for developmentally disabled persons under part VIII of ch. 400, F.S., without the facility first obtaining a certificate of need as required by s. 408.036(1)(a), F.S.

Section 47 amends s. 408.036, F.S., to eliminate a cross-reference to an exception to the certificate-of-need requirements for a hospice. No exceptions are currently provided in s. 408.043, F.S.

Section 48 amends s. 408.043, F.S., to remove the term "primarily" to clarify that a certificate of need is required to establish or expand an inpatient hospice facility unless the facility is licensed as a health care facility, such as a hospital or skilled nursing facility.

Section 50 amends s. 408.061, F.S., to remove an inappropriate reference to an administrative rule that describes data reporting.

Section 51 amends s. 408.07, F.S., to conform the definition of a rural hospital to the provisions related to licensure of rural hospitals in s. 395.602, F.S., as amended in this bill.

Section 52 amends s. 408.10, F.S., to eliminate the requirement for the AHCA to investigate consumer complaints related to health care facilities' billing practices and publish related reports.

Section 54 amends s. 408.804, F.S., related to the general licensing provisions. The act of, or causing another to alter, deface, or falsify a license certificate is a misdemeanor of the second degree. A licensee or provider who displays an altered, defaced, or falsified license certificate is subject to an administrative fine of $1,000 for each day of illegal display and a license or application for a license is subject to revocation or denial.

Section 55 amends s. 408.806, F.S., related to general licensing provisions, to require the AHCA to send a courtesy notice to the licensee 90 days before renewal. However, the AHCA's failure to do so or the licensee's failure to receive the notice does not excuse the licensee's responsibility to timely submit the renewal application and fee. Submission of the renewal application, application fee, and any applicable late fees is required to renew the license.

Section 56 amends s. 408.813, F.S., related to general licensing provisions, to authorize the AHCA to impose an administrative fine, not to exceed $500 per violation, for violations that do

not qualify within the classification scheme of class I – class IV violations. Unclassified violations might include: violating any term or condition of a license; violating any provision of the general licensing provisions, authorizing statutes, or applicable rules; exceeding licensed capacity without authorization; providing services beyond the scope of the license; or violating a moratorium.

Section 57 amends s. 408.815, F.S., related to general licensing provisions, to authorize the AHCA to extend the license expiration date for up to 30 days and to impose other conditions during that 30-day extension in order to accomplish the safe and orderly discharge of clients. The authority to extend is at the discretion of the AHCA after considering the nature and number of clients, the availability and location of acceptable alternative placements, and the ability of the licensee to continue providing care to the clients. This authority does not create any right or entitlement to an extension of a license expiration date.

Section 58 amends s. 409.91196, F.S., related to Medicaid supplemental rebate agreements, to conform a cross-reference due to an amendment in another section of this bill.

Section 59 amends s. 409.912, F.S., to require a Medicaid claim for a prescription drug billed as a 340B prescribed medication to meet certain requirements and be billed at the actual acquisition cost.

Section 60 amends s. 409.91255 to transfer the FQHCs from the DOH to the AHCA and to require the Florida Association of Community Health Centers to develop a 5-year statewide assessment and strategic plan for FQHCs.

Section 61 amends s. 429.07, F.S., to repeal the LNS specialty license and its requirements and the quarterly monitoring requirements related to ALFs that are licensed to provide ECC services. The bill requires an ALF that has been cited within the previous 24 months for a class I or class II violation to be subject to unannounced monitoring. This monitoring may occur through a desk review or onsite, unless a cited violation relates to providing or failing to provide nursing care. In that case, a registered nurse is required to participate in at least two onsite monitoring visits within a 12-month period. The monitoring requirement applies regardless of the status of the enforcement or disciplinary action for the cited violation.

The biennial facility licensure fee is set at $371 and the per-bed licensure fee for a standard license is increased to $71 (an increase of $10) from the current per-bed licensure fee (CPI adjusted) of $61. The other licensure fees in this section are amended to reflect the current CPI adjusted fee, only. The total standard licensure fee is increased from the current fee (CPI adjusted) of $13,443 to $18,000.

Section 62 amends s. 429.11, F.S., to remove language related to provisional licenses within the authorizing statutes for the ALFs since provisional licenses are authorized in the general licensing provisions in part II of ch. 408, F.S.

Section 64 amends s. 429.17, F.S., to conform provisions related to the ALF licenses to the repeal of the LNS specialty license. This section of law is also amended to remove the

requirement for a plan of correction as a part of issuing a conditional license for an ALF since this is authorized in the general licensing provisions in part II of ch. 408, F.S.

Section 65 amends s. 429.19, F.S., to clarify that a monitoring fee may be assessed against an ALF in addition to an administrative fine.

Section 67 amends s. 429.255, F.S., to eliminate the authorization for an ALF to use volunteers to provide certain health-related services, including: administering medications, taking residents' vital signs, managing individual pill organizers for residents who self-administer medication, giving prepackaged enemas, observing residents and documenting observations on the resident's record or reporting observations to the resident's physician, and performing all duties within the scope of their license or certification in a facility licensed to provide ECC services.

In addition, this section authorizes contracted personnel or facility staff who are licensed under the nurse practice act to provide LNS to residents in a standard-licensed ALF. The licensee is responsible for maintaining documentation of health-related services provided as required by rule and ensuring that staff are adequately trained to monitor residents who have received these health-related services.

Section 69 amends s. 429.35, F.S., to authorize the AHCA to provide the results of an inspection of an ALF to the local ombudsman council and others electronically or through the AHCA's website.

Section 70 amends s. 429.41, F.S., to conform provisions related to rulemaking for ALFs to changes made in this bill.

Section 71 amends s. 429.53, F.S., related to consultation by the agency pertaining to an ALF. The bill expands the staff who may provide consultation and eliminates the requirement for the AHCA to consult in areas that are beyond its jurisdiction and areas of expertise.

Section 72 amends s. 429.54, F.S., to require licensed ALFs to report electronically to the AHCA, semiannually, certain data related to the facility's residents and staffing. This data includes, but is not limited to the:

- Number of residents;
- Number of residents receiving LMH services;
- Number of residents receiving ECC services;
- Number of residents receiving LNS; and
- Professional personnel providing resident services.

The DOEA, in consultation with the AHCA, is required to adopt rules related to these reporting requirements.

Section 73 amends s. 429.71, F.S., related to violations by adult family-care homes, to cross-reference the definitions of the classes of violations in the general licensing provisions in part II of ch. 408, F.S., thereby eliminating redundant definitions for deficiencies in this section. The provisions within the section related to the plan of correction are removed since it is also addressed in the general licensing provisions.

Section 74 amends s. 429.915, F.S., to remove the requirement for a plan of correction as a part of issuing a conditional license for an adult day care facility since this is authorized in the general licensing provisions in part II of ch. 408, F.S.

Section 78 amends s. 483.294, F.S., to correct the inspection frequency for licensed multiphasic health testing centers to biennially, consistent with the general licensing provisions in part II of ch. 408, F.S.

Section 79 amends s. 626.9541, F.S., to authorize group or individual health plans to offer rewards and incentives to members participating in voluntary wellness or health improvement programs.

Section 85 amends s. 651.118, F.S., related to nursing homes in continuing care communities, to conform a cross-reference to changes made in another section of this bill.

Section 87 amends s. 766.202, F.S., to add licensed orthotists and prosthetists to the definition of a health care provider under ch. 766, F.S., related to medical malpractice.

Section 88 provides an effective date of July 1, 2011.

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 Art. I, s. 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:

This bill authorizes an ALF to provide LNS without obtaining an additional specialty license at a fee of $304 plus $10 per-bed fee based on the total licensed resident capacity of the facility. The per-bed licensure fee for all ALFs is increased $10 biennially for non-OSS beds to offset the loss of revenue currently generated from the LNS license and will be used to fund monitoring of any ALF that has been cited with a class I or class II deficiency. The maximum amount that an ALF is required to pay biennially for the

licensure fees associated with the standard license is increased by $4,557 to accommodate the increased per-bed licensure fee increase.

B. Private Sector Impact:

This bill streamlines regulations for 29 provider types regulated by the AHCA through repeal of obsolete or duplicative provisions in licensing laws and reform of regulations related to inspections, electronic publication of documents and reports, timeframes for reporting licensure changes, and financial information and bonds.

The bill does not require an ALF to provide LNS, but an ALF may choose to do so with appropriate nursing personnel without the requirement to obtain an additional specialty license. All ALFs are required to report electronically, at least semiannually, certain information about the facility's residents and professional staffing. Monitoring inspections will be tied to performance rather than requiring a set number of monitoring inspections for each specialty license.

C. Government Sector Impact:

Same as comment for the private sector impact. The AHCA estimated in a similar bill in the 2010 Session, that $55,700 will be saved in certified mail costs as a result of the courtesy notice for license renewal. An analysis for SB 1736 from the AHCA is not available. The AHCA will be able to target its monitoring resources on facilities that have been cited for certain violations rather than whether a facility has a particular type of specialty license. This should generate efficiencies and focus resources on resident protection activities.

The AHCA and the DOH are required to adopt rules, some of which require collaboration with other state agencies.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The DCF noted in its bill analysis that in seven counties, the Sheriff's Office conducts the child protective investigation, not CDF. Accordingly, the DCF recommends the following amendment:
Strike lines 526 through 528 and insert:
Department <u>of Children and Family Services, or their authorized agent,</u> a staff physician to act a liaison between the hospital and the Department of Children and Family Services <u>or Sheriff's Office</u> which is investigating the

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Regulation (Garcia) recommended the following:

Senate Amendment (with title amendment)

Delete line 16
and insert:
for coverage under Medicaid, subject to federal rules. If federal rules do not allow for the presumptive eligibility contemplated in this subsection, the Agency for Health Care Administration shall seek federal waiver authority to implement such presumptive eligibility.

================ T I T L E A M E N D M E N T ================
And the title is amended as follows:

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Delete line 6

and insert:

infant; requiring the Agency for Health Care Administration to seek a federal waiver under certain conditions; providing an effective date.

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 Regulation Committee

BILL:	SB 1454
INTRODUCER:	Senator Garcia
SUBJECT:	Treatment of a Surrendered Newborn Infant
DATE:	March 17, 2011
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Brown	Stovall	HR	**Pre-meeting**
2.			BC	
3.				
4.				
5.				
6.				

I. Summary:

The bill provides that when a surrendered newborn infant is admitted to a hospital under s. 383.50, F.S., the birth mother who bore the infant, until the time of discharge from the hospital, is presumed eligible for coverage under Medicaid, subject to federal rules. This presumptive Medicaid eligibility for the birth mother is provided in conjunction with the newborn infant's presumptive Medicaid eligibility under current law, which is also subject to federal rules.

This bill substantially amends the following sections of the Florida Statutes: 383.50.

II. Present Situation:

Infant "safe haven" legislation has been enacted in most states as "an incentive for mothers in crisis to safely relinquish their babies to designated locations where the babies are protected and provided with medical care until a permanent home is found."[1] Safe haven laws generally allow the parent to remain anonymous and avoid prosecution for abandonment or neglect in exchange for safely surrendering the baby.[2]

Florida passed newborn safe haven legislation in 2000.[3] Regarding the treatment of a surrendered newborn infant, current Florida law in s. 383.50, F.S., provides:

[1] Child Welfare Information Gateway, Infant Safe Haven Laws (May 2010), available at http://www.childwelfare.gov/systemwide/laws_policies/statutes/safehaven.pdf (last visited March 17, 2011).
[2] *Id.*
[3] *See* s. 1, ch. 2000-188, Laws of Florida.

- The term "newborn infant" means a child who a licensed physician reasonably believes is approximately 7 days old or younger at the time the child is left at a hospital, emergency medical services station, or fire station.
- The parent who leaves the newborn infant is presumed to have intended to leave the newborn infant and consented to termination of parental rights. If a parent seeks to claim the newborn after surrendering the infant, this presumption can be reversed until a Florida circuit court enters a judgment to terminate parental rights.
- Each emergency medical services station or fire station staffed with full-time firefighters, emergency medical technicians, or paramedics is required to accept any newborn infant left with a firefighter, emergency medical technician, or paramedic. Such personnel are required to provide emergency medical services to the extent he or she is trained to provide those services and to arrange for the immediate transportation of the newborn infant to the nearest hospital having emergency services.
- Except when there is actual or suspected child abuse or neglect, any parent who surrenders a newborn infant and expresses intent to leave the newborn infant and not return, has the absolute right to remain anonymous and to leave at any time and may not be pursued or followed unless the parent seeks to reclaim the newborn infant. When an infant is born in a hospital and the mother expresses intent to leave the infant and not return, upon the mother's request, the hospital or registrar shall complete the infant's birth certificate without naming the mother on the birth certificate.
- Any newborn infant admitted to a hospital in accordance with these provisions is presumed eligible for coverage under Medicaid, subject to federal rules.[4]
- A criminal investigation will not be initiated solely because a newborn infant is left at a hospital under these provisions unless there is actual or suspected child abuse or neglect.

The Department of Children and Families (DCF) does not collect statistical data that specifies how many infants come into state care after being surrendered under s. 383.50, F.S. According to the Gloria M. Silverio Foundation's website, "A Safe Haven for Newborns," 11 infants were left at safe havens (hospitals, emergency medical service stations, or fire stations) in Florida in 2010. A total of 156 newborns have been left since the implementation of the law in 2000.[5]

Presumptive Eligibility for Medicaid: Adults

The only provision for presumptive eligibility for Medicaid currently in effect in Florida is presumptive eligibility for pregnant women. Medicaid services for presumptively eligible pregnant women are restricted by federal statute to prenatal care only.

In order to be eligible for labor, delivery, or other Medicaid services in addition to prenatal care, the woman must be eligible under one of the full Medicaid coverage groups. As part of the presumptive eligibility determination process for a pregnant woman, an application for full

[4] *See* s. 383.50(8), F.S.
[5] *Safe Haven for Newborns Statistics,* available at http://www.asafehavenfornewborns.com//index.php?option=com_content&view=article&id=63&Itemid=165 (last visited March 17, 2011).

Medicaid benefits is filed with the DCF. The woman's presumptive eligibility period ends when the DCF approves or denies the application for full Medicaid benefits. If the application for full Medicaid benefits is approved for the pregnant woman, full Medicaid coverage is available for all covered services during the prenatal period, labor, delivery, and the two-month postpartum period.

There are currently no federal rules permitting presumptive eligibility for inpatient hospital care for adults.

Presumptive Eligibility for Medicaid: Children

Federal rules give states the option to provide presumptive eligibility to children; however, if a states chooses presumptive eligibility for children, it must be applied to *all* children. Florida has not chosen presumptive eligibility for children.

Under the provisions of s. 383.50, F.S., if federal Medicaid rules were to allow for *selective* presumptive eligibility for children, then surrendered newborn infants in Florida could be made presumptively eligible under current Florida policy.

Currently, if surrendered newborn infants come under state care, DCF policy provides for expedited Medicaid determinations. Upon a determination of eligibility, the eligibility is retroactive to the date the DCF received the application. Therefore, eligible infants under these circumstances become Medicaid eligible back to the date of application submission.

III. Effect of Proposed Changes:

Under current federal rules, Florida is unable to presumptively assume Medicaid eligibility on behalf of birth mothers who surrender their newborn infants. Federal rules currently only permit coverage of prenatal services for pregnant women. There is no provision in current federal rules to allow for presumptive eligibility of other adults for other services. Florida could do so only if federal rules change or if Florida were granted a federal waiver, and only then could the bill have any practical effect.

The Agency for Health Care Administration advises that even if federal policy were changed to permit presumptive eligibility for adults other than pregnant women, it is unlikely it would be limited solely to birth mothers of surrendered infants and solely for the period of hospitalization.

Additionally, given the provisions of s. 383.50, F.S., that grant the absolute right to remain anonymous to parents who safely surrender their newborn infants, Medicaid eligibility could be authorized only for those mothers who choose to forfeit their anonymity.

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 the 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:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Under current federal rules, the bill would have no immediate effect, other than to allow for presumptive eligibility for birth mothers of surrendered infants as provided by the bill in case federal law ever does change in this regard. This is similar to the effects of the presumptive eligibility for surrendered newborns under the current provisions of s. 383.50(8), F.S., which provides for selective presumptive eligibility for those newborns, subject to federal rules that currently do not allow selective presumptive eligibility for children. In order for these provisions to have practical effect, the federal rules must change or Florida must be granted a waiver.

VIII. Additional Information:

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

None.

B. Amendments:

None.