The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

HEALTH REGULATION
Senator Garcia, Chair
Senator Sobel, Vice Chair

MEETING DATE: Wednesday, March 9, 2011
TIME: 3:15 —5:15 p.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 584** Flores (Identical H 49)	Massage Therapy; Authorizes the Board of Massage Therapy to issue temporary permits to applicants who meet certain qualifications to practice massage therapy. Provides for the expiration of temporary permits. Provides limitations. Provides for a temporary permit fee. HR 03/09/2011 Fav/CS BC	Fav/CS Yeas 9 Nays 2
2	**SB 702** Flores (Compare H 471)	Umbilical Cord Blood Banking; Requires the Department of Health to post on its website certain resources and a website link to specified materials regarding umbilical cord blood banking. Requires the department to encourage certain health care providers to make available to their pregnant patients information related to umbilical cord blood banking. Provides that a health care provider or health care facility and its employees or agents are not liable for damages in a civil action, etc. HR 03/09/2011 Favorable JU BC	Favorable Yeas 11 Nays 0
3	**SB 398** Jones (Identical H 633)	Chiropractic Medicine; Revises the requirements for obtaining a chiropractic medicine faculty certificate. Requires a person to register as a chiropractic assistant if he or she renders therapeutic services or administers therapeutic agents related to a chiropractic physician's treatment of a patient. Authorizes the spouse or adult children of a deceased chiropractic physician to hold, operate, pledge, sell, mortgage, assign, transfer, own, or control the deceased chiropractic physician's ownership interests under certain conditions, etc. HR 02/22/2011 Temporarily Postponed HR 03/09/2011 Fav/CS BC RC	Fav/CS Yeas 12 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
4	**SB 490** Jones (Compare CS/H 257)	Medical Expense/Pretrial Detainee/Sentenced Inmate; Provides that the responsibility for paying the expenses of medical care, treatment, hospitalization, and transportation for a person who is ill, wounded, or otherwise injured during or as a result of an arrest for a violation of a state law or a county or municipal ordinance is the responsibility of the person receiving the medical care, treatment, hospitalization, or transportation. Removes provisions establishing the order by which medical providers receive reimbursement for the expenses incurred in providing the medical services or transportation, etc. CA 02/21/2011 Favorable HR 03/09/2011 Fav/CS BC	Fav/CS Yeas 11 Nays 1
5	**SB 548** Hays (Identical H 4027)	Obsolete Health Care Provisions; Repeals provisions relating to the designation of separate restrooms and separate dressing rooms for males and females, Florida Healthy People 2010 Program, and the MedAccess program within the Agency for Health Care Administration. HR 03/09/2011 Favorable BC	Favorable Yeas 11 Nays 0
6	**SB 864** Health Regulation	Certificates of Need; Extends until July 1, 2016, provisions authorizing the Agency for Health Care Administration to automatically grant a nursing home's request for a reduction in annual Medicaid patient days as a condition of its certificate of need in specified circumstances. Extends the moratorium on nursing home certificates of need until July 1, 2016. Provides conditions to be met by nursing homes in order to qualify for an exemption to the moratorium on certificates of need for nursing home facilities. HR 03/09/2011 Favorable BC	Favorable Yeas 12 Nays 0
	Consideration of proposed committee bill:		
7	**SPB 7060**	Ratification of Rules; Ratifies a specified rule for the sole and exclusive purpose of satisfying any condition on effectiveness established by s. 120.541(3), F.S., which requires ratification of any rule that meets any of the specified thresholds that may likely have an adverse impact or excessive regulatory cost.	Submitted as Committee Bill
	Consideration of proposed committee bill:		

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
8	**SPB 7062**	Rulemaking; Provides legislative intent regarding the rulemaking process within the Department of Health and the Agency for Health Care Administration. Requires the Department of Health or the Agency for Health Care Administration to meet certain notice requirements by prominent display of such notices on the home page of its website rather than by publication in the Florida Administrative Weekly, etc.	Submitted as Committee Bill

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 584
INTRODUCER:	Health Regulation Committee and Senator Flores
SUBJECT:	Massage Therapy
DATE:	March 9, 2011 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	O'Callaghan	Stovall	HR	**Fav/CS**
2.			BC	
3.				
4.				
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 committee substitute (CS) of SB 584 authorizes a person, who meets certain licensure requirements and graduates from a massage therapy school that is accredited and approved by the Board of Massage Therapy (board), to obtain a temporary permit from the board to practice massage therapy. The temporary permit is valid for 6 months after its issuance by the board, until the applicant fails the massage licensure examination, or until the applicant receives a massage therapist license, whichever occurs first. The CS allows those with a temporary permit to practice massage only under the supervision of a licensed massage therapist, who has an active and unencumbered license.

The CS requires an applicant seeking a temporary permit to practice massage therapy to pay a one-time fee of $50.

The CS provides an effective date of January 3, 2012.

This CS substantially amends the following sections of the Florida Statutes: 480.041 and 480.044.

II. Present Situation:

Background

The American Massage Therapy Association (AMTA)[1] estimated that in 2010, massage therapy was a $12-17 billion industry. The AMTA also estimated that there are approximately 280,000 to 320,000 massage therapists and massage school students in the United States. According to the U.S. Department of Labor in 2010, employment for massage therapists is expected to increase 19 percent from 2008 to 2018, faster than the average for all occupations.[2]

In May 2008, median hourly wages of massage therapists, including gratuities, were $16.78. The middle 50 percent earned between $11.36 and $25.14. The lowest 10 percent earned less than $8.01, and the highest 10 percent earned more than $33.47. Because many therapists work part time, yearly earnings can vary considerably, depending on the therapist's schedule. Generally, massage therapists earn some portion of their income as gratuities. For those who work in a hospital or other clinical setting, however, tipping is not common.[3]

Currently, 43 states and the District of Columbia regulate massage therapists or provide voluntary state certification.[4] In states that regulate massage therapy, massage therapists must meet the legal requirements to practice, which may include minimum hours of initial training and passing an exam. In states that do not regulate massage therapy, this task may fall to local municipalities. Most states that license massage therapists require a passing grade on the Massage & Bodywork Licensing Exam (MBLEx) or one of two exams provided by the National Certification Board for Therapeutic Massage & Bodywork.[5]

Florida Regulation of Massage Therapists and Massage Establishments

Massage therapists and massage establishments in Florida are regulated by the board, within the DOH, under the Massage Practice Act, ch. 480, F.S., and Chapter 64B7, Florida Administrative Code. A person must be licensed as a massage therapist to practice massage for compensation, unless otherwise specifically exempted under the Massage Practice Act.[6] In order to be licensed as a massage therapist, an applicant must:

- Be at least 18 years old or have received a high school diploma or graduate equivalency diploma;

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[1] AMTA is the largest non-profit, professional association serving more than 56,000 massage therapists, massage students, and massage schools. *See* AMTA, *2011 Massage Therapy Industry Fact Sheet*, available at: http://www.amtamassage.org/articles/2/PressRelease/detail/2320 (Last visited on March 4, 2011).

[2] U.S. Department of Labor, Bureau of Labor Statistics; *Occupational Outlook Handbook, 2010-11 Edition: Massage Therapists*; available at http://www.bls.gov/oco/ocos295.htm#projections_data (Last visited on March 1, 2011).

[3] *Id.*

[4] AMTA, *2011 Massage Therapy Industry Fact Sheet*, available at: http://www.amtamassage.org/articles/2/PressRelease/detail/2320 (Last visited on March 4, 2011). A list of states and a summary of their massage regulations is available at: http://www.massagetherapy.com/_content/careers/MTreg.pdf (Last visited on March 4, 2011). Currently, Alaska, Idaho, Kansas, Minnesota, Oklahoma, Vermont, and Wyoming do not regulate massage therapy.

[5] AMTA, *2011 Massage Therapy Industry Fact Sheet*, available at: http://www.amtamassage.org/articles/2/PressRelease/detail/2320 (Last visited on March 4, 2011).

[6] Section 480.047(1)(a), F.S. *See also* s. 480.033(4), F.S.

- Complete a course of study at a board-approved massage school[7] or apprenticeship program; and
- Pass an examination,[8] which is currently offered in English and in Spanish.[9]

Licensed massage therapists may practice in a licensed massage establishment, at a client's residence or office, or at a sports event, convention or trade show.[10] Sexual misconduct, defined as a violation of the professional relationship through the use of such relationship to engage or attempt to engage in sexual activity outside the scope of the profession, is strictly prohibited.[11]

A person may be approved by the board to become an apprentice to study massage under the instruction of a licensed massage therapist, if the person meets the qualifications stated in Rule 64B7-29.002, Florida Administrative Code. To qualify for an apprenticeship, the applicant must have secured the sponsorship of a sponsoring massage therapist, complete a DOH application, pay a $100 fee, and must not be enrolled simultaneously as a student in a board-approved massage school.[12]

Section 480.43, F.S., provides that a massage establishment license is required at any facility where massage therapy services are offered by a licensed massage therapist and directs the board to adopt application criteria. It also provides that massage establishment licenses may not be transferred to a new owner, but may be transferred to a new location if the new location is inspected and approved by the board and an application and inspection fee has been paid. A license may be transferred from one business name to another if approved by the board and if an application fee has been paid.

The board's rules include insurance requirements, compliance with building codes, and safety and sanitary requirements, and require a licensed massage therapist to be onsite any time a client is receiving massage services.[13] Upon receiving an application, the DOH inspects the establishment to ensure it meets the licensure requirements.[14] Once licensed, the DOH inspects the establishment at least annually.[15]

An application for a massage establishment license may be denied for an applicant's conviction of crimes related to the practice of massage, and must be denied for convictions of enumerated crimes within 15 years of application[16] and for past sexual misconduct.[17]

It is a misdemeanor of the first degree to operate an unlicensed massage establishment.[18] Currently, upon receiving a complaint that unlicensed activity is occurring, the DOH's Medical

[7] A list of board-approved massage schools is available at: http://www.doh.state.fl.us/mqa/massage/lst_ma-school.pdf (Last visited on March 4, 2011).
[8] Section 480.042, F.S.
[9] Rule 64B7-25.001(3), F.A.C.
[10] Section 480.046(1)(n), F.S.
[11] Section 480.0485, F.S. *See also* Rule 64B7-26.010, F.A.C.
[12] *See* rule 64B7-27.005, for the apprentice fee amount.
[13] Rule 64B7-26.003, F.A.C.
[14] Rule 64B7-26.004, F.A.C.
[15] Rule 64B7-26.005, F.A.C.
[16] Section 456.0635, F.S.
[17] Section 456.063, F.S.

Quality Assurance inspectors coordinate with local law enforcement. Unlicensed practice of massage therapy is punishable as a third-degree felony.[19] The DOH may issue cease and desist notices, enforceable by filing for an injunction or writ of mandamus and seek civil penalties against the unlicensed party in circuit court.[20] The DOH may also impose, by citation, an administrative penalty up to $5,000. While the DOH has investigative authority, it does not have arrest authority or sworn law enforcement personnel.

III. Effect of Proposed Changes:

Section 1 amends s. 480.041, F.S., to authorize the board to issue a temporary permit to practice massage therapy to an applicant who graduates from a massage therapy school that is board-approved and accredited by an accrediting agency recognized by the U.S. Department of Education.

An applicant only qualifies to apply for a temporary permit if he or she is at least 18 years of age or has received a high school diploma or graduate equivalency diploma, has completed a course of study at an accredited and board-approved massage school, and has not yet taken the examination required for licensure. An applicant must apply to the DOH in writing upon forms prepared and furnished by the DOH. Applicant's who receive a temporary permit are subject to the provisions in s. 480.046, F.S., which specifies circumstances under which the DOH can deny a license or conduct a disciplinary action.

This section specifically exempts applicants for temporary permits from the:

- Licensure requirements that require a passing grade on an examination administered by the DOH;
- Board's rules that require education, examination, and certification for the practice of colonic irrigation;
- Board's rules relating to licensing procedures for those desiring to be licensed in Florida and who hold an active license in, and have practiced in, another state, territory, or jurisdiction of the U.S. or any foreign national jurisdiction which has licensing standards substantially similar to, equivalent to, or more stringent than the standards in Florida for licensure.

The temporary permit is only valid for 6 months after issuance by the board, until the applicant fails the massage licensure examination, or receives a massage therapist license, whichever occurs first. A person practicing massage therapy under a temporary permit must be supervised by a licensed massage therapist who has a full, active, and unencumbered license.

Section 2 amends s. 480.044, F.S., to require the board to set a $50 fee for temporary permits for providing massage therapy services.

Section 3 provides an effective date of January 3, 2012.

[18] Section 480.047, F.S.
[19] Section 456.065, F.S.
[20] *Id.*

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this CS 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 CS 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 CS 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:

Applicants seeking a temporary permit to perform massage therapy services will be required to pay a fee of $50.

B. Private Sector Impact:

Businesses offering massage therapy services may be able to offer services to the public for less money if persons with temporary permits, while supervised, are able to provide such services at a reduced rate.

C. Government Sector Impact:

The DOH has estimated that approximately 2,606 applicants would have requested a temporary permit if 75 percent of the 3,475 applicants for massage therapy licensure in fiscal year 2009-10 requested a temporary permit. The DOH has reported that it will not require additional resources to implement the provisions of this bill and will absorb the costs associated with rulemaking responsibilities and the changes that will be needed for the DOH's application forms and database. The estimated revenue the DOH expects to generate from the temporary permit fees is $130,300.[21]

VI. Technical Deficiencies:

The bill in lines … requires applicants seeking a temporary permit to meet all of the qualifications for licensure under s. 480.041, F.S., except for a provision under paragraph (1)(b) pertaining to the completion of an apprenticeship program and paragraphs (1)(c), (4)(b), and (4)(c). Paragraphs (4)(b) and (4)(c) require the *board to adopt rules* concerning the practice of

[21] Department of Health, *Bill Analysis, Economic Statement, and Fiscal Note for SB 584*, dated February 8, 2011. A copy of this analysis is on file with the Senate Health Regulation Committee.

colonic irrigation and licensing procedures for practitioners licensed in other states. Therefore, it may be more appropriate to say in lines … that an applicant must meet all of the licensure requirements except for a provision under paragraph (1)(b) pertaining to the completion of an apprenticeship program, paragraph (1)(c), and any rules adopted under paragraphs (4)(b) and (4)(c).

VII. Related Issues:

In line 33, it is unclear whether the intent is to require a licensed massage therapist to provide "direct supervision" of a person practicing massage therapy under a temporary permit. Furthermore, the term "supervision" is not defined in ch. 480, F.S., the Massage Practice Act.

On January 28, 2011, during a board meeting, the board voted unanimously to oppose this bill. The board gave the following reasons:

- Temporary permits do not serve the public health and safety;
- Temporary permit holders do not meet basic entry level requirements with regards to practicing with reasonable skill and safety because they have not proven competency by passing the entry level examinations. The examinations are provided daily via computer based testing and may be taken prior to or immediately after graduation from an approved program.
- Supervision required is not sufficiently defined without rulemaking authority by the board.
- The bill will increase regulatory costs.[22]

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 the Health Regulation Committee on March 9, 2011:
The CS differs from the bill in that it:

- Authorizes the Department of Health to prepare and furnish the appropriate application forms to applicants seeking temporary permits to practice massage therapy.
- Sets the temporary permit fee at $50 to avoid rulemaking procedures to determine a fee.
- Extends the effective date to January 3, 2012, to allow the Department of Health time to implement provisions of the bill.
- Clarifies that the board may only issue a temporary permit to an applicant who graduates from a massage school that is accredited by an accrediting agency recognized by the U.S. Department of Education.
- Clarifies that an applicant may not complete an apprentice program in lieu of completing a course of study at a board-approved massage school in order to be eligible to apply for a temporary permit.

[22] *Supra* fn. 21.

- Specifies that an applicant may apply for a temporary permit if the applicant has completed a course of study at a massage school that has been board-approved and accredited by an accrediting agency recognized by the U.S. Department of Education.

B. Amendments:

None.

154674

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/09/2011	.	
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The Committee on Health Regulation (Garcia) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Subsection (5) is added to section 480.041, Florida Statutes, to read:

480.041 Massage therapists; qualifications; temporary permits; licensure; endorsement.—

(5) An applicant for a temporary permit shall apply to the department in writing upon forms prepared and furnished by the department in accordance with the board's rules.

(a) The board may issue a temporary permit to practice

massage therapy to an applicant who:

1. Graduates from a massage therapy school that is accredited by an accrediting agency recognized by the United States Department of Education.

2. Meets all of the qualifications for licensure under this section, except for the provision of paragraph (1)(b) that pertains to the completion of an apprenticeship program and paragraphs (1)(c), (4)(b), and (4)(c).

(b) If an applicant desires to practice massage therapy before becoming licensed by examination and completes a course of study at a massage school that has been board-approved and accredited under (5)(a)1., the applicant may apply for a temporary permit in accordance with rules adopted under this chapter.

(c) A temporary permit is valid for 6 months after issuance by the board or until the applicant fails the massage licensure examination or receives a massage therapist license, whichever occurs first.

(d) An applicant for licensure by examination who practices under a temporary permit may practice massage therapy only under the supervision of a licensed massage therapist who has a full, active, and unencumbered license.

Section 2. Paragraph (m) is added to subsection (1) of section 480.044, Florida Statutes, to read:

480.044 Fees; disposition.—

(1) The board shall set fees according to the following schedule:

(m) Temporary permit fee: $50.

Section 3. This act shall take effect January 3, 2012.

154674

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43
44 ================ T I T L E A M E N D M E N T ================
45 And the title is amended as follows:
46 Delete everything before the enacting clause
47 and insert:
48 A bill to be entitled
49 An act relating to massage therapy; amending s.
50 480.041, F.S.; requiring applicants to apply for a
51 temporary permit upon forms prepared and furnished by
52 the Department of Health in accordance with the Board
53 of Massage Therapy's rules; authorizing the Board of
54 Massage Therapy to issue temporary permits to
55 applicants who meet certain qualifications to practice
56 massage therapy; providing for the expiration of
57 temporary permits; providing limitations; amending s.
58 480.044, F.S.; providing for a temporary permit fee;
59 providing an effective date.

182458

LEGISLATIVE ACTION

Senate	.	House
Comm: UNFAV	.	
03/09/2011	.	
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The Committee on Health Regulation (Jones) recommended the following:

Senate Amendment to Amendment (154674)

Delete line 16
and insert:
States Department of Education and demonstrate an annual first time passage rate of at least 75 percent.

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 702
INTRODUCER:	Senator Flores
SUBJECT:	Umbilical Cord Blood Banking
DATE:	March 9, 2011
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	O'Callaghan	Stovall	HR	**Favorable**
2.			JU	
3.			BC	
4.				
5.				
6.				

I. Summary:

This bill requires the Department of Health (DOH) to post on its Internet website resources and an electronic link to materials relating to umbilical cord blood which have been developed by the Parent's Guide to Cord Blood Foundation, Inc., including:

- An explanation of the potential value and uses of umbilical cord blood;
- An explanation of the differences between using one's own cord blood cells or another's in the treatment of disease;
- An explanation of the differences between public and private umbilical cord blood banking;
- The options available to a mother relating to stem cells that are contained in the umbilical cord blood after the delivery of her newborn, including donating, storing, or discarding the stem cells;
- The medical processes involved in the collection of cord blood;
- Criteria for medical or family history that can impact a family's consideration of umbilical cord blood banking;
- Options for ownership and future use of donated umbilical cord blood;
- The average cost of public and private umbilical cord blood banking;
- The availability of public and private cord blood banks to residents of Florida; and
- An explanation of which racial and ethnic groups are in particular need of publicly donated cord blood samples based on certain medical data.

This bill requires the DOH to encourage health care providers, who provide health care services directly related to a woman's pregnancy to make available to the pregnant woman before her third trimester, or at the woman's next scheduled appointment with the provider during her third trimester, the information required under the bill to be posted by the DOH on its Internet website.

This bill also absolves any health care provider or health care facility, including any employee or agent of the provider or facility, of any liability from a civil action, any criminal prosecution, or any disciplinary action if the provider or facility acted in good faith to comply with the provisions of the bill.

This bill creates an undesignated section of law.

II. Present Situation:

Umbilical Cord Blood Banking[1]

After a baby is delivered, the mother's body releases the placenta, which is the temporary organ that transferred oxygen and nutrients to the baby while in the mother's uterus. Historically, the umbilical cord and placenta were discarded after birth without a second thought. But during the 1970s, researchers discovered that umbilical cord blood could supply the same kinds of blood-forming (hematopoietic) stem cells as a bone marrow donor. Consequently, umbilical cord blood began to be collected and stored.

Blood-forming stem cells are primitive cells found primarily in the bone marrow that are capable of developing into the three types of mature blood cells contained in our blood: red blood cells, white blood cells, and platelets. Cord blood stem cells may also have the potential to give rise to other cell types in the body.

Some serious illnesses (such as certain cancers, blood diseases, and immune system disorders) require radiation and chemotherapy treatments to kill diseased cells in the body. Unfortunately, these treatments also kill many "good" cells along with the bad, including healthy stem cells that live in the bone marrow. Depending on the type of disease and treatment needed, a patient may need a bone marrow transplant (from a donor whose marrow cells closely match their own). Blood-forming stem cells from a donor are transplanted into the ill person, and those cells then manufacture new, healthy blood cells and enhance the person's blood-producing and immune system capability.

Collection of Cord Blood

Collection of the cord blood takes place shortly after birth in both vaginal and cesarean (C-section) deliveries. The cord blood is collected using a specific kit that parents must order usually at least by the 34th week of pregnancy from their chosen cord blood bank. The kit may include a family medical history questionnaire, a consent form, and the collection materials. The informed consent must be signed prior to the onset of active labor and before the cord blood collection. The consent must contain information pertaining to what tests are to be performed on the cord blood and how the parents will be informed should the test results be abnormal.[2]

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[1] The following information under this subheading is adapted from KidsHealth from Nemours, *Banking Your Newborn's Cord Blood*, available at: http://kidshealth.org/parent/_cancer_center/treatment/cord_blood.html (Last visited on March 3, 2011). Nemours is a nonprofit organization established in 1936, which supports several children's health facilities and supports clinical research for children's health needs. *See* KidsHealth from Nemours, *About Nemours*, available at: http://kidshealth.org/parent/kh_misc/nemours.html (Last visited on March 3, 2011).

[2] American Academy of Pediatrics, *Frequently Asked Questions about Cord Blood Banking*, available at: http://www.aap.org/advocacy/releases/jan07cordbloodfaq.htm (Last visited on March 3, 2011).

After a vaginal delivery, the umbilical cord is clamped on both sides and cut. In most cases, an experienced obstetrician or nurse collects the cord blood before the placenta is delivered. One side of the umbilical cord is unclamped, and a small tube is passed into the umbilical vein to collect the blood. After blood has been collected from the cord, needles are placed on the side of the surface of the placenta that was connected to the fetus to collect more blood and cells from the large blood vessels that fed the fetus.

During cesarean births, cord-blood collection is more complicated because the obstetrician's primary focus in the operating room is tending to the surgical concerns of the mother. After the baby has been safely delivered and surgery has concluded, the cord blood can be collected. However, less cord blood is usually collected when delivery is by C-section. The amount collected is critical because the more blood collected, the more stem cells collected. If using the stem cells ever becomes necessary, having more stem cells to implant increases the chances of engraftment, which means a successful transplantation.

After cord blood collection has taken place, the blood is placed into bags or syringes and is usually taken by courier to the cord-blood bank. Once there, it is typed, screened for infectious diseases and for hereditary hematologic diseases, and is given an identifying number.[3] Then the stem cells are separated from the rest of the blood and are stored cryogenically (frozen in liquid nitrogen) in a collection facility, also known as a cord blood bank.

Storage and Use of Blood-forming Stem Cells

Because cord blood research only began in the 1970s, the maximum time for storage and potential usage for blood-forming stem cells are still being determined. Blood-forming stem cells that have been stored for more than a decade have been used successfully in transplants.

If the blood-forming stem cells are needed, blood-forming stem cells can be taken from storage, thawed, and used in either "autologous" procedures (when someone receives his or her own umbilical cord blood in a transplant) or "allogeneic" procedures (when a person receives umbilical cord blood donated from someone else, such as a sibling, close relative, or anonymous donor).

The primary reason that parents consider banking their newborn's cord blood is because they have a child or close relative with, or a family medical history of, diseases that can be treated with bone marrow transplants. Some diseases that more commonly involve bone marrow transplants include certain kinds of leukemia or lymphoma, aplastic anemia, severe sickle cell anemia, and severe combined immunodeficiency.

In most cases, stem cell transplants are performed only on children or young adults. The larger the size of the person, the more blood-forming stem cells are needed for a successful transplant. Umbilical cord blood stem cells aren't adequate in quantity to complete an adult's transplant. In addition, it is unknown whether stem cells taken from a relative offer more success than those taken from an unrelated donor. Stem cells from cord blood from both related and unrelated donors have been successful in many transplants, because blood-forming stem cells taken from

[3] *Id.*

cord blood are "naïve," which is a medical term for early cells that are still highly adaptable and are less likely to be rejected by the recipient's immune system. Therefore, donor cord-blood stem cells do not need to be a perfect match to create a successful bone marrow transplant.

Physical, Emotional, and Financial Concerns

The physical risks to the health of the mother and baby at the time of collection of the cord blood are low, but they do exist. Clamping the umbilical cord too soon after birth may increase the amount of collected blood, but it could cause the baby to have a lower blood volume and possible anemia soon after birth.

The American Academy of Pediatrics (AAP), have expressed concern that cord blood banks may capitalize on the fears and emotions of vulnerable new parents by providing misleading information about the statistics of bone marrow transplants. Parents of children of ethnic or racial minorities, adopted children, or children conceived through in vitro fertilization may be especially encouraged to bank cord blood because it's statistically harder to find a match in these cases.[4]

In 1999, the AAP stated that it doesn't recommend cord-blood banking for families who don't have a history of disease, because research has not yet determined the likelihood that a child would ever need his or her own stem cells, nor has it confirmed that transplantation using self-donated cells rather than cells from a relative or stranger is safer or more effective. According to the AAP, "private storage of cord blood as 'biological insurance' is unwise. However, banking should be considered if there is a family member with a current or potential need to undergo a stem cell transplantation."[5]

Although typically there is no cost or a nominal cost for donating cord blood to a public cord blood bank, the price of banking cord blood with a private cord blood bank can be quite expensive. There are usually two fees associated with cord blood banking with a private cord blood bank. The first is the initial fee which pays for enrollment and the collection and storage of the cord blood for at least the first year, and the second is an annual storage fee. Some facilities offer a variety of options for the initial fee with predetermined periods of storage. The initial fee

[4] For a successful transplant, the tissue type of a bone marrow donor or a cord blood unit needs to match the patient's as closely as possible. Tissue types are inherited, so patients are more likely to match someone who shares their racial or ethnic heritage and patients from racially or ethnically diverse communities can have a harder time finding a match. Because cord blood does not need to match a patient as closely as donated bone marrow, cord blood transplants may offer hope to these patients. More than 40 percent of minority patients who received a transplant used cord blood. National Marrow Donor Program, *Cord Blood Donation: Frequently Asked Questions*, available at: http://www.marrow.org/HELP/Donate_Cord_Blood_Share_Life/Cord_Blood_Donation_FAQs/index.html (Last visited on March 3, 2011).

[5] American Academy of Pediatrics, News Release, *Cord Blood Banking For Future Transplantation Not Recommended*, July 6, 1999, available at: http://www.nationalcordbloodprogram.org/AAP%20News%20Release%20-%20AAP%20CORD%20BLOOD%20BANKING%20FOR%20FUTURE%20TRANSPLANTATION%20NOT%20RECOMMENDED.htm (Last visited on March 3, 2011). *See also* American Academy of Pediatrics, News Release, *AAP Encourages Public Cord Blood Banking*, January 2, 2007, available at: http://www.aap.org/advocacy/releases/jan07cordblood.htm (Last visited on March 3, 2011), wherein the AAP stated, "Storing cord blood at private banks for later personal or family use as a general 'insurance policy' is discouraged."

ranges from $900 to $2,100 depending on the predetermined period of storage. Annual storage fees beyond the initial storage fee are approximately $100.[6]

Parent's Guide to Cord Blood Foundation, Inc.

The Parent's Guide to Cord Blood Foundation, Inc. (Foundation), is a nonprofit foundation, which was incorporated in 2007.[7]

The primary mission of the Foundation is to educate parents with accurate and current information about cord blood medical research and cord blood storage options.[8] The second mission of the Foundation is to conduct and publish statistical analyses on medical research or policy developments which could expand the likelihood of cord blood usage.[9]

The Foundation's website, which has been operational since 1998, explains the medical motivations for banking umbilical cord blood, and the difference between public bank donations versus paying for private storage of umbilical cord blood. In addition, the Foundation's website contains:[10]

- A list of all public cord blood banks which collect donations in the United States, irrespective of their business model or accreditations.[11]
- A compilation of private United States cord blood banks.[12]
- An international list of private/family cord blood banks, which is sorted by geographic region.
- An international list of private cord blood banks.
- A table of private banks, which compares their prices and accreditations at a glance.[13]
- A consumer questionnaire that provides a guide to evaluate the services of private banks.
- A summary of diseases which have been treated by blood stem cells.[14]

The Foundation reports[15] that its website has been accredited by the international standard for medical websites, Health on the Net Foundation (HON), since 2001.[16]

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[6] American Pregnancy Association, *Cord Blood Banking*, available at: http://www.americanpregnancy.org/labornbirth/cordbloodbanking.html (Last visited on March 3, 2011).
[7] Parent's Guide to Cord Blood Foundation, Inc., *Parent's Guide to Cord Blood Foundation*, available at: http://parentsguidecordblood.org/content/usa/aboutus/index.shtml?navid=1 (Last visited on March 3, 2011).
[8] Parent's Guide to Cord Blood Foundation, Inc., *Mission Statement*, available at: http://parentsguidecordblood.org/index.shtml (Last visited on March 3, 2011).
[9] *Id.*
[10] *Id.*
[11] Parent's Guide to Cord Blood Foundation, Inc., *Public Cord Blood Banks in the USA*, available at: http://parentsguidecordblood.org/content/usa/banklists/publicbanks_new.shtml?navid=15 (Last visited on March 4, 2011). According to the Foundation's website, there are 38 public cord blood banks in the U.S. and only 2 provide banking services specifically in Florida. However, 8 cord blood banks provide banking services in all states.
[12] Parent's Guide to Cord Blood Foundation, Inc., *Family Cord Blood Banks in the USA*, available at: http://parentsguidecordblood.org/content/usa/banklists/listusa.shtml?navid=16 (Last visited on March 4, 2011). The Foundation's website lists 32 private cord blood banks, 6 of which provide services in Florida.
[13] The table is available at: http://parentsguidecordblood.org/content/usa/banklists/summary.shtml?navid=17#us (Last visited on March 4, 2011).
[14] The summary of diseases, which have been treated by blood stem cells, is available at: http://parentsguidecordblood.org/content/usa/medical/diseases.shtml?navid=37 (Last visited on March 4, 2011).
[15] *Supra* fn. 8.

III. Effect of Proposed Changes:

This bill requires the Department of Health (DOH) to post on its Internet website resources and an electronic link to materials relating to umbilical cord blood which have been developed by the Parent's Guide to Cord Blood Foundation, Inc., including:

- An explanation of the potential value and uses of umbilical cord blood, including cord blood cells and stem cells, for individuals who are, or who are not, biologically related to a mother or her newborn child;
- An explanation of the differences between using one's own cord blood cells, a biologically related person's cord blood stem cells, or a biologically unrelated person's cord blood stem cells in the treatment of disease;
- An explanation of the differences between public and private umbilical cord blood banking;
- The options available to a mother relating to stem cells that are contained in the umbilical cord blood after the delivery of her newborn, including donating to a public umbilical cord blood bank, storing the stem cells in a private umbilical cord blood bank for use by immediate and extended family members, storing the stem cells for use by family members through a program that provides free services if there is an existing medical need, or discarding the stem cells;
- The medical processes involved in the collection of cord blood;
- Criteria for medical or family history that can impact a family's consideration of umbilical cord blood banking, including the likelihood of using a baby's cord blood to serve as a match for a family member who has a medical condition;
- Options for ownership and future use of donated umbilical cord blood;
- The average cost of public and private umbilical cord blood banking;
- The availability of public and private cord blood banks to residents of Florida, including a list of public cord blood banks and the hospitals they serve, a list of private cord blood banks, and the availability of free family banking and sibling donor programs if there is an existing medical need by a family member; and
- An explanation of which racial and ethnic groups are in particular need of publicly donated cord blood samples based on medical data developed by the Health Resources and Services Administration of the U.S. Department of health and Human Services.

This bill requires the DOH to encourage health care providers, who provide health care services directly related to a woman's pregnancy to make available to the pregnant woman before her third trimester, or at the woman's next scheduled appointment with the provider during her third trimester, the information required under the bill to be posted by the DOH on its Internet website.

This bill also absolves any health care provider or health care facility, including any employee or agent of the provider or facility, of any liability from a civil action, any criminal prosecution, or

[16] The Health On the Net Foundation (HON) promotes and guides the deployment of useful and reliable online health information, and its appropriate and efficient use. Created in 1995, HON is a non-profit, non-governmental organization, accredited to the Economic and Social Council of the United Nations. For 15 years, HON has focused on the essential question of the provision of health information to citizens, information that respects ethical standards. To cope with the unprecedented volume of healthcare information available on the Net, the HONcode of conduct offers a multi-stakeholder consensus on standards to protect citizens from misleading health information. Health On the Net Foundation, Home Page, available at: http://www.hon.ch/ (Last visited on March 3, 2011).

any disciplinary action if the provider or facility acted in good faith to comply with the provisions of the bill.

The bill provides that it is to take effect 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:

None.

C. Government Sector Impact:

The DOH reports that they will absorb any costs associated with implementing the bill and that the time required for periodic updates to the DOH's website and encouragement of providers to disseminate information on cord blood banking can be accomplished with existing staff and by using the existing network of maternal and child health partners.[17]

VI. Technical Deficiencies:

None.

VII. Related Issues:

The DOH reports that the Foundation's website is copyrighted and requires permission from the copyright owner to repeat the information contained on the website. Therefore, the DOH reports

[17] Department of Health, *Bill Analysis, Economic Statement, and Fiscal Note for SB 702*, dated February 11, 2011. A copy of this analysis is on file with the Senate Health Regulation Committee.

that it will need to include a disclaimer on its website advertising the Foundation's link that access to the website through the DOH does not give the viewer of the information on the website or the DOH permission to copy or redistribute any information from the Foundation's website.[18]

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] *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:	CS/SB 398
INTRODUCER:	Committee on Health Regulation and Senator Jones
SUBJECT:	Chiropractic Medicine
DATE:	March 9, 2011 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Brown	Stovall	HR	**Fav/CS**
2.			BC	
3.			RC	
4.				
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 makes several amendments to Florida Statutes relating to the regulation of chiropractic medicine. The bill expands eligibility for obtaining a chiropractic medicine faculty certificate. The bill specifies that chiropractic continuing education courses that pertain to a specific company brand, product line, or service may not be approved. The bill amends the grounds for denial of a chiropractic physician's license or disciplinary action to specify that chiropractic physicians must preserve the identity of funds and property of a patient if the value of the funds and property is greater than $501. The bill specifies that money or other property entrusted to a chiropractic physician by a patient may not exceed the value of $1,500. The bill requires that the indirect supervision of a certified chiropractic physician's assistant (CCPA) must take place only at the supervising physician's address of record. The bill redefines the curriculum for the CCPA program by removing the requirement that the program must cover a period of 24 months. The bill requires that registered chiropractic assistants (RCAs) must register with the Board of Chiropractic Medicine (Board) and that an RCA's registration application and registration renewal application must be signed by a chiropractic physician who is an owner of the RCA's place of employment. The bill requires an RCA to notify the Board within 30 days after changing employment and becoming employed by a new chiropractic practice. The bill requires an RCA's employer of record to notify the Board within 30 days after the RCA is no longer

employed by that employer. The bill requires the Board to develop rules to facilitate the RCA registration process. The bill also expands and revises the exceptions to proprietorship and control of a chiropractic practice by persons other than licensed chiropractic physicians.

This bill substantially amends the following sections of the Florida Statutes: 460.4062, 460.408, 460.413, 460.4165, 460.4166, and 460.4167.

II. Present Situation:

Chiropractic Medicine Faculty Certificates

The Department of Health (DOH) is authorized to issue a chiropractic medicine faculty certificate to individuals who meet certain criteria specified in the Florida Statutes. A chiropractic medicine faculty certificate authorizes the certificate holder to practice chiropractic medicine only in conjunction with his or her faculty position at a university or college and its affiliated clinics that are registered with the Board as sites at which holders of chiropractic medicine faculty certificates will be practicing. The DOH is authorized to issue a chiropractic medicine faculty certificate without examination to an individual who demonstrates to the Board of Chiropractic Medicine (Board) that he or she, among other requirements, has accepted a full-time faculty appointment to teach chiropractic medicine at a publicly-funded state university or college or at a college of chiropractic located in Florida and accredited by the Council on Chiropractic Education, and who provides a certification from the dean of the appointing college acknowledging the appointment.[1] There is no such provision for researchers or part-time faculty in the requirements for obtaining a chiropractic medicine faculty certificate, a medical faculty certificate, or an osteopathic faculty certificate.

Continuing Chiropractic Education

The Board requires licensed chiropractors to periodically demonstrate their professional competence as a condition of license renewal by completing up to 40 hours of continuing education. Florida Statutes indicate that the Board shall approve continuing education courses that build upon the basic courses required for the practice of chiropractic medicine.[2] To receive Board approval, a continuing education course must meet a number of criteria specified in rule, including the requirement for the course to be offered for the purpose of keeping the licensee apprised of advancements and new developments in areas such as general or spinal anatomy; physiology; general or neuro-muscular diagnosis; X-ray technique or interpretation; chemistry; pathology; microbiology; public health; principles or practice of chiropractic; risk management; laboratory diagnosis; nutrition; physiotherapy; phlebotomy; acupuncture; proprietary drug administration; AIDS; and law relating to the practice of chiropractic, the Board, and the regulatory agency under which the Board operates.[3]

Grounds for Denial of a Chiropractic Medicine License or Disciplinary Action

Current law and rules of the Board allow chiropractic physicians to accept and hold in trust unearned fees in the form of cash or property other than cash which are received by a chiropractor prior to the rendering of services or the selling of goods and appliances. Chiropractors who utilize such trust funds are required to maintain trust accounting records and

[1] *See* s. 460.4062(1), F.S.
[2] *See* s. 460.408(1)(b), F.S.
[3] *See* s. 64B2-13.004, F.A.C.

observe certain trust accounting procedures. Failure to preserve the identity of funds and property of a patient constitutes grounds for denial of a license or disciplinary action.[4]

Supervision of Certified Chiropractic Physician's Assistants

A CCPA may perform chiropractic services in the specialty area or areas for which he or she is trained or experienced when such services are rendered under the supervision of a licensed chiropractic physician or group of chiropractic physicians certified by the Board, under certain requirements and parameters.

"Direct supervision" is defined as responsible supervision and requires, except in case of an emergency, the physical presence of the licensed chiropractic physician on the premises for consultation and direction. "Indirect supervision" means responsible supervision and control by the supervising chiropractic physician and requires the "easy availability" or physical presence of the licensed chiropractic physician for consultation and direction of the actions of the CCPA. "Easy availability" means the supervising chiropractic physician must be in a location to enable him or her to be physically present with the CCPA within at least 30 minutes and must be available to the CCPA when needed for consultation and advice either in person or by communication devices such as telephone, two-way radio, medical beeper, or other electronic means.[5]

Under current law, indirect supervision of a CCPA is authorized if the indirect supervision occurs at the address of record or any place of practice of a chiropractic physician to whom he or she is assigned.[6] Indirect supervision is not authorized for CCPAs performing services at a health care clinic licensed under part X of ch. 400, F.S.[7]

Education and Training of Certified Chiropractic Physician's Assistants

The DOH is directed under current law to issue certificates of approval for education and training programs for CCPAs which meet Board standards. Any basic program curriculum certified by the Board must cover a period of 24 months and consist of at least 200 didactic classroom hours during the 24 months.[8]

Registered Chiropractic Assistants

An RCA assists in all aspects of chiropractic medical practice under the direct supervision and responsibility of a chiropractic physician or CCPA. An RCA assists with patient care management, executes administrative and clinical procedures, and often performs managerial and supervisory functions, all of which may include performing clinical procedures such as preparing patients for the chiropractic physician's care, taking vital signs, and observing and reporting patients' signs or symptoms; administering basic first aid; assisting with patient examinations or treatments other than manipulations or adjustments; operating office equipment; collecting routine laboratory specimens, administering nutritional supplements, and performing office procedures required by the chiropractic physician or the CCPA.

[4] *See* s. 460.413(1)(y), F.S., and s. 64B2-14.001, F.A.C.
[5] *See* s. 64B2-18.001(8)-(9), F.A.C.
[6] Department of Health, *Bill Analysis, Economic Statement and Fiscal Note, SB 398,* January 27, 2011, p. 3, on file with the Committee on Health Regulation.
[7] *See* s. 460.4165(14), F.S.
[8] *See* s. 460.4165(5), F.S.

RCAs may be registered by the Board for a biennial fee not to exceed $25, but Board registration is not mandatory.[9] In state fiscal year 2009-2010, the DOH received 907 applications for voluntary RCA registration.[10]

Proprietorship and Control by Persons Other Than Licensed Chiropractic Physicians
Generally only a sole proprietorship, group practice, partnership, or corporation that is wholly owned by one or more chiropractic physicians, or by a chiropractic physician and the spouse, parent, child, or sibling of that chiropractic physician, may employ a chiropractic physician or engage a chiropractic physician as an independent contractor to provide chiropractic services. However, s. 460.4167, F.S., provides for a number of exceptions, which include medical doctors, osteopaths, hospitals, and state-licensed insurers, among others. No exception exists for the surviving spouse, parent, child, or sibling of a deceased chiropractic physician or for a health maintenance organization or prepaid health clinic regulated under ch. 641, F.S., to employ or engage a chiropractic physician.[11]

Current law also prohibits persons who are not chiropractic physicians, entities not wholly owned by one or more chiropractic physicians, and entities not wholly owned by chiropractic physicians and the spouse, parent, child, or sibling of a chiropractic physician, from employing or entering into a contract with a chiropractic physician and thereby exercising control over patient records, decisions relating to office personnel and hours of practice, and policies relating to pricing, credit, refunds, warranties, and advertising. No exceptions to this prohibition are contained in current law.[12]

III. Effect of Proposed Changes:

Section 1 amends s. 460.4062, F.S., relating to chiropractic medicine faculty certificates, to authorize the DOH to issue a faculty certificate to a person who performs research or has accepted a part-time faculty appointment to teach in a program of chiropractic medicine at a publicly funded state university, college, or a chiropractic college in Florida, assuming the person meets other statutory requirements for faculty certification.

Section 2 amends s. 460.408, F.S., relating to continuing chiropractic education, to prohibit the Board from approving continuing education courses consisting of instruction in the use, application, prescription, recommendation, or administration of a specific company's brand of products or services as contact classroom hours of continuing education. The bill also *allows* the Board to approve courses sponsored by chiropractic colleges if all other requirements of Board criteria for course approval are met, as opposed to the *required* approval of such courses in current law.

Section 3 amends s. 460.413, F.S., relating to grounds for denial of a license or disciplinary action, to specify that failing to preserve the identity of funds and property of a patient is grounds for license denial or disciplinary action only when the value of the funds and property is greater

[9] *See* s. 460.4166, F.S.
[10] Supra, note 5, p. 7.
[11] *See* s. 460.4167(1), F.S.
[12] *See* s. 460.4167(4), F.S.

than $501. The requirement in current law that money or other property entrusted to a chiropractor for a specific purpose, including advances for costs and expenses of examination or treatment, must be held in trust and must be applied only to that purpose, is amended under the bill to prevent such advances from exceeding the value of $1,500.

Section 4 amends s. 460.4165, F.S., relating to certified chiropractic physician's assistants, to limit the venues at which CCPAs are allowed to perform chiropractic services under the indirect supervision of a chiropractic physician by removing the chiropractor's place of practice as an authorized venue. A CCPA may continue to perform chiropractic service under indirect supervision at the supervising chiropractor's address of record unless the address or record is a health clinic licensed under part X of ch. 400, F.S.

The bill removes the requirement that education and training programs for CCPAs must cover a period of 24 months.

Section 5 amends s. 460.4166, F.S., relating to registered chiropractic assistants, to specify that clinical procedures performed by an RCA include the operation of therapeutic office equipment.

The bill creates a mandatory RCA registration process, effective April 1, 2012, for any person who performs any duties of an RCA for a biennial fee not to exceed $25, unless the person is otherwise certified or licensed to perform those functions. A person employed as an RCA must apply for an initial registration with the Board by March 31, 2012, or within 30 days after becoming employed as an RCA, whichever is later. The applicant must list his or her place of employment and all chiropractors under whose supervision the applicant performs the duties of an RCA. The application must be signed by a chiropractor who is an owner of the RCA's place of employment. The initial registration becomes effective on April 1, 2012, or applies retroactively to the RCA's date of employment, whichever is later. The bill allows the RCA to be supervised by any chiropractor or CCPA employed by the RCA's employer or listed on the application.

The bill requires an RCA, within 30 days after a change of employment, to notify the Board of the new place of employment and the names of the chiropractic physicians under whose supervision the RCA performs the duties of an RCA at the new place of employment, and the notification must be signed by a chiropractor who is an owner of the RCA's new place of employment. The bill allows the RCA to be supervised by any chiropractor or CCPA employed by the RCA's new employer or listed on the notification.

The bill requires an RCA's employer as registered with the Board, within 30 days after an RCA leaves employment, to notify the Board that the RCA is no longer employed by that employer.

The bill renders an employee who performs none of the duties of an RCA as ineligible to register as an RCA.

The bill creates a registration renewal process for an RCA and requires registrations to be renewed biennially for a renewal fee not to exceed $25. The renewal application must specify the RCA's place of employment and all chiropractors under whose supervision the RCA performs the duties on an RCA. The renewal must be signed by a chiropractor who is an owner of the

RCA's place of employment, and the bill allows the RCA to be supervised by any chiropractor or CCPA employed by the RCA's employer or listed on the registration renewal.

The bill requires the Board to prescribe, by rule, application forms for the initial registration of an RCA, the RCA's notice of change of employment, the employer's notice of an RCA's termination of employment, and the registration renewal for an RCA.

The bill specifies that if an RCA is employed by an entity not owned in whole or in part by a chiropractor, the RCA registration, notification, and renewal documents requiring signatures must be signed by a person having an ownership interest in the entity that employs the RCA and a licensed chiropractor who supervises the RCA.

The bill eliminates the voluntary RCA registration process under current law, effective July 1, 2011, in favor of the new mandatory RCA registration process which becomes effective April 1, 2012.

Section 6 amends s. 460.4167, F.S., relating to proprietorship by persons other than licensed chiropractic physicians, to recognize other entities such as limited liability companies, limited partnerships, professional associations, and trusts, as authorized proprietorships that may employ a chiropractic physician or engage a chiropractic physician as an independent contractor to provide chiropractic services.

More specifically, the bill creates or revises the following exceptions to the requirement that no person other than a sole proprietorship, group practice, partnership, or corporation that is wholly owned by one or more licensed chiropractic physicians, or by a licensed chiropractic physician and the spouse, parent, child, or sibling of that chiropractic physician, may employ a chiropractic physician or engage a chiropractic physician as an independent contractor to provide chiropractic services:

- A limited liability company, limited partnership, any person, professional association, or any other entity that is wholly owned by:
  - A licensed chiropractic physician and the spouse or surviving spouse, parent, child, or sibling of the chiropractic physician; or
  - A trust whose trustees are licensed chiropractic physicians and the spouse, parent, child, or sibling of a chiropractic physician;
- A limited liability company, limited partnership, professional association, or any other entity wholly owned by a licensed chiropractor or chiropractors, a licensed medical doctor or medical doctors, a licensed osteopath or osteopaths, or a licensed podiatrist or podiatrists;
- An entity that is wholly owned, directly or indirectly, by a licensed or registered hospital or other entity licensed or registered under ch. 395, F.S.;
- An entity that is wholly owned and operated by an organization that is exempt from federal taxation under s. 501(c)(3) or (4) of the Internal Revenue Code;
- A health care clinic licensed under part X of ch. 400, F.S. that provides chiropractic services by a licensed chiropractic physician; and
- A health maintenance organization or prepaid health clinic regulated under ch. 641, F.S.

Upon the death of chiropractic physician who wholly owns a sole proprietorship, group practice, partnership, corporation, limited liability company, limited partnership, any person, professional

association, or any other entity, with his or her spouse, parent, child, or sibling, and that wholly-owned entity employs a licensed chiropractic physician or engages a chiropractor as an independent contractor to provide chiropractic services, the bill allows the deceased chiropractic physician's surviving spouse or adult children to hold, operate, pledge, sell, mortgage, assign, transfer, own, or control the deceased chiropractic physician's ownership interests for so long as the surviving spouse or adult children remain the sole proprietor of the chiropractic practice.

The bill also grants authority to an authorized employer of a chiropractic physician to exercise control over:

- The patient records of the employed chiropractor;
- Policies and decisions relating to pricing, credit, refunds, warranties, and advertising; and
- Decisions relating to office personnel and hours of practice.

Section 7 provides that the bill takes effect July 1, 2011.

Other Potential Implications:
The DOH advises that the mandatory regulation of RCAs may enable chiropractic physicians to seek third-party reimbursements for therapeutic services or the administration of therapeutic agents by RCAs.

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:

The bill requires the Board to assess a biennial fee for RCA registration not to exceed $25.

B. Private Sector Impact:

The DOH has been asked to provide a fiscal analysis of the committee substitute.

C. Government Sector Impact:

The DOH has been asked to provide a fiscal analysis of the committee substitute.

The DOH advises that after CCPAs are no longer authorized to perform services with indirect supervision anywhere other than the address of record of their supervising chiropractors, Section 4 of the bill would affect the department's enforcement branch if complaints are filed against CCPAs who continue to perform services at a place of practice other than their supervising chiropractor's address of record, the fiscal impact of which is indeterminate.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Section 5 of the bill requires an RCA to submit an initial application within 30 days after employment, and the registration applies retroactively to the date of employment. The DOH advises that the grace period of 30 days after employment to submit the registration application could conflict with s. 456.065, F.S., which provides for civil and criminal penalties for the unlicensed practice of a profession. Under the bill, unlicensed practice for 30 days of employment is acceptable if the registration is applied for no later than the end of the 30 days. If the Board does not receive an RCA application, then retroactivity will not apply and the unregistered RCA may be prosecuted for unlicensed practice.

Section 456.0635, F.S., requires a board or the DOH to refuse to issue or renew a license, certificate, or registration to any applicant if the applicant has been convicted of, or entered a plea of guilty or nolo conterdere to a felony under ch. 409, F.S., relating to social and economic assistance; ch. 817, F.S., relating to fraudulent practices; ch. 893, F.S., relating to controlled substances; or certain federal laws, unless the sentence and any subsequent period of probation ended more than 15 years prior to the date of the application. The bill's mandatory RCA registration might impact the ability of certain persons to remain or become employed in a chiropractor's office.

VIII. Additional Information:

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

CS by Health Regulation on March 9, 2011:
The CS made the following changes to the bill:

- The CS *allows* the Board to approve continuing education courses sponsored by chiropractic colleges if all other requirements of Board criteria for course approval are met, as opposed to the *required* approval of such courses in current law.
- The CS specifies that failing to preserve the identity of funds and property of a patient is grounds for license denial or disciplinary action only when the value of the funds

and property is greater than $501. The requirement in current law that money or other property entrusted to a chiropractor for a specific purpose, including advances for costs and expenses of examination or treatment, must be held in trust and must be applied only to that purpose, is amended under the CS to prevent such advances from exceeding the value of $1,500.

- The CS eliminates the voluntary registration for RCAs under current law and replaces it with a mandatory registration for all RCAs. The CS also eliminates the requirement in the original bill for chiropractors who supervise RCAs to be approved by the Board and for the Board to assess a fee up to $75 for that approval. The CS requires an RCA's initial registration, notification of change of employment, and biennial registration renewal to be signed by a chiropractor who is an owner of the RCA's place of employment, or by a non-chiropractor with an ownership interest in the place of employment and a supervising chiropractor in instances where the place of employment is not owned in whole or in part by a licensed chiropractor.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate . House

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

Senate Amendment (with title amendment)

Delete lines 75 - 81
and insert:
Section 2. Paragraphs (a) and (b) of subsection (1) of section 460.408, Florida Statutes, are amended to read:
460.408 Continuing chiropractic education.—
(1) The board shall require licensees to periodically demonstrate their professional competence as a condition of renewal of a license by completing up to 40 contact classroom hours of continuing education.
(a) Continuing education courses sponsored by chiropractic

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colleges whose graduates are eligible for examination under any provision of this chapter may ~~shall~~ be approved upon review by the board if all other requirements of board rules setting forth criteria for course approval are met.

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

And the title is amended as follows:

Delete line 5

and insert:

amending s. 460.408, F.S.; authorizing the Board of Chiropractic Medicine to approve continuing education courses sponsored by chiropractic colleges under certain circumstances; prohibiting the Board of

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/09/2011	.	
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The Committee on Health Regulation (Jones) recommended the following:

Senate Amendment (with title amendment)

Delete lines 75 - 197
and insert:
Section 2. Subsection (1) of section 460.408, Florida Statutes, is amended to read:
460.408 Continuing chiropractic education.—
(1) The board shall require licensees to periodically demonstrate their professional competence as a condition of renewal of a license by completing up to 40 contact classroom hours of continuing education.
(a) Continuing education courses sponsored by chiropractic

colleges whose graduates are eligible for examination under any provision of this chapter may ~~shall~~ be approved upon review by the board if all other requirements of board rules setting forth criteria for course approval are met.

(b) The board shall approve those courses that build upon the basic courses required for the practice of chiropractic medicine, and the board may also approve courses in adjunctive modalities. Courses that consist of instruction in the use, application, prescription, recommendation, or administration of a specific company's brand of products or services are not eligible for approval.

Section 3. Paragraph (y) of subsection (1) of section 460.413, Florida Statutes, is amended to read:

460.413 Grounds for disciplinary action; action by board or department.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(y) Failing to preserve identity of funds and property of a patient, the value of which is greater than $501. As provided by rule of the board, money or other property entrusted to a chiropractic physician for a specific purpose, including advances for costs and expenses of examination or treatment which may not exceed the value of $1,500, is to be held in trust and must be applied only to that purpose. Money and other property of patients coming into the hands of a chiropractic physician are not subject to counterclaim or setoff for chiropractic physician's fees, and a refusal to account for and deliver over such money and property upon demand shall be deemed a conversion. This is not to preclude the retention of money or

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other property upon which the chiropractic physician has a valid lien for services or to preclude the payment of agreed fees from the proceeds of transactions for examinations or treatments. Controversies as to the amount of the fees are not grounds for disciplinary proceedings unless the amount demanded is clearly excessive or extortionate, or the demand is fraudulent. All funds of patients paid to a chiropractic physician, other than advances for costs and expenses, shall be deposited in one or more identifiable bank accounts maintained in the state in which the chiropractic physician's office is situated, and no funds belonging to the chiropractic physician shall be deposited therein except as follows:

1. Funds reasonably sufficient to pay bank charges may be deposited therein.

2. Funds belonging in part to a patient and in part presently or potentially to the physician must be deposited therein, but the portion belonging to the physician may be withdrawn when due unless the right of the physician to receive it is disputed by the patient, in which event the disputed portion shall not be withdrawn until the dispute is finally resolved.

Every chiropractic physician shall maintain complete records of all funds, securities, and other properties of a patient coming into the possession of the physician and render appropriate accounts to the patient regarding them. In addition, every chiropractic physician shall promptly pay or deliver to the patient, as requested by the patient, the funds, securities, or other properties in the possession of the physician which the

patient is entitled to receive.

Section 4. Subsections (2) and (5) of section 460.4165, Florida Statutes, are amended to read:

460.4165 Certified chiropractic physician's assistants.—

(2) PERFORMANCE BY CERTIFIED CHIROPRACTIC PHYSICIAN'S ASSISTANT.—Notwithstanding any other provision of law, a certified chiropractic physician's assistant may perform chiropractic services in the specialty area or areas for which the certified chiropractic physician's assistant is trained or experienced when such services are rendered under the supervision of a licensed chiropractic physician or group of chiropractic physicians certified by the board. Any certified chiropractic physician's assistant certified under this section to perform services may perform those services only:

(a) In the office of the chiropractic physician to whom the certified chiropractic physician's assistant has been assigned, in which office such physician maintains her or his primary practice;

(b) Under indirect supervision if the indirect supervision occurs at the supervising chiropractic physician's address of record ~~or place of practice~~ required by s. 456.035, other than at a clinic licensed under part X of chapter 400, of the chiropractic physician to whom she or he is assigned as defined by rule of the board;

(c) In a hospital in which the chiropractic physician to whom she or he is assigned is a member of the staff; or

(d) On calls outside of the office of the chiropractic physician to whom she or he is assigned, on the direct order of the chiropractic physician to whom she or he is assigned.

(5) PROGRAM APPROVAL.—The department shall issue certificates of approval for programs for the education and training of certified chiropractic physician's assistants which meet board standards. Any basic program curriculum certified by the board shall ~~cover a period of 24 months. The curriculum must~~ consist of a curriculum of at least 200 didactic classroom hours ~~during those 24 months~~.

(a) In developing criteria for program approval, the board shall give consideration to, and encourage, the use ~~utilization~~ of equivalency and proficiency testing and other mechanisms whereby full credit is given to trainees for past education and experience in health fields.

(b) The board shall create groups of specialty classifications of training for certified chiropractic physician's assistants. These classifications must ~~shall~~ reflect the training and experience of the certified chiropractic physician's assistant. The certified chiropractic physician's assistant may receive training in one or more such classifications, which shall be shown on the certificate issued.

(c) The board shall adopt and publish standards to ensure that such programs operate in a manner which does not endanger the health and welfare of the patients who receive services within the scope of the program. The board shall review the quality of the curricula, faculties, and facilities of such programs; issue certificates of approval; and take whatever other action is necessary to determine that the purposes of this section are being met.

Section 5. Subsections (2) and (3) of section 460.4166, Florida Statutes, are amended, and subsections (4), (5), and (6)

are added to that section, to read:

460.4166 Registered chiropractic assistants.—

(2) DUTIES.—Under the direct supervision and responsibility of a licensed chiropractic physician or certified chiropractic physician's assistant, a registered chiropractic assistant may:

(a) Perform clinical procedures, which include:

1. Preparing patients for the chiropractic physician's care.

2. Taking vital signs.

3. Observing and reporting patients' signs or symptoms.

(b) Administer basic first aid.

(c) Assist with patient examinations or treatments other than manipulations or adjustments.

(d) Operate therapeutic office equipment.

(e) Collect routine laboratory specimens as directed by the chiropractic physician or certified chiropractic physician's assistant.

(f) Administer nutritional supplements as directed by the chiropractic physician or certified chiropractic physician's assistant.

(g) Perform office procedures required by the chiropractic physician or certified chiropractic physician's assistant under direct supervision of the chiropractic physician or certified chiropractic physician's assistant.

(3) REGISTRATION.—

(a) A registered chiropractic assistant shall register with ~~assistants may be registered by~~ the board for a biennial fee not to exceed $25. Effective April 1, 2012, a person must register with the board as a registered chiropractic assistant if the

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person performs any duties described in subsection (2) unless the person is otherwise certified or licensed to perform those duties.

(b) A person employed as a registered chiropractic assistant shall submit to the board an initial application for registration by March 31, 2012, or within 30 days after becoming employed as a registered chiropractic assistant, whichever is later, specifying the applicant's place of employment and the names of all chiropractic physicians under whose supervision the applicant performs the duties described in subsection (2). The application for registration must be signed by a chiropractic physician who is an owner of the place of employment specified in the application. Upon the board's receipt of an application, the effective date of the registration shall be April 1, 2012, or shall apply retroactively to the applicant's date of employment as a registered chiropractic assistant, whichever is later, and the registered chiropractic assistant may be supervised by any licensed chiropractic physician or certified chiropractic physician's assistant who is employed by the registered chiropractic assistant's employer or listed on the registration application.

(c) A registered chiropractic assistant, within 30 days after a change of employment, must notify the board of the new place of employment and the names of all chiropractic physicians under whose supervision the registered chiropractic assistant performs duties described in subsection (2) at the new place of employment. The notification must be signed by a chiropractic physician who is an owner of the new place of employment. Upon the board's receipt of the notification, the registered

chiropractic assistant may be supervised by any licensed chiropractic physician or certified chiropractic physician's assistant who is employed by the registered chiropractic assistant's new employer or listed on the notification.

(d) Within 30 days after a registered chiropractic assistant is no longer employed at his or her place of employment as registered with the board, the registered chiropractic assistant's employer as registered with the board shall notify the board that the registered chiropractic assistant is no longer employed by that employer.

(e) An employee who performs none of the duties described in subsection (2) is not eligible to register under this section.

(4) REGISTERED CHIROPRACTIC ASSISTANT REGISTRATION RENEWAL.—

(a) A registered chiropractic assistant's registration must be renewed biennially. Each renewal must include:

1. A renewal fee as set by the board not to exceed $25.

2. The registered chiropractic assistant's current place of employment and the names of all chiropractic physicians under whose supervision the applicant performs duties described in subsection (2). The application for registration renewal must be signed by a chiropractic physician who is an owner of the place of employment specified in the application.

(b) Upon registration renewal, the registered chiropractic assistant may be supervised by any licensed chiropractic physician or certified chiropractic physician's assistant who is employed by the registered chiropractic assistant's employer or listed on the registration renewal.

(5) APPLICATION AND NOTIFICATION FORMS.—The board shall prescribe, by rule, forms for the applications and notifications required under subsections (3) and (4).

(6) If a person employed as a registered chiropractic assistant is employed by an entity not owned in whole or in part by a licensed chiropractic physician under s. 460.4167, the documents requiring signatures under this section must be signed by a person with an ownership interest in the entity that employs the registered chiropractic assistant and a licensed chiropractic physician who supervises the registered chiropractic assistant.

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

And the title is amended as follows:

Delete lines 5 - 34

and insert:

amending s. 460.408, F.S.; authorizing the Board of Chiropractic Medicine to approve continuing education courses sponsored by chiropractic colleges under certain circumstances; prohibiting the board from approving the use of certain courses in continuing chiropractic education; amending s. 460.4165, F.S.; providing that services rendered by a certified chiropractic physician’s assistant under indirect supervision may occur only at the supervising chiropractic physician’s address of record; deleting the length of time specified for the basic program of education and training for certified chiropractic

physician's assistants; amending s. 460.4166, F.S.; authorizing a registered chiropractic assistant to operate therapeutic office equipment; requiring a registered chiropractic assistant to register with the board effective April 1, 2012, and pay a fee for registration; requiring a registered chiropractic assistant to submit an initial application by March 31, 2012, or within 30 days after becoming employed, whichever is later; requiring an applicant to specify place of employment and supervising chiropractic physicians; requiring an application to be signed by a chiropractic physician who is an owner of the applicant's place of employment; providing an effective date of a registered chiropractic assistant's registration; authorizing who may supervise a registered chiropractic assistant; requiring a registered chiropractic assistant to notify to the board of his or her change of employment; requiring a chiropractic physician to sign the registered chiropractic assistant's notification of change in employment; requiring a registered chiropractic assistant's employer to notify the board when a registered chiropractic assistant is no longer employed by that employer; providing eligibility conditions for registering as a registered chiropractic assistant; requiring the biennial renewal of a registered chiropractic assistant's registration and payment of a renewal fee; requiring the board to adopt by rule forms for certain statutorily required

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applications and notifications; providing for the signature of certain forms and notices by specified owners and supervisors under certain conditions; 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:	CS/SB 490
INTRODUCER:	Committee on Health Regulation and Senator Jones
SUBJECT:	Medical Expenses of Pretrial Detainees or Sentenced Inmates
DATE:	March 10, 2011 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Wolfgang	Yeatman	CA	**Favorable**
2.	Brown	Stovall	HR	**Fav/CS**
3.			BC	
4.				
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:

SB 490 limits county or municipal medical costs of an in-custody pretrial detainee or sentenced inmate to 110 percent of the Medicare allowable rate (not to exceed 125 percent of the Medicare rate if the third-party provider has reported a negative operating margin to the Agency for Health Care Administration) if no formal written agreement exists between the county or municipality and the third-party medical care provider. The bill exempts amounts billed and paid for physicians providing emergency services within a hospital emergency department from the maximum allowable rate.

The bill requires that before a third-party provider can seek reimbursement from a county or municipal general fund, it must show that a "good faith effort" was made to collect payment for medical care expenses from an in-custody pretrial detainee or sentenced inmate.

The bill specifies responsibility of the governmental body for payment of any in-custody medical costs ceases upon release of the in-custody pretrial detainee or sentenced inmate.

The bill also changes the language that states that the responsibility of paying for an injury that occurred as a result of arrest is on the person receiving care (current law uses the language "at the time of arrest").

The bill defines the term "in-custody pretrial detainees or sentenced inmates" and specifies that law enforcement or the county or municipal detention facility is responsible for restricting the personal freedom of in-custody pretrial detainees or sentenced inmates receiving medical treatment or services from third-party providers.

This bill substantially amends sections 901.35 and 951.032 of the Florida Statutes.

II. Present Situation:

Financial Responsibility for Medical Expenses

Pre-trial detainees have a constitutional right to "reasonable and adequate nourishment and medical care,"[1] but the cost of the medical care is the primary responsibility of the person receiving the medical care.[2] A medical services provider shall recover the expenses of medical care, treatment, hospitalization, and transportation (hereinafter referred to simply as "medical care") for a person ill, wounded, or otherwise injured during or at the time of arrest for any violation of state law or a county or municipal ordinance from the following sources in the following order:

(1) Insurance of the person receiving the medical care;

(2) The person receiving medical care;

(3) A financial settlement for the medical care.[3]

When reimbursement from these sources is unavailable, the cost of medical care shall be paid from the general fund of the county in which the person was arrested. If the arrest was for violation of a municipal ordinance then the municipality shall pay the medical service provider.[4] Section 951.032, F.S., articulates the local government's rights to reimbursement from the person seeking medical attention.[5]

The injury or illness need not be caused by the arrest.[6] The responsibility for payment of medical costs exists until the arrested person is released from the custody of the arresting agency. The

[1] *Williams v. Ergle*, 698 So. 2d 1294 (Fla. 5th DCA 1997).
[2] Section 901.35, F.S.
[3] *Id.*
[4] *Id.*
[5] *See Williams v. Ergle*, 698 So. 2d 1294, (Fla. 5th DCA 1997) (stating that pretrial detainees are prisoners for the purposes of state statutes allowing recovery of certain medical expenses from prisoners).
[6] *See North Brevard County Hospital District v. Brevard County Bd. of County Commissioners*, 899 So. 2d 1200, 1202-03 (Fla. 5th DCA 2005) ("One cannot fault Brevard County or the trial court in its attempt to circumvent s. 901.35, F.S. The implications of the statute can be financially devastating to a local government in view of the ever increasing cost of medical care, especially when the Legislature has not placed a cap on the liability of government.") (citing Joseph G. Jarret, *The High Cost of Arrestee Medical Treatment: The Effects of F.S. § 901.35 on Local Government Coffers*, 78 FLA. B.J. 46 (Nov. 2004)); Fla. Atty. Gen. Op. 85-6, (Feb. 4, 1985).

rates medical service providers can charge local governments are not capped.[7] At least one Florida appellate court has held that the costs of medical services are not among the costs covered by the constitutional provision that prohibits compelling persons charged with a crime to pay costs before a judgment of conviction has become final.[8]

A county detention facility or municipal detention facility incurring expenses for providing medical care may seek reimbursement for the expenses incurred in the following order:

- From the prisoner or person receiving care, including authorizing a lien against a prisoner's cash account for medical care by deducting the cost from the prisoner's cash account.
- From an insurance company, health care corporation, or other source if the prisoner or person is covered by an insurance policy or subscribes to a health care corporation or other source for those expenses.[9]

Section 951.23, F.S., provides the following relevant definitions:

"County prisoner" means a person who is detained in a county detention facility by reason of being charged with or convicted of either a felony or misdemeanor.[10]

"Municipal prisoner" means a person who is detained in a municipal detention facility by reason of being charged with or convicted of violation of municipal law or ordinance.

"County detention facility" means a county jail, a county stockade, a county work camp, a county residential probation center, and any other place except a municipal detention facility used by a county or county officer for the detention of persons charged with or convicted of either a felony or misdemeanor.

"Municipal detention facility" means a city jail, a city stockade, a city prison camp, and any other place except a county detention facility used by a municipality or municipal officer for the detention of persons charged with or convicted of violation of municipal laws or ordinances.

Medicare Rates

The Social Security Act, 42 U.S.C. § 1395, addresses Medicare. Medicare is federal health insurance for people age 65 or older, people under age 65 with certain disabilities, and people of any age with End-Stage Renal Disease (ESRD) (permanent kidney failure requiring dialysis or a kidney transplant). Medicare consists of Part A (hospital insurance), Part B (medical insurance), and Part D (prescription drug coverage).

Medicare reimburses providers based on the type of service they provide. The Federal Centers for Medicare and Medicaid Services (CMS) develops annual fee schedules for physicians,

[7] Joseph G. Jarret, *The High Cost of Arrestee Medical Treatment: The Effects of F.S. § 901.35 on Local Government Coffers*, 78 FLA. B.J. 46 (Nov. 2004).
[8] *Williams v. Ergle*, 698 So.2d 1294 (Fla. 5th DCA 1997) (citing Art. I, s. 19, Fla. Const.).
[9] Section 951.23, F.S.
[10] Note that case law has held that pretrial detainees are "prisoners" for purposes of state statutes allowing recovery of subsistence costs and certain medical expenses from prisoners. *Williams v. Ergle*, 698 So. 2d 1294 (Fla. 5th DCA 1997).

ambulance services, clinical laboratory services, and durable medical equipment, prosthetics, orthotics, and supplies. Other Medicare providers are paid via a prospective payment system (PPS). The PPS is a method of reimbursement in which Medicare payment is made based on a predetermined, fixed amount. The payment amount for a particular service is derived based on the classification system of that service (for example, diagnosis-related groups for inpatient hospital services). The CMS uses separate PPSs for reimbursement to acute inpatient hospitals, home health agencies, hospices, hospital outpatient departments, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term care hospitals, and skilled nursing facilities.

Medicare rates are generally higher than Medicaid rates, but could be lower than rates charged by a medical services provider. In 2008, the General Appropriations Implementing Bill, chapter 2008-153, Laws of Florida, capped medical payment rates the Department of Corrections (DOC) could pay to a hospital, or a health care provider providing services at a hospital. Payments were capped at 110 percent of the Medicare allowable rate for inmate medical care when no contract existed between the department and a hospital, or a health care provider providing services at a hospital. However, the DOC was allowed to pay a hospital up to 125 percent of the Medicare allowable rate if the hospital had reported a negative operating margin to the Agency for Health Care Administration for the previous year.

In 2009, s. 945.6041, F.S., created by chapter 2009-63, Laws of Florida, codified the payment caps. Section 945.6041, F.S., also made other medical service providers, defined in s. 766.105, F.S., and medical transportation services subject to the medical payment cap. The DOC has saved $20 million in the year after payment caps were implemented.[11] The DOC expenditures from the Inmate Health Services appropriation category, from which hospital and physician services are paid, totaled $170 million in FY 2008-09.

Indigent Health Care

Federal[12] and state law, as well as hospital collection policies, manage the way that medical care providers handle indigent patients. The Florida Health Care Responsibility Act[13] places the ultimate financial obligation for the out-of-county hospital care of qualified indigent patients on the county in which the indigent patient resides.[14] This part of ch. 154, F.S., defines "qualified indigent person" or "qualified indigent patient" as:

> a person who has been determined pursuant to s. 154.308 to have an average family income, for the 12 months preceding the determination, which is below 100 percent of the federal nonfarm poverty level; who is not eligible to participate in any other government program that provides hospital care; who has no private insurance or has inadequate private insurance; and who does not reside in a public institution as defined under the medical assistance program for the needy under Title XIX of the Social Security Act, as amended.[15]

[11] Senate Policy and Steering Committee on Ways and Means, *CS/CS/CS/SB 218 Bill Analysis* (April 8, 2010).
[12] Title XIX of the Social Security Act, 42 U.S.C §§ 1396 et seq.
[13] Sections 154.301-154.331, F.S.
[14] Section 154.302, F.S.
[15] Section 154.304, F.S.

III. Effect of Proposed Changes:

Section 1 of the bill amends s. 901.35(1), F.S., to specify that except as provided in s. 951.032, F.S., a person is responsible for paying any medical care expenses if he or she is ill, wounded, or otherwise injured during or *as a result of* an arrest for any state law or county or municipal ordinance. This specification, "as a result of an arrest," replaces current language, "at the time of an arrest." The bill removes all language regarding how a medical care provider can recover medical care expenses from arrestees from s. 901.35(2), F.S., and adds it to s. 951.032, F.S., (which relates to how county and municipal detention facilities recover medical costs from prisoners).

Section 2 of the bill amends s. 951.032, F.S., by replacing each use of the term "prisoner" with the term "in-custody pretrial detainee or sentenced inmate." However, the process by which county and municipal facilities recover medical care expenses from such persons remains unchanged.

The bill defines an "in-custody pretrial detainee or sentenced inmate" as a person whose physical freedom is restricted by a certified law enforcement officer or certified correctional officer pending disposition of an arrest or completion of a county court sentence. The term also includes a person who is furloughed by a criminal court for the express purpose of receiving medical treatment if a condition of the furlough is the immediate return to the custody of a county or municipal detention facility following completion of such treatment.

The bill moves language regarding how a medical care service provider can recover medical care expenses from s. 901.35, F.S., to s. 951.032, F.S. This language specifies that a third-party provider shall recover the expenses of medical care from an in-custody pretrial detainee or sentenced inmate from the following sources in the following order:

(1) Insurance of the person receiving the medical care;

(2) The person receiving medical care;

(3) A financial settlement for the medical care; or

(4) The general fund of the county or municipality.

The bill requires the third-party provider to make a "good faith effort" to recover the payment before it can seek reimbursement from the general fund of a county or municipality in which a person was arrested. A "good faith effort" is described as one that is consistent with that provider's usual policies and procedures related to the collection of fees from indigent patients who are not in the custody of a county or municipal detention facility.

The bill requires that, in the absence of a written agreement, remuneration made from county or municipal general funds for an in-custody pretrial detainee or sentenced inmate's medical care, must be billed and paid at 110 percent of the Medicare allowable rate. The bill provides that compensation may not exceed 125 percent of the Medicare allowable rate if the third-party provider has reported a negative operating margin for the previous year to the Agency of Health Care Administration through hospital-audited financial data. However, the bill does not apply the maximum to amounts billed and paid for medical physicians or osteopathic physicians licensed

under ch. 458, F.S., or ch. 459, F.S., respectively, for emergency services provided within a hospital emergency department.

The bill specifies that the responsibility of a governmental body (a county or municipality) for payment of medical costs ceases upon release of the in-custody pretrial detainee or sentenced inmate.[16]

The bill requires an in-custody pretrial detainee or sentenced inmate who has health insurance, subscribes to a health care corporation, or receives health care benefits from any other source to assign such benefits to the health care provider.

The bill specifies that law enforcement or the county or municipal detention facility is responsible for restricting the personal freedom of in-custody pretrial detainees or sentenced inmates receiving medical treatment or services from third-party providers.

Section 3 of 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:

With the exception of certain physician services provided within hospital emergency departments, providers of medical care will be limited regarding the rates they are allowed to charge for services provided to arrested parties when: (1) the person receiving the services cannot provide for payment of the costs and (2) the provider does not have a

[16] This applies even if those costs were incurred while the pretrial detainee or sentenced inmate was in custody. *See Jones v. Jenne*, 2008 WL 2323890 (S.D. Fla. 2008) (interpreting similar language in s. 901.35, F.S.).

formal written agreement with the county or municipality in which the person was arrested. To the extent such providers are currently charging and being paid more than 110 percent of Medicare rates or more than 125 percent of Medicare rates under certain conditions, the bill could result in decreased revenue for providers.

C. Government Sector Impact:

To the extent counties and municipalities are currently paying more than 110 percent of Medicare rates or more than 125 percent of Medicare rates under certain conditions for medical services, not including certain physician services provided within hospital emergency departments, that are provided to persons ill, wounded, or otherwise injured during or at the time of arrest, the bill could result in cost savings for counties and municipalities.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill's language regarding maximum payment at a percentage of the Medicare allowable rate is similar to the provisions of s. 945.6041, F.S., regarding payments by the DOC to a third-party health care provider for medical services provided to inmates if the health care provider does not have a contract for such services with the DOC or a private correctional facility that houses the inmate.

However, the bill's language differs from the DOC requirements in the following ways:

- The bill requires that remuneration must be *billed and paid* at a rate not to exceed 110 percent of Medicare, while s. 945.6041, F.S., requires only that compensation may not exceed 110 percent of Medicare rates. The bill and s. 945.6041, F.S., contain virtually identical provisions that compensation paid to hospitals may not exceed 125 percent of Medicare rates under certain conditions.
- The bill contains an exception to this maximum payment for amounts billed and paid for physicians licensed under ch. 458 or ch. 459, F.S., for emergency services provided within a hospital emergency department. Section 945.6041, F.S., contains no such exception. It is not clear if this exception within the bill applies only to payments made directly to physicians by the governmental body or whether the exception also applies to payments made to hospitals by the governmental body for services provided by physicians at the hospital.

VIII. Additional Information:

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

CS by Health Regulation on March 9, 2011:
The CS makes three changes when compared to the bill as filed:

- The CS makes a technical correction to a statutory reference;

- The CS provides a definition of "in-custody pretrial detainees or sentenced inmates;" and
- The CS specifies that law enforcement or the county or municipal detention facility is responsible for restricting the personal freedom of in-custody pretrial detainees or sentenced inmates receiving medical treatment or services from third-party providers.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/09/2011	.	
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	.	

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

Senate Amendment

Delete line 154
and insert:
listed in subsection (3), but that such reimbursement is not

960182

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/09/2011	.	
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	.	

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

Senate Amendment (with title amendment)

Delete lines 162 - 184
and insert:
(5) Absent a written agreement between the third-party provider and the governmental body, the remuneration made pursuant to subsection (4) must be billed by the third-party provider and paid by the governmental body at a rate not to exceed 110 percent of the Medicare allowable rate for the service. Compensation to a third-party provider may not exceed 125 percent of the Medicare allowable rate if there is no written agreement between the third-party provider and the

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governmental body and if the third-party provider reported a negative operating margin for the previous year to the Agency for Health Care Administration through hospital-audited financial data.

(6) The provisions of subsection (5) do not apply to amounts billed and paid for physicians licensed under chapter 458 or chapter 459 for emergency services provided within a hospital emergency department.

(7) The responsibility of the governmental body for payment of any in-custody medical costs ceases upon release of the in-custody pretrial detainee or sentenced inmate.

(8) An in-custody pretrial detainee or sentenced inmate who has health insurance, subscribes to a health care corporation, or receives health care benefits from any other source shall assign such benefits to the health care provider.

(9) For purposes of this section, in-custody pretrial detainees or sentenced inmates shall be defined as persons whose physical freedom is restricted by a certified law enforcement officer or certified correctional officer pending disposition of an arrest or completion of a county court sentence. Included within this definition are persons who are furloughed by a criminal court for the express purpose of receiving medical treatment where a condition of the furlough is the immediate return to the custody of a county or municipal detention facility following completion of such treatment.

(10) Law enforcement or the county or municipal detention facility is responsible for restricting the personal freedom of in-custody pretrial detainees or sentenced inmates receiving treatment or services under this section.

960182

42
43 ================ T I T L E A M E N D M E N T ================
44 And the title is amended as follows:
45 Delete line 38
46 and insert:
47 to the health care provider; providing a definition of
48 the term in-custody pretrial detainees or sentenced
49 inmates; providing that law enforcement or county or
50 municipal detention facilities are responsible for
51 restricting the personal freedom of certain in-custody
52 pretrial detainees or sentenced inmates; providing an
53 effective

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 548
INTRODUCER:	Senator Hays
SUBJECT:	Obsolete Health Care Provisions
DATE:	March 4, 2011 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Brown	Stovall	HR	**Favorable**
2.			BC	
3.				
4.				
5.				
6.				

I. Summary:

The bill repeals provisions from Florida Statutes relating to the designation of separate restrooms and separate dressing rooms for males and females, the Florida Healthy People 2010 program, and the MedAccess program.

This bill repeals the following sections of the Florida Statutes: 381.0091, 381.736, 408.90, 408.901, 408.902, 408.903, 408.904, 408.905, 408.906, 408.907, and 408.908.

II. Present Situation:

Separate Restrooms and Separate Dressing Rooms for Males and Females

Current law provides that any business may designate separate restrooms and separate dressing rooms for males and females and may prohibit the use of such designated restrooms or dressing rooms by persons of the opposite gender.[1]

In buildings or facilities owned or operated by the state or any political subdivision of the state that contain more than one restroom, the restrooms for males must be separate from those for females and each restroom that has capacity for more than one occupant must be designated by appropriate signage as a restroom for males or for females.[2]

[1] *See* s. 381.0091(1), F.S.
[2] *See* s. 381.0091(2), F.S.

The Florida Healthy People 2010 Program

In 2004 the Legislature created the Florida Healthy People 2010 program.[3] Under the program, the Department of Health (DOH) is directed to, with existing resources, monitor and report Florida's status regarding the federal Healthy People 2010 program's goals and objectives that were being tracked and were available to the DOH on July 1, 2004. The goals and objectives of the federal program are described in Florida Statutes as being designed to measure and help improve the health of all Americans by increasing the quality and years of healthy life and eliminating health disparities among different segments of the population.[4]

The DOH is further required under the program to:

- Provide a report by December 31 of each year to the Legislature on the status of health disparities among minorities and non-minorities using health indicators consistent with those identified by the federal program;

- Work with minority physician networks to develop programs to educate health care professionals about the importance of culture in health status, for the purpose of reducing negative health consequences that result from ignoring racial and ethnic cultures;

- Work with and promote the establishment of public and private partnerships with charitable organizations, hospitals, and minority physician networks to increase the proportion of health care professionals from minority backgrounds; and

- Promote research at colleges and universities that have historically large minority enrollments on methods for reducing health disparities by working with such colleges and universities and with community representatives to encourage local minority students to pursue professions in health care.[5]

In December 2010, the Federal Government replaced the Healthy People 2010 program with the Healthy People 2020 program for health promotion and disease prevention.

Minority Physician Networks

In 2004, the Legislature required the Agency for Health Care Administration (AHCA) to contract for Medicaid services with established minority physician networks that provide services to historically underserved minority patients.[6] A minority physician network is defined as a network of primary care physicians with experience managing Medicaid or Medicare recipients that is predominantly owned by minorities and which may have a collaborative partnership with a public college or university and a tax-exempt charitable corporation.[7]

The AHCA first began contracting with two minority physician networks in 2003 and by June 2006, the networks were serving over 137,000 Medicaid recipients. However, by October 2010,

[3] *See* s. 1, ch. 2004-365, Laws of Florida.
[4] *See* s. 381.736(1), F.S.
[5] *See* s. 381.736(2)-(5), F.S.
[6] *See* s. 3, ch. 2004-365, Laws of Florida.
[7] *See* s. 409.901(24), F.S.

both minority physician networks had been acquired or had entered into acquisition agreements with two Medicaid health maintenance organizations, and Florida's minority physician network enrollees transitioned into Medicaid HMO membership during 2009 and 2010.[8]

The MedAccess Program

In 1993 the Legislature created the MedAccess program, which became statutorily effective July 1, 1994, to be administered by the AHCA.[9] The program is designed for the state to provide certain health care benefits to uninsured Floridians with a gross family income equal to or less than 250 percent of the federal poverty level who also meet other eligibility requirements. The AHCA is authorized to pay health care providers under the program at the same reimbursement rates and fees in effect under the Medicaid program.[10]

Despite being statutorily authorized by the Legislature, effective July 1, 1994, the MedAccess program has never been funded and therefore has never been implemented by the AHCA.

III. Effect of Proposed Changes:

The bill:

- Repeals statutory provisions relating to separate restrooms and dressing rooms for males and females. The provisions in s. 381.0091, F.S., relating to restrooms and dressing rooms at private-sector business are permissive in nature and do not require businesses to comply. However, that same statute contains requirements for government buildings and facilities relating to separate restrooms for men and women, and those requirements are eliminated under the bill.

- Repeals statutory provisions for the creation and administration of the Florida Healthy People 2010 program. The provisions in s. 381.736, F.S., requiring certain monitoring and reporting activities by the DOH regarding health disparities and other DOH activities to address cultural diversity are eliminated under the bill.

- Repeals statutory provisions for the creation and administration of the MedAccess program. Without funding the program has been defunct since it was created in 1993, and the bill eliminates the program from Florida Statutes.

The bill's effective date is 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.

[8] Issue Brief 2011-221, *Overview of Medicaid Managed Care Programs in Florida,* Senate Committee on Health Regulation, November 2010, p. 4.
[9] *See* s. 39, ch. 93-129, Laws of Florida.
[10] *See* ss. 408.90-408.908, 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:

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.

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 864
INTRODUCER:	Health Regulation Committee
SUBJECT:	Certificates of Need
DATE:	March 9, 2011
REVISED:	

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

I. Summary:

This bill is the result of a review of the moratorium on nursing home certificates of need, which is discussed in Florida Senate Interim Report 2011-125.[1]

This bill extends, until July 1, 2016, the moratorium on nursing home certificates of need and the requirement for the Agency for Health Care Administration (Agency) to reduce upon request, the mandatory percentage of Medicaid patient days in certain nursing homes.

This bill substantially amends the following sections of the Florida Statutes: 408.040 and 408.0435.

II. Present Situation:

Certificates of Need

A certificate of need (CON) is a written statement issued by the Agency evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility, health service, or hospice.[2] Under this regulatory program, the Agency must provide approval through the CON review and approval process prior to a provider establishing a new nursing home or adding nursing home beds.

[1] The Florida Senate Interim Report 2011-125 is available at http://www.flsenate.gov/data/Publications/2011/Senate/reports/interim_reports/pdf/2011-125hr.pdf (Last visited on January 25, 2011).

[2] Section 408.032(3), F.S.

The Florida CON program has three levels of review: full, expedited, and the granting of an exemption.[3] The nursing home projects addressed in s. 408.036, F.S., related to CONs are as follows:

Projects Subject to Full Comparative Review

- Adding beds in community nursing homes; and
- Constructing or establishing new health care facilities, which include skilled nursing facilities (SNFs).[4]

Projects Subject to Expedited Review

- Replacing a nursing home within the same district; and
- Relocating a portion of a nursing home's licensed beds to a facility within the same district.

Exemptions from CON Review

- Converting licensed acute care hospital beds to Medicare and Medicaid certified skilled nursing beds in a rural hospital;
- Adding nursing home beds at a SNF that is part of a retirement community which had been in operation on or before July 1, 1949 for the exclusive use of the community residents;
- Combining licensed beds from two or more licensed nursing homes within a district into a single nursing home within that district if 50 percent of the beds are transferred from the only nursing home in a county and that nursing home had less than a 75 percent occupancy rate;[5]
- State veteran's nursing homes operated by or on behalf of the Florida Department of Veterans' Affairs;
- Combining into one nursing home, the beds or services authorized by two or more CONs issued in the same planning subdistrict;
- Separating into two or more nursing homes in the subdistrict, the beds or services that are authorized by one CON;
- Adding no more than 10 total beds or 10 percent of the licensed nursing home beds of that facility, whichever is greater; or if the nursing home is designated as a Gold Seal nursing home, no more than 20 total beds or 10 percent of the licensed nursing home beds of that facility for a facility with a prior 12-month occupancy rate of 96 percent or greater; and
- Replacing a licensed nursing home on the same site, or within 3 miles, if the number of licensed beds does not increase.

The CON program applies to all nursing home beds, regardless of the source of payment for the beds (private funds, insurance, Medicare, Medicaid, or other funding sources).

Determination of Need

A CON is predicated on a determination of need. The future need for community nursing home beds is determined twice a year and published by the agency as a fixed bed need pool for the

[3] Section 408.036, F.S.
[4] Section 408.032(16), F.S., defines a SNF as an institution, or a distinct part of an institution, which is primarily engaged in providing, to inpatients, skilled nursing care and related services for patients who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons.
[5] This exemption is repealed upon the expiration of the moratorium by operation of s. 408.036(3)(f), F.S.

applicable planning horizon. The planning horizon for CON applications is 3 years. Need determinations are calculated for subdistricts within the Agency's 11 service districts[6] based on estimates of current and projected population as published by the Executive Office of the Governor.

The need formula[7] links the projected subdistrict need to a projected increase in the district need for nursing home beds. The district increase is based on the expected increase in the district population age 65 to 74 and age 75 and over, with the age group 75 and over given 6 times more weight in projecting the population increase. The projected district bed need total is then allocated to its subdistricts. The result for a given subdistrict is adjusted to reflect the current subdistrict occupancy of beds, and a desired standard of 94 percent occupancy. The subdistrict net need is the excess of the allocated beds over the licensed or approved beds in the subdistrict. If current occupancy of licensed beds is less than 85 percent, the net need in the subdistrict is zero regardless of whether the formula otherwise shows a net need.

The Agency is required to issue a CON to the holder of a provisional certificate of authority to construct nursing home beds for the exclusive use of the prospective residents of the proposed continuing care facility under a different bed-need assessment scheme.[8] The Agency is required to approve at least one sheltered nursing home bed[9] for every four proposed residential units. Additional sheltered nursing home beds must be approved based on actual utilization and demand by current residents. Sheltered nursing home beds are not included in the need formula for community nursing home beds.

Application Process

Nursing home bed projects subject to competitive review are included in the batching cycle for "other beds and programs." The review process takes approximately 120 days.[10] The fixed bed need determination is published in the Florida Administrative Weekly. A letter of intent describing the applicant, the project type including the number of beds, and its location must be submitted to the Agency at least 30 days prior to the applicable batching cycle application due date.[11] A grace period after the initial letter of intent deadline provides an opportunity for other applicants to compete with an initial letter of intent. The grace period extends this initial phase by an additional 16 days for the submission of a competitor's letter of intent.

The CON application must be submitted to the Agency by the date published for that batching cycle. The Agency must perform a completeness review of the application within 15 calendar days of the application submission deadline.[12] The applicant has 21 calendar days after receipt of

[6] The nursing home subdistricts are set forth in Rule 59C-2.200, F.A.C.
[7] Rule 59C-1.036, F.A.C.
[8] Section 651.118, F.S.
[9] A sheltered nursing home bed is a nursing home bed located within a continuing care facility for which a CON is issued pursuant to s. 651.118(2), F.S. Generally these beds must be used for residents of the continuing care facility. However, the beds may be used for persons who are not residents of the continuing care facility for a period of up to 5 years after the date of issuance of the initial nursing home license. A continuing care community may request an extension of this timeframe for up to 30 percent of the sheltered nursing home beds based on demonstrated financial need.
[10] Presentation by the Agency on Florida CONs to the House Health Innovation Committee on January 8, 2008. A copy of the presentation slides is available from the Senate Committee on Health Regulation.
[11] Rule 59C-1.008, F.A.C.
[12] Rule 59C-1.010, F.A.C.

the Agency's request for additional information to provide the requested information, otherwise the application is withdrawn from further consideration. The Agency must determine whether the application is complete or withdrawn within 7 calendar days after receipt of the requested information.

The Agency will conduct public hearings on the applications, if requested and the Agency determines that a proposed project involves issues of great local public interest.[13]

The Agency reviews CON applications for additional nursing home beds in context with the following criteria:[14]

- The need for the health care facilities and health services being proposed. An application for nursing facility beds will not be approved in the absence or insufficiency of a numeric need unless the absence or insufficiency of numeric need is outweighed by other information presented in a CON application showing special circumstances consistent with the additional criteria that follows;[15]
- The availability, quality of care, accessibility, and extent of utilization of existing health care facilities and health services in the service district of the applicant;
- The ability of the applicant to provide quality of care and the applicant's record of providing quality of care;
- The availability of resources, including health personnel, management personnel, and funds for capital and operating expenditures, for project accomplishment and operation;
- The extent to which the proposed services will enhance access to health care for residents of the service district;
- The immediate and long-term financial feasibility of the proposal;
- The extent to which the proposal will foster competition that promotes quality and cost-effectiveness;
- The costs and methods of the proposed construction, including the costs and methods of energy provision and the availability of alternative, less costly, or more effective methods of construction;
- The applicant's past and proposed provision of health care services to Medicaid patients and the medically indigent; and
- The applicant's designation as a Gold Seal Program nursing facility pursuant to s. 400.235, F.S., when the applicant is requesting additional nursing home beds at that facility.

The Agency issues a State Agency Action Report which states the Agency's intent to grant or deny a CON for projects in their entirety or for identifiable portions thereof and states the conditions required, if any, of the CON holder. If there is no challenge to all or any part of the agency decision embodied in the State Agency Action Report within 21 days after publication in the Florida Administrative Weekly, the decision becomes final and the CON is issued.[16]

Applicants in the same batching cycle and exiting health care facilities in the same district that will be substantially affected by the issuance of any CON may challenge the issuance or denial

[13] Section 408.039, F.S.
[14] Section 408.035, F.S.
[15] Rule 59C-1.036, F.A.C.
[16] *Supra* fn. 12.

of a CON. The Division of Administrative Hearings conducts the hearing, which must commence within 60 days after the administrative law judge has been assigned except upon unanimous consent of the parties or pursuant to a motion of continuance granted by the administrative law judge.[17] A party to an administrative hearing for an application for a CON may seek judicial review of the final order issued by the administrative law judge to the District Court of Appeal.

Moratorium on Nursing Home CONs

In 2001, the Legislature enacted the first moratorium on the issuance of CONs for additional community nursing home beds until July 1, 2006.[18] In 2006, the Legislature extended the moratorium until July 1, 2011.[19] In addition, the Legislature provided for additional exceptions to the moratorium to address occupancy needs that might arise.

The Legislature has provided for certain exceptions to the moratorium on CONs as follows:

- Adding sheltered nursing home beds;
- Beds may be added in a county that has no community nursing home beds and the lack of beds is the result of the closure of nursing homes that were licensed on July 1, 2001;[20]
- Adding the greater of no more than 10 total beds or 10 percent of the licensed nursing home beds of a nursing home located in a county having up to 50,000 residents,[21] if:
  - The nursing home has not had any class I or class II deficiencies22 within the 30 months preceding the request for addition;
  - The prior 12-month average occupancy rate for the nursing home beds at the facility meets or exceeds 94 percent and the facility has not had any class I or class II deficiencies since its initial licensure; or
  - For a facility that has been licensed for less than 24 months, the prior 6-month average occupancy rate for the nursing home beds at the facility meets or exceed 94 percent and the facility has not had any class I or class II deficiencies since its initial licensure; and
- Adding the greater of no more than 10 total beds or 10 percent of the number of licensed nursing home beds if:
  - The facility has not had any class I or class II deficiencies within the 30 months preceding the request for addition;

[17] *Supra* fn. 13.
[18] Chapter 2001-45, L.O.F. s. 52.
[19] Chapter 2006-161, L.O.F.
[20] The request to add beds under this exception to the moratorium is subject to the full competitive review process for CONs.
[21] Twenty-five counties have fewer than 50,000 residents. These counties include: Baker, Bradford, Calhoun, DeSoto, Dixie, Franklin, Gadsden, Gilchrist, Glades, Gulf, Hamilton, Hardee, Hendry, Holmes, Jefferson, Lafayette, Levy, Liberty, Madison, Okeechobee, Suwannee, Taylor, Union, Washington and Wakulla. Source: The Florida Legislature Office of Demographic and Economic Research as of April 1, 2010, *The Florida Legislature Econographic News*, 2010 Volume Ia, available at: http://edr.state.fl.us/Content/population-demographics/reports/econographicnews-2010v1a.pdf, (Last visited on January 28, 2011).
[22] Deficiencies in nursing homes are classified according to the nature and scope of the deficiency. A class I deficiency is a deficiency that the Agency determines presents a situation in which immediate corrective action is necessary because the facility's noncompliance has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident receiving care in a facility. A class II deficiency is a deficiency that the Agency determines has compromised a resident's ability to maintain or reach his or her highest practicable physical, mental, and psychosocial well-being, as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services. *See* s. 400.23(8), F.S.

- The prior 12-month average occupancy rate for the nursing home beds at the facility meets or exceeds 96 percent;
- The prior 12-month occupancy rate for the nursing home beds in the subdistrict is 94 percent or greater; and
- Any beds authorized for the facility under this exception in a prior request have been licensed and operational for at least 12 months.[23]

Nursing Home Occupancy Levels

As of January 1, 2011, there are 674 licensed nursing homes and 82,562 licensed nursing home beds in Florida.[24]

Over the last 10 years, the average nursing home occupancy level in Florida has remained below 90 percent and has been declining steadily. However, since the moratorium was reenacted in 2006, the Leon and Okeechobee subdistricts have exceeded slightly the 94 percent occupancy level. The number of resident days for persons aged 65 and older has been declining steadily. The annual statewide nursing home occupancy levels are presented below:[25]

Year	Percent Occupancy Level	Number of resident days per 1000 population aged 65+
2000	85.29	8849
2001	85.07	8679
2002	86.75	8639
2003	87.67	8655
2004	88.12	8445
2005	87.17	8346
2006	88.22	8094
2007	88.05	7942
2008	87.35	7756
2009	86.92	7618

The Agency projected the nursing home occupancy levels and need projections for January 2016 and the statewide occupancy level is projected at 86.55 percent. However, three subdistricts will exceed the desired standard of 94 percent occupancy based on the Agency's projection. This calculation projects additional nursing home beds will be needed in three rural subdistricts.[26] Exceptions to the moratorium currently authorized in law will enable nursing homes which have

[23] The request to add beds under the exception to the moratorium is subject to the procedures related to an exemption to the CON requirements.

[24] Source: Agency for Health Care Administration, as of January 1, 2011. Data available at: http://www.fdhc.state.fl.us/MCHQ/Long_Term_Care/FDAU/docs/SummaryAllActive.pdf, (Last visited on January 27, 2011).

[25] Agency for Health Care Administration report provided to professional staff of the Florida Senate Health Regulation Committee on July 28, 2010, a copy of which is available upon request from the Senate Health Regulation Committee.

[26] Okeechobee will need 16 additional nursing home beds (currently it has 180 licensed beds), Columbia/ Hamilton/ Suwannee will need 86 additional nursing home beds (currently it has 766 licensed beds), and Putnam will need 39 additional nursing home beds (currently it has 337 licensed beds). *See supra* fn. 25.

not been poor performers that are located in these areas to incrementally expand to meet increased demand if it materializes as projected.

CON Conditions

Section 408.040, F.S., authorizes the Agency to impose conditions on the issuance of a CON or an exemption. Each nursing home participating in the Medicaid program provided a statement of intent in its application for a CON that includes a specified percentage of the annual patient days at the facility that will be utilized by patients eligible for care under the Medicaid program. The Medicaid-patient-days condition is included on the CON or exemption for these nursing homes.

The holder of a CON or an exemption with conditions may be granted a modification of the conditions by the Agency based on a demonstration of good cause. Additionally, if a nursing home is located in a county in which a long-term care community diversion pilot project has been implemented or in a county with a managed care program for Medicaid recipients who are 60 years of age or older, the Agency must grant a nursing home's request to reduce its annual Medicaid-patient-days condition by not more than 15 percent. A nursing home may submit only one request every 2 years for the automatic reduction. The authority for the automatic reduction expires June 30, 2011.[27]

Since 2006, when this provision authorizing the automatic reduction went into effect,[28] the Agency has granted the automatic 15 percent reduction 230 times.[29] Some licensed nursing homes have been granted reductions on three separate occasions.

Senate Interim Report 2011-125

During the 2010-2011 interim, professional staff of the Senate Committee on Health Regulation examined factors impacting an extension of the moratorium on nursing home certificates of need.

Senate professional staff recommended in Interim Report 2011-125 that the Legislature reenact and continue the moratorium on the CON for community nursing home beds through the year 2016 based on the following findings:

- The public prefers home and community-based residency options;
- Projected nursing home occupancy levels through 2016 are to decrease;
- The economic climate continues to affect existing nursing homes; and
- The Legislature continues to place an emphasis on, and facilitates, the ability of Floridians to reside in less restrictive settings than nursing homes.

In addition, Senate professional staff recommended that the exceptions and exemptions that the Legislature has enacted to implement the moratorium and address potential surges in occupancy levels be retained. Staff also suggested that language regarding the exception to the moratorium in a county having up to 50,000 residents should be clarified to reflect that a facility requesting additional beds must certify that it has not had any class I or class II deficiencies within

[27] Section 408.040(1)(d), F.S.
[28] Chapter 2006-161, L.O.F.
[29] Source: Agency for Health Care Administration email to Senate Health Regulation professional staff dated August 19, 2010, a copy of which is available from the Senate Health Regulation Committee.

30 months or since it was initially licensed if licensed within 25–29 months preceding the request for additional beds.

Furthermore, Senate professional staff recommended that the Legislature reenact the automatic 15 percent reduction of the annual Medicaid-patient-days condition for nursing homes located in a county in which a long-term care community diversion pilot project has been implemented or in a county with a managed care program for Medicaid recipients who are age 60 years or older. The recommendation for continuing the automatic reduction is based on the ongoing emphasis to reduce nursing home care in favor of community-based care. Staff recommended that the automatic reduction expire on a date that coincides with the date for continuation of the moratorium in order to allow a reassessment of the long-term care environment and help ensure that reduction requests do not eliminate the availability of Medicaid nursing home beds below future needs.

III. Effect of Proposed Changes:

Section 1 amends s. 408.040, F.S., to extend until July 1, 2016, the requirement that the Agency automatically grant to certain nursing homes[30] their request to reduce the condition on their CON requiring a percentage of annual patient days to be utilized by patients eligible for care under the Medicaid program.

Section 2 amends s. 408.0435, F.S., to extend until July 1, 2016, the moratorium on certificates of need for additional community nursing home beds.

This section clarifies that a nursing home requesting, under one of the statutory exceptions, a CON during the moratorium must certify that it has not had any class I or class II deficiencies within 30 months preceding the request for additional beds or since initial licensure if licensed less than 30 months. In addition, the facility must certify that it has had an average occupancy rate for nursing home beds that meets or exceeds 94 percent for the designated timeframe. A facility that has been licensed 24 months or longer must certify that the prior 12-month average occupancy rate met or exceeded 94 percent, while a facility that has been licensed for less than 24 months must certify that the prior 6-month average occupancy rate met or exceeded 94 percent.

Section 3 provides that the bill will take effect upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

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

[30] Section 408.040, F.S., provides that only nursing homes located in a county in which a long-term care community diversion pilot project has been implemented or in a county with a managed care program for Medicaid recipients who are 60 years of age or older or dually eligible for Medicare and Medicaid are eligible for the automatic reduction.

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 the 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 continues the current moratorium on certificates of need for additional community nursing home beds. Therefore, unless an exception or exemption applies, new nursing home facilities may not be built and existing facilities may not be expanded to provide additional community nursing home beds.

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.

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:	SPB 7060
INTRODUCER:	For consideration by the Health Regulation Committee
SUBJECT:	Ratification of Rules
DATE:	March 7, 2011 REVISED:

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

I. Summary:

The proposed committee 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 proposed committee 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.
[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

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;
- Informed consent and agreement for treatment;

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.

- 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 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]

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

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 proposed committee 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 proposed committee 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 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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A Statement of Estimated Regulatory Cost (SERC) of Proposed Rules in Regulation of Pain Management Clinics in Florida

BOM 64B8-9.0131

Standards of Practice for Physicians Practicing in PMC

Florida Department of Health

January 18, 2011

Center for Economic Forecasting and Analysis
Florida State University
3200 Commonwealth Blvd.
Tallahassee, Fl. 32303

Project Timeline

12/15/2010 to 1/18/2011

Institutional Capacity

The Center for Economic Forecasting and Analysis (CEFA) is part of the Florida State University Institute of Science and Public Affairs (ISPA), which is a multi-disciplinary research institute. CEFA specializes in applying advanced, computer-based economic models and techniques to examine and help resolve pressing public policy issues across a spectrum of research areas. CEFA provides advanced research and training to students in the areas of health care, education, high technology, energy, and environmental economics, economic impact analysis, among others.

Scope and Deliverable

CEFA has estimated the costs for both the agencies and the Pain Management Clinics (PMC) that are required to comply with the following rules:

- BOM Rule: 64B8-9.0131 Standards of Practice for Physicians Practicing in PMC
- BOM Rule: 64B8-9.0132 Requirement for PMC Registration; Inspection or Accreditation
- BOM: 64B8-9.0131(Subparagraph (2)(n): Training Requirements
- BOM/BOOM: 64B8-9.0134/64B15-14.0054 Maximum Number of Prescriptions in Registered PMC.
- BOM/BOOM: 64B8-9.0133/64B15-14.0053 Approval of Nationally Recognized Pain Management Accrediting Organizations
- DOH: 64B-7.001: Pain Management Clinic Registration Requirements
- DOH: 64B-7.003: Counterfeit-Resistant Prescription Blanks

CEFA has estimated for each of the rules:

1. The number of individuals that are likely to be required to comply with the rule and a general description of the types of individuals likely to be affected by the rule.
2. The cost to state and local government entities of implementing and enforcing the proposed rules and their anticipated effect on state and local revenues.
3. The transaction costs likely to be incurred by individuals and government agencies, required to comply with the rules

The Florida Pain Management Clinic Industry Overview

Sections 458.3265, and 459.0137, F.S., created the registration and inspection of pain management clinics with the Department of Health and required the Boards of Medicine and Osteopathic Medicine to promulgate rules for the standards of practice of physicians practicing in pain management clinics and rules to implement certain other pain management clinic provisions. The Allopathic Medical Practice Act, Chapter 458, F.S. (MD) and the Osteopathic Medical Practice Act, Chapter 459, F.S. (DO) are similar and the proposed pain management clinic rules of both of these physician boards are also similar. Pain management clinics may have MD or DO licensed Florida physicians or a combination of both practicing at the clinic at any one time. The Board of Osteopathic Medicine has in effect a standards of practice rule, a training rule and a registration/inspection or accreditation rule which are similar to the proposed Board of Medicine rules being addressed in this SERC.

Below is an overview of the Pain Management Clinics in Florida. The data is from a December 9, 2010 download of the "Application Status" file from the Florida Department of Health. No changes since 12/09/2010 have been considered – therefore if an additional clinic was approved, or a clinic lost its "clear" status after December 9, 2010, they have not been accounted for in this study.
This data includes records for clinics adding locations, adding new physicians and some are in progress and haven't been approved as of December 9, 2010. Others are listed as withdrawn, "admin. revoked", closed, denied or under emergency suspension. The records that were not listed as "clear" were deleted. Then, all multiples for any clinic were deleted to give the final number of clinics with clear status as 932 on the December 9, 2010 date.

Clinic Locations: this table shows the number of registered Pain Management Clinics, ranked from largest to smallest, by county, for the top 10 counties as of 12/09/2010.

County	Clinics
BROWARD	117
HILLSBOROUGH	113
PALM BEACH	108
MIAMI-DADE	89
DUVAL	51
ORANGE	49
PINELLAS	47
PASCO	31
VOLUSIA	30
LEE	29

Density: To estimate the density of Pain Management Clinics by county, the number of clinics was divided by the population, 18 and over, in the county. This yields the following density figures, from highest to lowest for the top 10 counties.

County	Clinics/100k pop.
HILLSBOROUGH	12.52
PALM BEACH	10.68
FRANKLIN	10.63
BROWARD	8.61
PASCO	8.34
DUVAL	7.88
SARASOTA	7.74
VOLUSIA	7.50
NASSAU	7.31
HERNANDO	7.27
PUTNAM	7.15
MANATEE	7.14

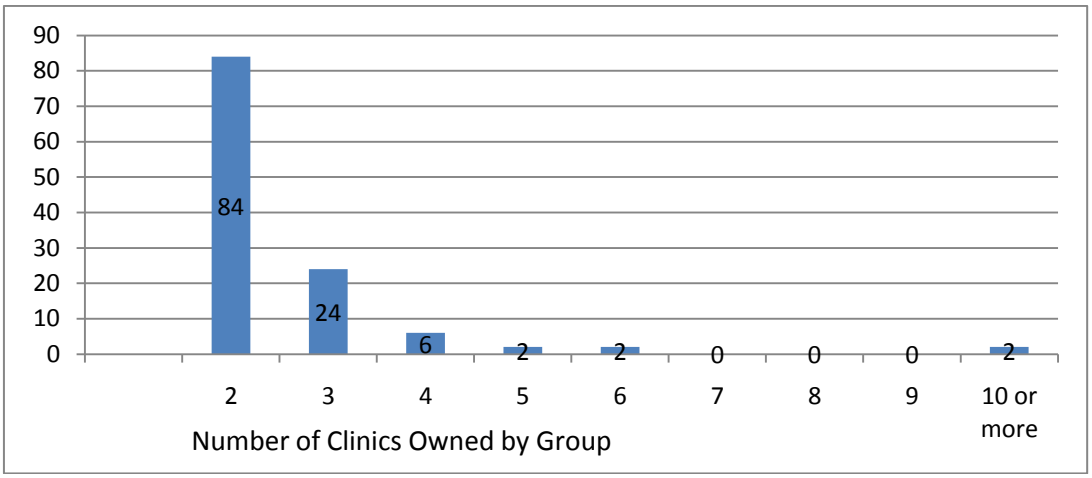
Appendix 2 shows the total for all counties that have at least 1 registered Pain Management Clinic.

Many of the clinics have physicians who are registered to dispense medication on the premises of the clinic. To do this, the physician must register with the Florida Department of Health and pay a $100 fee. The following table shows the number of clinics whose Designated Physician is registered to dispense medication for the top 10 counties in Florida.

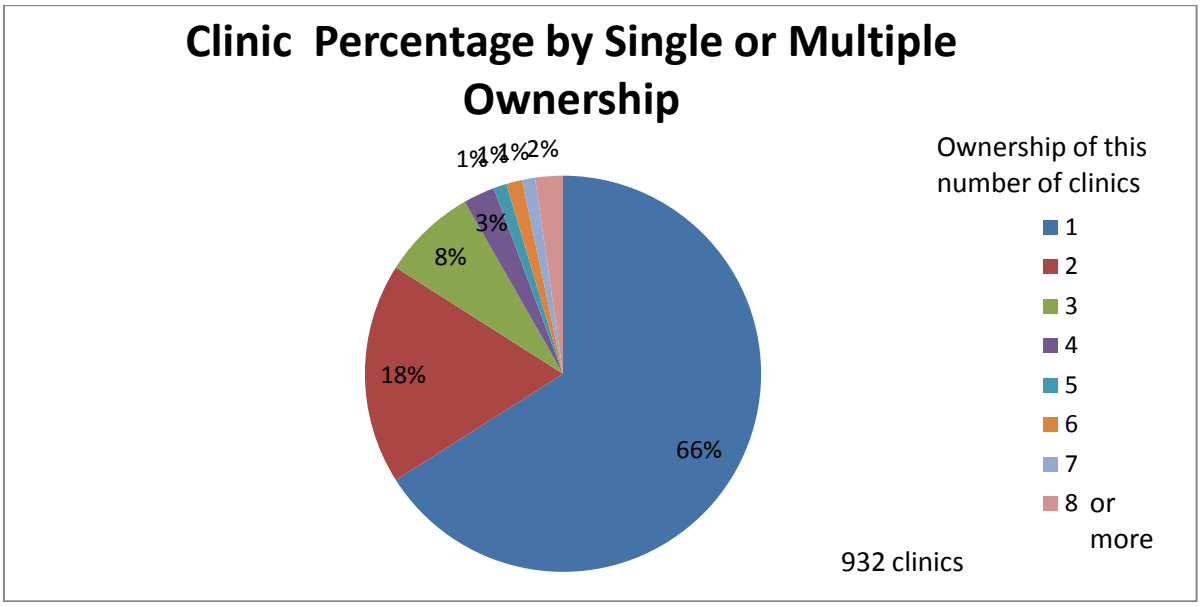
County	Clinics	Dispensing
PALM BEACH	108	77
BROWARD	117	73
MIAMI-DADE	89	50
HILLSBOROUGH	113	45
PINELLAS	47	32
DUVAL	51	31
ORANGE	49	29
PASCO	31	18
SARASOTA	24	18
LEE	29	16

Appendix 2 shows the total for the whole state.

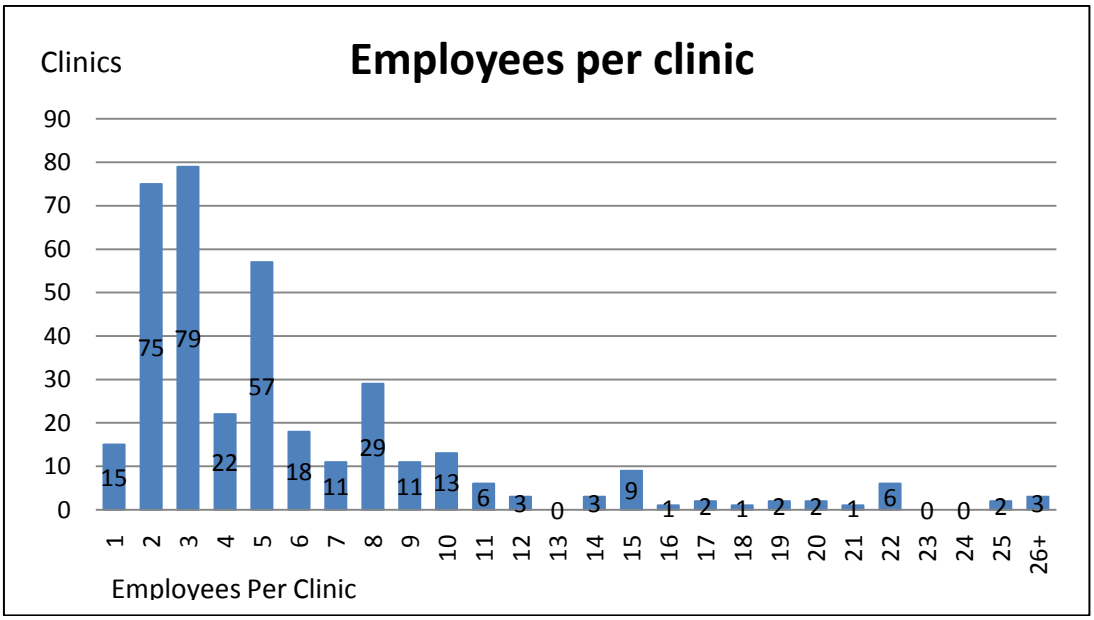
To check for concentration of ownership, the data was analyzed to see how many groups own more than one Pain Management Clinic in Florida. The number of clinics that are owned as an individual clinic is 615 clinics (66%). Of the remaining 317 clinics, the below graph shows that there are 84 groups that own 2 clinics, 24 that own 3 clinics, 6 that own 4 clinics, 2 that own 5 clinics, 2 that own 6 clinics and then one group that owns 10 clinics and one that appears to own 21 clinics. Checking the concentration, the clinics owned by groups that four or less Pain Management Clinics compose 94.31% of the clinics. These were found by analyzing the data for common listed owners and common mailing addresses and are shown in the graph below.



The graph below shows the same information, by percentage of the total clinics.



To check for concentration in any given county or group of counties, the ownership groups were analyzed to see which counties they operated in. Appendix 3 shows the list of those groups owning three or more pain clinics and the counties that they operate in.
Data from the same database as above, as well as additional data from Dun & Bradstreet's Selectory database was obtained and analyzed. Cross-referencing the DOH data and the current Selectory database, 371 of the 932 clinics were found on the database. Information on the number of employees was recorded and analyzed. The median number of employees was 4 for this sample. The employee number was derived using Selectory data for total sales and sales per employee.



A majority, 248 of the 371 (66.8%) of the clinics found in the Selectory database have 5 employees or less. Those that have 3 or less employees (169 of 371) account for 45.5% of these clinics.

Estimating the Number of Physicians

Establishing an upper and lower bound: Physicians are allowed work at more than one clinic at a time, including working part-time at a Pain Management Clinic and having a separate practice. There is no requirement for all physicians to register with DOH. However, each clinic must register a Designated Physician that is responsible for the clinic.
To establish an upper and lower bound for the "actual number of physicians working" to estimate things like the number of patients seen and the number of prescriptions written, the lower bound will be 932 for physicians, one for each Pain Management Clinic.
Since data is not available, other methods are used to estimate physicians working in Pain Management Clinics. Data was obtained from an advertising website and analyzed. The number of clinics found on one marketing website was 366, showing 574 physicians. That website is Ucomparehealthcare.com.
Their data was analyzed and it showed the doctors per clinic in the below percentages:

Clinics with	**Percentage**
1 physician	74.90%
2 physicians	13.10%
3 physicians	7.10%
4 physicians	1.40%
5 physicians	1.40%
6 or more	0.02%

Although we cannot identify how similar this sample is to the rest of the population, the analysis of the above data yields 1.57 physicians per clinic. That would lead us to an estimate of 1462 physicians as an upper bound. This data is possibly skewed upward for a couple of reasons. First, it might be more likely that the larger businesses would seek opportunities to advertise. Most importantly, one of the groups in this sample shows 20 physicians working at their clinic. The clinic is, indeed registered as a Pain Management Clinic in Florida, yet having 20 physicians shown working at one clinic likely skews this sample upward.
Using this sample, there are 566 physicians that are known, although one cannot be sure what percentage of time each physician is working at that clinic. If one uses the minimum (one physician at the clinic) for the unknown clinics in addition to this number, one obtains a lower-bound estimate of 1140.
To estimate the actual number of physicians working at Pain Management Clinics in Florida, a normal distribution was set up, with a 90% confidence interval between the lower and upper bounds. This resulted in a distribution with a mean of 1314 physicians and a standard deviation of 106.4.
The estimate that will be used for the number of physicians working full-time at registered Pain Management Clinics in Florida is a normal probability distribution function with a mean of 1314 and a standard deviation of 106.4. This yields an expectation of a 90% probability of the actual physician number being between 1140 and 1462.

Small business and number of PMCs affected: Most of the 932 registered PMCs in Florida will qualify as a small businesses under Florida 288.703.

Methods Used in this Study
Data was requested, purchased and gathered from various sources and then confirmed with physicians and industry professionals. Data that had a significant amount of uncertainty was estimated at upper and lower bounds, and then by statistical means. This study estimates some items and costs by the Monte Carlo method, where probability distributions are developed to use in the analysis. During each of the iterations of the model, values are drawn from the input probability distribution and used in calculating the range of the outputs.
Full-time is defined as 250 work days per year. When used, calculations use 40 hour work weeks and 50-week years.

Summary of Proposed Rule 64B8-9.0131. *Standards of Practice for Physicians Practicing in Pain Management Clinics.*

This proposed rule is applicable to allopathic physicians practicing in privately owned pain management clinics that are required to be registered pursuant to Section 458.3265, F.S. who primarily engage in the treatment of pain by prescribing or dispensing controlled substance medications. Allopathic (M.D.) and Osteopathic (D.O.) physicians both practice in Pain Management Clinics. The statute provides that both the allopathic board of medicine and the osteopathic board of medicine establish rules for standards of practice at Pain Management Clinics. A rule similar to this one is in effect for osteopathic medical physicians practicing at PMCs.

The requirements are presented in the following categories:

a. Evaluation of patient and medical diagnosis
b. Treatment plan
c. Informed consent and agreement for treatment
d. Periodic review
e. Consultation
f. Patient drug testing
g. Patient medical records
h. Denial or termination of controlled substance therapy
i. Facility and physical operations
j. Storage and handling of prescription drugs
k. Health and safety
l. Quality assurance
m. Data collection and reporting

A complete copy of the proposed rule is shown in Appendix 1.

Total Estimated Statewide Costs: Given the below assumptions, there is a 90% probability that the statewide cost of this rule is:
1st year: $56.449 Million to $72.519 Million, with a mean of $64.459 Million
Year 2 thru 5: $52.902 Million to $68.972 Million, with a mean of $60.912 Million

On a **per-clinic** basis, at the mean	**Per Existing Patient**	**Per New Patient**
1st Year: $69,162	**1st Year**: $43.73	**1st Year**: $60.83
Year 2 thru 5: $65,356	**Year 2 thru 5**: $40.91	

Model Clinic

This estimate will be for an average existing clinic. Characteristics of the average clinic, for estimation purposes, are that they:

1. Are currently meeting drug storage and drug records requirements under the statute
2. Meet the facility requirements for clinics
3. Have a phone line that is listed, but do not have a 24-hour dedicated fax line
4. Use in-house drug testing, unless required to do otherwise

To meet the other requirements of the proposed rule, this average clinic needs:

1. Indoor Sign
2. Outdoor Sign
3. Dedicated fax line plus installation
4. Basic Life Support Training for one person
5. Infection control program
6. Quality Assurance program established and inspection every three years
7. Emergency lighting and communications
8. Written, facility-specific disaster plan

Estimates were obtained for salaries of office personnel in these type clinics from online salary estimates and from discussions with physicians. For use in this study, although there is a wide range in Florida physician office and outpatient clinic salaries, the office manager is estimated at $40 per hour and other clinic personnel at $20 per hour, including benefits.

Evaluation of the Patient: A complete medical history, physical exam, written individualized treatment plan, informed consent and agreement for treatment, written controlled substance agreement, consultation, and possible referral are required for each patient. Any time involved in taking on a new patient, in this example, is assumed to be built in to new patient office visit charges typically used by Pain Management Clinics.

Patient Drug Testing: The drug test cup used for this estimate is a Clinical Laboratory Improvement Amendment (CLIA)-waived 12-panel test that measures ph, specific gravity and temperature and includes a built-in adulterant test. The cost estimate, including freight, is figured at $10.43. Administrative costs will be calculated at 20 minutes per in-house drug test. In the administrative cost is time for administrative employee to order and receive drug-test cups, deal with patient, collect cup, and view and record results. This administrative time estimate is $6.66 per in-house drug test. Outside drug tests, where a specimen is collected in the physician's clinic and sent out for either gas or liquid chromatography/mass spectrometry test will be estimated at $100, including administrative time to receive and record results. Cost estimates for sending a patient to an outside laboratory for their drug test are estimated at $150 to $300. This is one of the available options under the proposed rule, but it is not used in the following estimate due to the high cost.

For the following estimate, a minimum cost strategy was used for this example of a one-physician clinic. Drug testing is estimated to be done in the clinic, using CLIA-waived drug test cups. Drug testing will be sent out for gas or liquid chromatography/mass spectrometry, only when it meets the following requirements to do so:

1. The result indicates an adulterant was used
2. The result indicates absence of an expected substance
3. The result indicates the presence of a substance that is not expected
4. Either the patient or the physician dispute the outcome of the in-clinic test

Given that it's extremely difficult to estimate the number of unexpected results, including any false positives and false negatives that might occur; an example of additional costs will be shown separately to indicate the possible additional cost of these occurrences.

Therefore, when interpreting the results for the following drug testing model, one should note that it only includes the costs of drug testing in the clinic where none of the drug tests have results that would require the clinic to send the sample out for gas or liquid chromatography/mass spectrometry. Once again, examples of those additional costs will be separate.

To estimate drug testing costs on a state-wide basis requires a significant amount of analysis. The costs are influenced heavily by:

1. The amount of patients a physician sees
2. The number of new patients. They must be drug tested 3 times per year
3. The number of existing patients. They must be drug tested 2 times per year
4. The frequency of the patient visiting the physician. An existing patient taking up a "patient slot" versus a new patient in that slot influences the cost

Estimating the lower and upper bounds:

The lower bound example uses a clinic that sees 20 patients per day, with none being new patients. If these patients all come in 12 times per year, each would expect to be drug tested once every 6 visits – the required 2 tests per year. Therefore the expected daily number of drug tests would be 3.33. Expected daily cost of this example would be $57.00, given that each drug test cup costs $10.43 and the labor cost to administer the test and record the results is $6.67. Assuming the full-time example of 250 working days per year, this comes out to $14,250 on a yearly basis for this physician.

The upper bound example of drug testing assumes 50 patients per physician per day, and of those, 5 are new patients. Note that this example is on a per-physician basis, where the lower-bound uses the minimum number of physicians (1 physician per clinic) to keep the 932 clinics open. Existing patients come in four times per year in this upper-bound example; therefore they are expected to be drug-tested on half of their visits. This physician would expect to average 27.5 drug tests per day. To be clear, the 45 existing patients would have a 50%

probability of being drug tested, and the 5 new patients would have 100% probability of being tested. Expected drug-test cost would be $470.25 per day for this physician. This upper-bound estimate yields $117,562.50 per physician, more than 8 times the amount for the lower bound.

The Model for estimating Drug-Testing Costs:

First, a table was developed to show the range of expected daily drug tests for a clinic seeing from 20 to 50 patients per day. This table assumes existing patients have 6 visits per year – a balance between those that come in monthly versus those that come in the minimum of four times per year to the clinic. Note that new patients are subtracted from total patients when calculating the probability of being drug-tested and obtaining the estimated number of drug tests.

Table 1: Expected Number of In-clinic Drug Tests Per Day:

	Total Patients per Day						
New Patients	**20**	**25**	**30**	**35**	**40**	**45**	**50**
0	6.7	8.3	10.0	11.7	13.3	15.0	16.7
1	7.3	9.0	10.7	12.3	14.0	15.7	17.3
2	8.0	9.7	11.3	13.0	14.7	16.3	18.0
3	8.7	10.3	12.0	13.7	15.3	17.0	18.7
4	9.3	11.0	12.7	14.3	16.0	17.7	19.3
5	10.0	11.7	13.3	15.0	16.7	18.3	20.0

To show the static results on a per-physician basis, as would the typical economic impact study, those costs would be estimated at the mean and multiplied together. For this static example, the following table shows the expected drug costs per day.

Table 2: Expected Drug Testing Costs Per Day.

	Total Patients Per Day						
New Patients	**20**	**25**	**30**	**35**	**40**	**45**	**50**
0	$114.00	$142.50	$171.00	$199.50	$228.00	$256.50	$285.00
1	$125.40	$153.90	$182.40	$210.90	$239.40	$267.90	$296.40
2	$136.80	$165.30	$193.80	$222.30	$250.80	$279.30	$307.80
3	$148.20	$176.70	$205.20	$233.70	$262.20	$290.70	$319.20
4	$159.60	$188.10	$216.60	$245.10	$273.60	$302.10	$330.60
5	$171.00	$199.50	$228.00	$256.50	$285.00	$313.50	$342.00

This is the dollar figure matching the earlier table of Expected number of Drug tests. Each drug test in this example costs $10.43 for the cup and $6.67 in administrative time – yielding a cost for each in-clinic drug test of $17.10.

On a yearly basis, the figures are multiplied by 250 – the number of working days used in this paper. Note that the reason these estimates are different from the ones used in the upper and lower bound examples is that this table assumes the patients visit the clinic 6 times per year, whereas the upper bound uses four times per year, the lower bound uses 12 times per year.

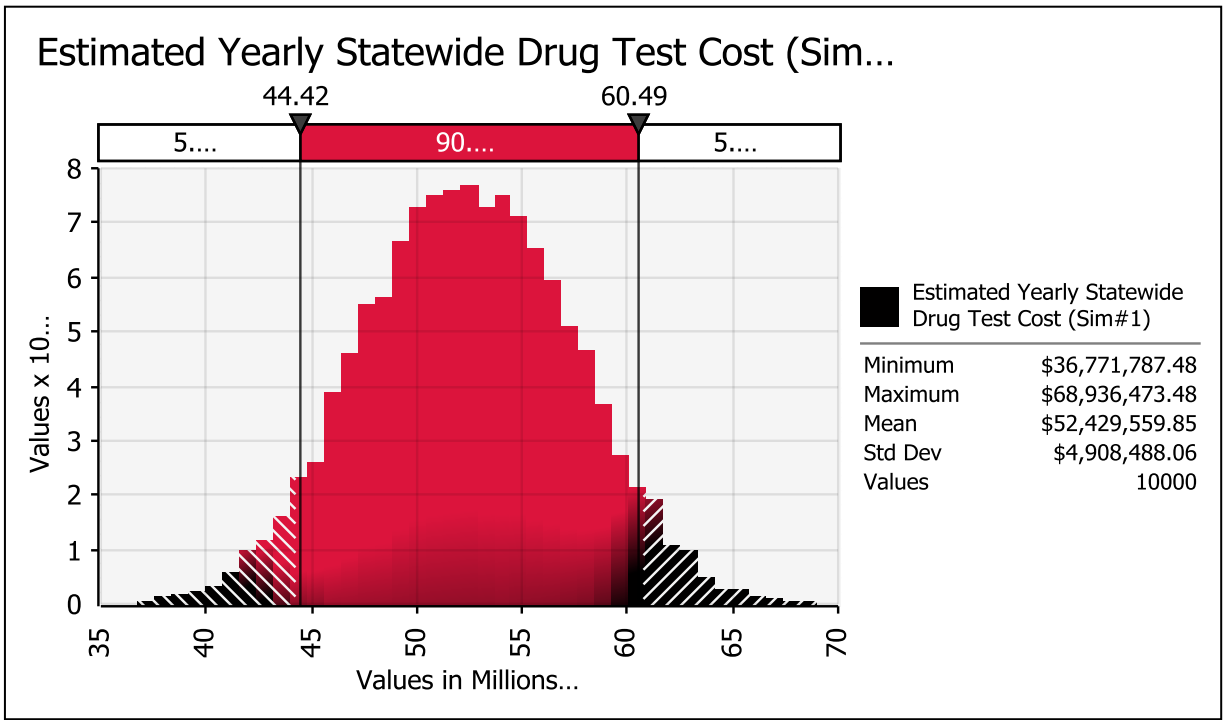
Table 3: Estimated yearly cost of drug testing per clinic:

	Total Patients Per Day						
New Patients	**20**	**25**	**30**	**35**	**40**	**45**	**50**
0	$28,500	$35,625	$42,750	$49,875	$56,999	$64,124	$71,249
1	$31,350	$38,475	$45,600	$52,725	$59,849	$66,974	$74,099
2	$34,200	$41,325	$48,450	$55,575	$62,699	$69,824	$76,949
3	$37,050	$44,175	$51,300	$58,425	$65,549	$72,674	$79,799
4	$39,900	$47,025	$54,150	$61,275	$68,399	$75,524	$82,649
5	$42,750	$49,875	$57,000	$64,125	$71,250	$78,374	$85,499

To estimate the statewide cost of the drug tests in the proposed rule on a per-physician basis, a model clinic to show one day's patient load was set up. Assumptions in this model are:

Total Number of Patients: (equals existing patients plus new patients) from 20 to 30 per day
Number of New Patients: 0 to 3 per day
Cost of Drug Test Cup: $8.43
Administrative time: 20 minutes per drug test
Administrative cost: $20 per hour, including benefits
Patients visit clinic: 6 times per year. Patients must come in a minimum of 4 times per year under the proposed rule to continue to receive treatment. Some patients come in every month. Invasive procedure physicians must do follow-ups more regularly than those that don't do invasive procedures. Under the proposed rule each existing patient must be randomly drug-tested twice per year and every new patient must be tested on the first visit and then two times per year. To be clear, on the day shown in the model, every existing patient has an expected probability of one-third (6 visits per year, two mandatory drug tests) and each new patient has a 100% probability of being tested. As an example, a clinic with 25 patients on any day where one patient is new would be expected to give 9 drug tests – one to the new patient and one to 8 of the 24 existing patients.

A Monte Carlo simulation model was run on @RISK 5.7 Professional software to estimate the likely statewide drug test costs. The variables used are:
Number of Patients per day: Mean of 25, standard deviation of 1.94, normally distributed
New Patients per day: Uniform distribution with a minimum at zero, maximum at 3
Drug Test Costs: $17.10. This is the $10.43 landed cost of the test, plus $6.67 administrative time.
Full-time Physicians: 1314, estimated earlier.
Below are the results of the stochastic model. The simulation was run 10 times with 10,000 iterations each. You can see that there is a 90% probability that, given the assumptions of the model, the statewide yearly cost of drug testing is between $44.42 million and $ 60.49 million – with a mean of $52.43 million.



One should note that these figures do not include an estimate of the drug tests that are required to be sent to an outside lab in cases of:

1. The result indicates an adulterant was used
2. The result indicates the absence of an expected substance
3. The result indicates the presence of a substance that is not expected
4. Either the patient or the physician dispute the outcome of the in-clinic test

Given that it is unknown how many instances one or more of these events will happen, a table is set up to give an example of the expected yearly cost if 5% of the in-clinic drug tests are sent out for gas or liquid chromatography/mass spectrometry. Note that 5% is not an estimate; it is just used as an example and is not included in the estimated costs of this proposed rule. The table below shows this example, in millions of dollars per year.

Table 4: Example Statewide Additional Drug Testing Cost if 5% are sent to outside lab, in $Million.

	Patients Per Day						
New Patients	**20**	**25**	**30**	**35**	**40**	**45**	**50**
0	$10.950	$13.687	$16.425	$19.162	$21.900	$24.637	$27.375
1	$12.045	$14.782	$17.520	$20.257	$22.995	$25.732	$28.470
2	$13.140	$15.877	$18.615	$21.352	$24.090	$26.827	$29.565
3	$14.235	$16.972	$19.710	$22.447	$25.185	$27.922	$30.660
4	$15.330	$18.067	$20.805	$23.542	$26.280	$29.017	$31.755
5	$16.425	$19.162	$21.900	$24.637	$27.375	$30.112	$32.850

Facility and physical operations:

Outdoor Signage: contains the clinic name, hours of operations and street address. Estimate is $300, including installation. Although there are many types of outdoor signs, a sign to meet the minimum standard was used.

Fax Line: Installation and monthly charges for a dedicated 24-hour fax line: Estimate $45.95 per month as a statewide average. Installation, paid the first year, was estimated at $81.00 per line.

Emergency Lighting: Estimated at two simple commercial emergency lights with batteries, plus installation. The estimate used is $500 per clinic.

Emergency communications: Estimated one pre-paid cell phone for emergencies, plus the cost of printing postcards for patients with emergency number on it. The estimate used is $500, one-time.

Indoor signage: must list the name and contact information of the clinic Designated Physician, and the names of all physicians practicing in the clinic. Estimate is $125, no installation charge.

Infection control: Equipment, supplies, analysis of data, written prevention policies and procedures, etc... Estimated at 5 hours of Office Manager time - $200 in labor for written policy manual. Equipment and supplies costs vary widely for those clinics doing non-invasive procedures versus clinics doing invasive procedures. The estimate for an average clinics' yearly cost of supplies is $500.

Emergency evacuation procedures, including provisions for the evacuation of disabled patients and employees: Estimated 8 hours of Office Manager's time to put together a basic evacuation plan for clinic, totaling $320. Evacuation signage for each room used by the public estimated at $500 as a one-time cost. Total estimate is $820, one-time.

Written, facility-specific disaster plan: Estimated 32 hours of the Office Manager's time to research and write this facility-specific plan. Estimate is $1280, one-time. Estimate for training personnel assumed to be normal part of salaries.

Employee trained in Basic Life Support: Estimated to include the cost of a Basic Life Support class for one employee per clinic. Class estimated at $65 for a health-provider CPR class and $35 for mileage and/or other incidentals on an every-other-year basis. Alternatively, a Red Cross Basic Life support could be taken every year. This estimate will be $50 per year. No change in salary is estimated.

Quality Assurance Program, Data Collection and Reporting: Estimated using an outside consultant for set-up, quarterly reporting and handling the inspection every three years. This estimate includes the data collection and reporting required. Likely options at the clinic level are:

1. Hiring a consultant Risk Manager to set up the program, do the quarterly reporting and the 3-year report. Typically the clinic sends weekly data and any incident reports to the consultant.
2. Doing the quarterly reporting by clinic personnel and hiring a Florida-licensed Risk Manager to set up the program and do the report once every three years.

The outside consultant is estimated at a range of $6,000 to $10,000 per year. The labor estimate for clinic personnel to gather the information and report weekly to the consultant is at 5% FTE (full-time equivalent) at the office administrative level, approximately $2,000 per year.
If a Risk Manager sets up the Quality Assurance program for the clinic, the estimate is $2,500. If the Office Manager does the quarterly reporting at the clinic level, it is estimated that will use 2.5% of the Office Manager's time ($2000/year) and 5% for administrative personnel time ($2,000/year). In this case, a Florida-licensed Risk Manager is hired once every three years to do the inspection and the report, at a cost of $2,500 to $5,000 plus travel expenses, depending upon the clinic's volume of patients. This estimate ranges from just $5,666 to $6,500 on a yearly basis.
The estimate of $8,000 per clinic will be used for all 932 clinics.

Table 5 shows these costs:

Item Estimated	One-time	Yearly
Indoor Sign	$ 125	
Outdoor Sign	$ 300	
Fax line	$ 81	$ 551
Life Support Training		$ 50
Infection Control	$ 200	$ 500
Quality Assurance Program		$ 8,000
Emergency Lighting	$ 500	
Emergency Evacuation Procedures	$ 820	
Written, facility-specific disaster plan	$ 1,280	
Emergency communication	$ 500	
Per-Clinic Totals	$ 3,806	$ 9,101

In the estimated costs, the one-time items will show up only in the first year, the yearly items will be included in both the first year and the subsequent years. Therefore the estimate of these costs is, on a per-clinic basis, $12,907 for the first year, and $9,101 for years 2 through 5.

Statement of Estimated Regulatory Costs:

a) The above economic analysis shows that the proposed rule, directly or indirectly:

1. Is not likely to have an adverse impact on economic growth, private-sector job creation of employment, or private-sector investment in excess of $1 million in the aggregate within 5 years after the implementation of the rule.
2. Is not 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.
3. 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.

b) 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.

The entities affected are the estimated 1314 physicians that are employed by, and the owners of approximately 932 registered Pain Management Clinics in Florida.

c) 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.

The Board has advised that the Department of Health, Division of Medical Quality Assurance, prepared a good faith estimate in its original SERC dated March 30, 2010 as follows:

> A good faith estimate of the cost to the Board of Medicine will be covered by the Department charges of $150 for registration of the clinic and $1,500 for the annual inspection, if the clinic is not certified by a board approved health care accrediting organization. Upon approval and implementation of this rule, the inspection program will commence and the results of the inspections will provide data that will provide actual costs incurred and the current fees can be adjusted accordingly if necessary. Costs incurred based on a licensee's failure to comply with the rule resulting in disciplinary action on a licensee are required by law to be recovered in the final order imposing discipline on the licensee.
>
> There are no anticipated costs to any other state or local government agencies in the implementation and enforcing of the proposed rule.
>
> It is unknown how the rule imposing practice standards will impact state or local revenues. If the rule results in higher costs for the care provided, state and local revenues may increase; and if the rule results in fewer clinics providing services the state and local revenues may decrease. Additionally; the rule may well reduce the costs involved in providing law enforcement and other services related to the abuse of prescription drug medication.

d) A good faith estimate of the transactional costs likely to be incurred by individuals and entities, including government entities, required to comply with this rule.

Expected statewide transactional costs are $64.459 Million in the first year, with $60.912 Million expected in the following years. On a per-clinic basis, this represents an estimated $69,162 in the first year, with an expected $65,356 in the following years. On a per-patient basis for an existing patient, 1st Year costs average $43.73 and Year 2 through 5 costs average $40.91 per year. For a new patient, 1st year costs average $60.83 per year.

e) An analysis of the impact on small businesses as defined by s. 288.703, and an analysis of the impact on small counties and small cities as defined in by s. 120.52. The impact analysis for small businesses must include the basis for the agency's decision not to implement alternatives that would reduce adverse impacts on small businesses.

Most of the entities registered as Pain Management clinics are small businesses.

There are no expected costs to small counties or small cities.

In response to this inquiry, the Board has advised that during the course of all of its rule meetings and rule hearings it considered alternatives and suggested rule language by interested persons in arriving at the proposed rule language.

Appendix 1

THE FULL TEXT OF THE PROPOSED RULE IS:

64B8-9.0131 Standards of Practice for Physicians Practicing in Pain Management Clinics. THIS RULE IS APPLICABLE TO PHYSICIANS PRACTICING IN PRIVATELY OWNED PAIN MANAGEMENT CLINICS THAT ARE REQUIRED TO BE REGISTERED PURSUANT TO SECTION 458.3265, F.S., WHO PRIMARILY ENGAGE IN THE TREATMENT OF PAIN BY PRESCRIBING OR DISPENSING CONTROLLED SUBSTANCE MEDICATIONS.

(1) Definitions. The following definitions apply to this rule only.

(a) Controlled Substance. A "controlled substance" is any substance named or described in Schedules I-V of Section 893.03, Florida Statutes.

(b) Adverse Incidents. An "adverse incident" is any incident set forth in Section 458.351(4)(a)-(e), Florida Statutes.

(c) "Board–certified pain management physician" means a physician who possesses Board certification by a specialty board recognized by the American Board of Medical Specialties (ABMS) and holds a sub-specialty certification in pain medicine; or Board certification in pain medicine by the American Board of Pain Medicine (ABPM).

(d) "Addiction medicine specialist" means a board certified psychiatrist with a subspecialty certification in addiction medicine or who is eligible for such subspecialty certification in addiction medicine or an addiction medicine physician certified or eligible for certification by the American Society of Addiction Medicine (ASAM).

(e) "Mental health addiction facility" means a facility licensed pursuant to Chapters 394 or 397, Florida Statutes.

(2) Standards of Practice in Pain Management Clinics.

(a) Evaluation of Patient and Medical Diagnosis. A complete medical history and a physical examination must be conducted prior to commencement of any treatment and documented in the medical record. The exact components of the physical examination shall be left to the judgment of the clinician who is expected to perform a physical examination proportionate to the diagnosis that justifies a treatment. The medical record must, at a minimum, document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, a review of prior medical records, previous diagnostic studies, and history of alcohol and substance abuse. The medical record shall also document the presence of one or more recognized medical indications for the use of a controlled substance.

(b) Treatment Plan. The written individualized treatment plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician shall adjust drug therapy to the individual medical needs of each patient. Other treatment modalities, including a rehabilitation program, shall be considered depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. The interdisciplinary nature of the treatment plan shall be documented.

(c) Informed Consent and Agreement for Treatment. The physician shall discuss the risks and benefits of the use of controlled substances including the risks of abuse/addiction, as well as physical dependence and its consequences, with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The physician shall employ the use of a written controlled substance agreement between physician and patient outlining patient responsibilities, including, but not limited to:

1. 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, drug testing 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;

2. Number and frequency of all prescription refills;

3. Patient compliance and reasons for which drug therapy may be discontinued (e.g., violation of agreement); and

4. Agreement that controlled substances for the treatment of chronic nonmalignant pain shall be prescribed by a single treating physician unless otherwise authorized by the treating physician and documented in the medical record.

(d) Periodic Review. The patient shall be seen by the physician at regular intervals, not to exceed three months, to assess the efficacy of treatment, assure that controlled substance therapy remains indicated, evaluate the patient's progress toward treatment objectives, consider adverse drug effects and review the etiology of the pain. Continuation or modification of therapy shall depend on the physician's evaluation of the patient's progress. If treatment goals are not being achieved, despite medication adjustments, the physician shall reevaluate the appropriateness of continued treatment. The physician shall monitor patient compliance in medication usage, related treatment plans, controlled substance agreements, and indications of substance abuse or diversion at a minimum of three-month intervals.

(e) Consultation. The physician shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention shall be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation, and requires consultation with or referral to an addictionologist or psychiatrist.

(f) 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 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 in this rule shall preclude a pain-management clinic from employing additional measures to assure the integrity of the urine specimens provided by patients.

1. Referral to an outside laboratory. A physician shall send the patient to a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory or a collection site owned or operated by a CLIA-certified laboratory;

2. Specimen collected in the pain-management clinic and sent to an outside laboratory for testing. A physician shall collect in the office the patient specimen to be used for drug testing in a device that measures pH, specific gravity, and temperature and then the specimen shall be sent to a CLIA-certified laboratory. The physician shall follow the collection procedures required by the agreement the pain-management clinic has entered into with the CLIA-certified laboratory it uses.

3. Specimen collected and tested in office. A physician shall collect and test in the office the specimen to be used for drug testing using CLIA-waived point-of-care test or CLIA-approved test that uses a device that measures the pH, specific gravity, and temperature. Results of the drug test shall be read according to the manufacturer's instructions.

(g) Patient Medical Records. The physician is required to keep accurate and complete records to include, but not be limited to:

1. The complete medical history and a physical examination, including history of drug abuse or dependence;
2. Diagnostic, therapeutic, and laboratory results;
3. Evaluations and consultations;
4. Treatment objectives;
5. Discussion of risks and benefits;
6. Treatments;
7. Medications (including date, type, dosage, and quantity prescribed);
8. Instructions and agreements;
9. Periodic reviews;
10. Drug testing results;
11. A photocopy of the patient's government issued photo identification; and
12. If a written prescription for a controlled substance is given to the patient, a duplicate of said prescription must be maintained in the patient's medical record.
13. Each pain management clinic physician's medical record shall contain the physician's full name presented in a legible manner. In addition, each clinic must maintain a log on the premises which shall contain the full name,

presented in a legible manner, along with a corresponding sample signature and initials of every physician, anesthesiologist assistant, and physician assistant working in the clinic.

14. Medical records must remain current, they must be maintained in an accessible manner and readily available for review and must be in full compliance with Rule 64B8-9.003, F.A.C., and Section 458.331(1)(m), F.S..

(h) Denial or Termination of Controlled Substance Therapy.

1. If a patient's initial drug testing reflects the adulteration of the specimen or the presence of illegal or controlled substances (other than medications with approved prescriptions), or when the testing result is questioned by either the patient or the physician, the specimen will be sent to a CLIA-certified laboratory for gas or liquid chromatography/mass spectrometry (GC/MS or LC/MS or LC/MS/MS or GC/MS/MS) confirmation. If the result of the GC/MS or LC/MS or LC/MS/MS or GC/MS/MS testing is positive, the physician shall refer the patient for further consultation with a board-certified pain management physician, an addiction medicine specialist, or to a mental health addiction facility as it pertains to drug abuse or addiction. After consultation is obtained, the physician shall document in the medical record the results of the consultation. The treating physician shall not prescribe or dispense any controlled substances until there is written concurrence of medical necessity of continued controlled substance therapy provided by a board-certified pain management physician, an addiction medicine specialist, or from a mental health addiction facility. If the treating physician is a board-certified pain management physician, or an addiction specialist, the physician does not need to refer the patient for further consultation. If the physician suspects diversion, then the patient shall be discharged and all results of testing and actions taken by the physician shall be documented in the patient's medical record.

2. For patients currently in treatment by the physician or any other physician in the same pain management clinic, patients with signs or symptoms of substance abuse, shall be immediately referred to a board-certified pain management physician, an addiction medicine specialist, or a mental health addiction facility as it pertains to drug abuse or addiction unless the physician is board-certified or board-eligible in pain management. Throughout the period of time prior to receiving the consultant's report, a prescribing physician shall clearly and completely document medical justification for continued treatment with controlled substances and those steps taken to assure medically appropriate use of controlled substances by the patient. Upon receipt of the consultant's written report, the prescribing physician will incorporate the consultant's recommendations for continuing, modifying, or discontinuing controlled substance therapy. The resulting changes in treatment shall be specifically documented in the patient's medical record.

3. For patients currently in treatment by the physician or any other physician in the same pain management clinic, evidence or behavioral indications of diversion shall be followed by discontinuation of controlled substance therapy and the patient shall be discharged and all results of testing and actions taken by the physician shall be documented in the patient's medical record.

(i) Facility and Physical Operations.

1. A pain management clinic shall be located and operated at a publicly accessible fixed location and shall contain the following:

a. A sign that can be viewed by the public that contains the clinic name, hours of operations, and a street address;

b. A publicly listed telephone number and a dedicated phone number to send and receive faxes with a fax machine that shall be operational twenty-four hours per day;

c. Emergency lighting and communications;

d. Reception and waiting area;

e. Restroom;

f. Administrative area including room for storage of medical records, supplies and equipment;

g. Private patient examination room(s);

h. Treatment room(s) if treatment is being provided to the patient;

i. A printed sign located in a conspicuous place in the waiting room viewable by the public disclosing the name and contact information of the clinic Designated Physician, and the names of all physicians practicing in the clinic;

j. Storage and handling of prescription drugs. Clinics that store and dispense prescription drug shall comply with Section 499.0121, Florida Statutes, Section 893.07, Florida Statutes, and Rule 64F-12.012, Florida Administrative Code.

2. Nothing in this subsection shall excuse a physician from providing any treatment or performing any medical duty without the proper equipment and materials as required by the standard of care.

(j) Infection Control.

1. The clinic shall maintain equipment and supplies to support infection prevention and control activities.

2. The clinic shall identify infection risks based on the following:

a. Geographic location, community, and population served;

b. The care, treatment and services it provides; and

c. An analysis of its infection surveillance and control data.

3. The clinic shall maintain written infection prevention policies and procedures that address the following:

a. Prioritized risks;

b. Limiting unprotected exposure to pathogen;

c. Limiting the transmission of infections associated with procedures performed in the clinic; and

d. Limiting the transmission of infections associated with the clinic's use of medical equipment, devices, and supplies.

(k) Health and Safety.

1. The clinic, including its grounds, buildings, furniture, appliances and equipment shall be structurally sound, in good repair, clean, and free from health and safety hazards.

2. The clinic shall have evacuation procedures in the event of an emergency which shall include provisions for the evacuation of disabled patients and employees.

3. The clinic shall have a written facility-specific disaster plan which sets forth actions that will be taken in the event of clinic closure due to unforeseen disasters which shall include provisions for the protection of medical records and any controlled substances.

4. Each clinic shall have at least one employee on the premises during patient care hours that is certified in Basic Life Support and is trained in reacting to accidents and medical emergencies until emergency medical personnel arrive.

(l) Quality Assurance. Each pain management clinic shall have an ongoing quality assurance program that objectively and systematically monitors and evaluates the quality and appropriateness of patient care, evaluates methods to improve patient care, identifies and corrects deficiencies within the facility, alerts the Designated Physician to identify and resolve recurring problems, and provides for opportunities to improve the facility's performance and to enhance and improve the quality of care provided to the public. The Designated Physician shall establish a quality assurance program that includes the following components:

1. The identification, investigation, and analysis of the frequency and causes of adverse incidents to patients,

2. The identification of trends or patterns of incidents,

3. The development of measures to correct, reduce, minimize, or eliminate the risk of adverse incidents to patients, and

4. The documentation of these functions and periodic review no less than quarterly of such information by the designated physician.

5. The Quality Assurance program must be reviewed once every three (3) years by a Florida-licensed risk manager and documentation of said review must be provided to the Department together with any corrective action plan within 30 days of the review and maintained for inspection purposes.

(m) Data Collection and Reporting.

1. Reporting of adverse incidents. The Designated Physician for each pain-management clinic shall report all adverse incidents to the Department of Health as set forth in Section 458.351, Florida Statutes.

2. The Designated Physician shall also report to the Board of Medicine, in writing, on a quarterly basis the following data:

a. Number of new and repeat patients seen and treated at the clinic who are prescribed or dispensed controlled substance medications for the treatment of chronic, non-malignant pain;

b. The number of patients discharged due to drug abuse;

c. The number of patients discharged due to drug diversion; and

d. The number of patients treated at the pain clinic whose domicile is located somewhere other than in Florida. A patient's domicile is the patient's fixed or permanent home to which he intends to return even though he may temporarily reside elsewhere.

3. All physicians practicing in pain-management clinics shall advise the Board of Medicine in writing, within 10 calendar days of beginning or ending his or her practice at a pain-management clinic.

Appendix 2 – Clinic totals, density and dispensing, by county

County	Total Clinics	Clinics/100k population*	Dispensing**	% Dispensing***
ALACHUA	5	2.51	3	60.0%
BAY	4	3.14	2	50.0%
BREVARD	16	3.73	8	50.0%
BROWARD	117	8.61	73	62.4%
CHARLOTTE	7	5.23	4	57.1%
CITRUS	8	6.80	4	50.0%
CLAY	9	6.56	4	44.4%
COLLIER	15	5.91	9	60.0%
COLUMBIA	3	5.60	3	100.0%
DUVAL	51	7.88	31	60.8%
ESCAMBIA	10	4.22	2	20.0%
FLAGLER	3	4.07	2	66.7%
FRANKLIN	1	10.63	0	0.0%
HERNANDO	10	7.27	4	40.0%
HIGHLANDS	2	2.49	1	50.0%
HILLSBOROUGH	113	12.52	45	39.8%
INDIAN RIVER	5	4.58	3	60.0%
JACKSON	1	2.46	1	100.0%
LAKE	11	4.37	9	81.8%
LEE	29	6.21	16	55.2%
LEON	5	2.34	1	20.0%
LEVY	1	3.26	1	100.0%
MANATEE	18	7.14	12	66.7%
MARION	12	4.57	7	58.3%
MARTIN	6	5.27	5	83.3%
MIAMI-DADE	89	4.62	50	56.2%
MONROE	1	1.62	0	0.0%
NASSAU	4	7.31	3	75.0%
OKALOOSA	4	2.92	2	50.0%
OKEECHOBEE	2	6.64	1	50.0%
ORANGE	49	5.98	29	59.2%
OSCEOLA	13	6.60	5	38.5%
PALM BEACH	108	10.68	77	71.3%
PASCO	31	8.34	18	58.1%
PINELLAS	47	6.33	32	68.1%
POLK	13	2.94	5	38.5%
PUTNAM	4	7.15	2	50.0%
SANTA ROSA	8	6.90	4	50.0%
SARASOTA	24	7.74	18	75.0%
SEMINOLE	17	5.36	10	58.8%
ST. JOHNS	9	6.17	3	33.3%
ST. LUCIE	12	5.82	8	66.7%
SUMTER	3	4.48	2	66.7%
VOLUSIA	30	7.50	11	36.7%
WALTON	1	2.28	1	100.0%
WASHINGTON	1	5.34	0	0.0%

* Population over 18, U.S. Census Bureau estimate for 2008

** Dispensing means registered physician that is qualified to dispense

*** Percentage of clinics that have registered physician who is qualified to dispense

Appendix 3 – Groups owning 3 or more PMC, by common owners, partners, and/or billing addresses.

Clinic Name	# of Clinics	Counties of Clinics
Total Medical Express	3	Palm Beach
Physicians Group Services	4	Clay, Duval(2), Nassau
Gulf-to-Bay Anesthesiology	5	Pinellas, Hillsborough(4)
Neurological Testing Centers of America	5	Broward(2), Miami-Dade(2)
Frank R. Collier, Jr. M.D., P.A.	3	Duval(2), Clay
Edwin Colon, M.D., P.A.	3	Pasco
Robert B. Dehgan, M.D., P.A.	3	Putnam, St. Johns, Duval
Southeastern Integrated Medical	5	Levy, Marion, Lake, Alachua, Columbia
Various Names (Dubravetz, owner)	4	Orange, Broward(2), St. Lucie
International Rehab/Comprehensive Pain Medicine/ Anesthesiology Assoc.	21	Miami-Dade(4), Broward(8), Palm Beach(3) Leon, Okaloosa, Escambia, Santa Rosa(2), Martin
Lescobar, P.A.	3	Broward(2), Miami-Dade
Physician Providers Group	3	Marion, Lake, Citrus
Premier Pain Care	3	Broward, Miami-Dade(2)
Institute of Pain Management	3	Duval(2), Clay
Spine Diagnostics Interventional Center	3	Collier(2), Hillsborough
Pain Care Management of….(Clearwater, Melbourne, Orlando)	3	Pinellas, Brevard, Orange
CMG, LLC	3	Martin, Palm Beach(2)
Laudan Partners, Inc.	3	Miami-Dade
West Coast Anesthesiology Associates, Inc.	3	Sarasota, Seminole, Lee
Comprehensive Pain Management Partners	6	Pasco(3), Sarasota, Hillsborough, Pinellas
Hess Spinal & Medical Centers	10	Hillsborough(4), Polk, Pinellas(3), Pasco, Manatee
Center for Quality Pain Care	3	Miami-Dade(2), Broward
Glory Medclinic, LLC	4	Pasco(2), Polk, Hillsborough
Yili Zhou, LLC	3	Marion(2), Columbia
A Pain Clinic of….(Boca Raton, Delray Beach, Ft. Lauderdale, WPB)	4	Broward, Palm Beach(3)
D.G. & Leeds/Medical Therapies, LLC	3	Orange(2), Seminole
Vidya P. Kini, M.D., P.L.	3	Lee
Biltmore Group, LLC	6	Orange, Marion(2), Broward, Osceola, Lee
PRC Associates, LLC	4	Volusia(3), Flagler
Joseph E. Monhanna, M.D., P.A.	3	Miami-Dade
Occupational and Rehabilitational Center	3	Duval(2), Clay
Various Names (Juan Carlos Perez-Espinoza, owner)	3	Miami-Dade
Advanced Pain Management Center, Inc.	3	Citrus, Hernando, Hillsborough
Sunshine Spine and Pain, P.A.	4	Duval
James D. Shortt, M.D., P.A.	4	Duval
Jose A. Torres, M.D., P.A.	3	Orange(2), Osceola
West Florida Pain Management, P.A.	3	Pinellas

As of 9 December, 2010

References:

Economic Impact Analysis of the Interim Final Electronic Prescription Rule. Drug Enforcement Administration, U.S. Department of Justice. March 2010

2009 Florida Physician Workforce Annual Report. November 1, 2009

The Economic Impact of Private Practice Physicians' Offices in Florida. Florida Medical Association and the Center for Economic Forecasting & Analysis at Florida State University. March, 2009

Persons Providing Helpful Information by Phone and/or e-mail:

Debra A. Conn Florida Licensed Risk Manager

Anna Hayden, D.O. Past President of Florida Osteopathic Medical Association

Jennifer Hoppe Associate Director, State and External Relations, Division of Business Development, Government & External Relations for The Joint Commission

Brenda K. Johnson, R.N., M.S., ARM Risk Management Consultant, Benedict & Associates, Inc., and Murex Risk Services, LLC.

Marie Kokol, LHRM Florida Agency for Health Care Administration (AHCA)

Paul Sloan Pain Management Clinic Owner

Carissa Stone, M.D. Pain Management Physician, Group Practice

Tom Terranova, M.A. Director of Legislative and External Relations, American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), Inc.

Deborah H. Tracy, M.D., M.B.A. Pain Management Physician, solo practitioner

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:	SPB 7062
INTRODUCER:	For Consideration by the Health Regulation Committee
SUBJECT:	Rulemaking
DATE:	March 7, 2011
REVISED:	

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

I. Summary:

The proposed committee bill declares that it is the Legislature's intent to expedite the rulemaking process within the Department of Health (DOH) and the Agency for Health Care Administration (AHCA) by requiring a timely rulemaking process, by streamlining the process for rule development, and by encouraging early and timely participation by interested persons in the process.

The proposed committee bill requires the DOH or the AHCA to submit a report to the Legislature and Governor if a proposed rule by the DOH or the AHCA does not become effective within a certain time after the effective date of an act that requires implementation of the act by that rule.

The proposed committee bill requires the DOH and the AHCA to provide notice of rule development workshops, notice of proposed rulemaking, hearing notices, notice of change to the proposed rule, notice of intent to adopt certain proposed rules, and notice of withdrawal of the proposed rule by the "prominent display" of such notices on the home page of their respective websites. The DOH and the AHCA is required to provide the Department of State with an electronic link to certain notices, a copy of which must be maintained by the Department of State and made available for public inspection.

The proposed committee bill also:

- Requires the DOH and the AHCA to provide a mailing address, telephone number, or email address on its notice of rule development in order to allow a person to request rulemaking updates via email.

- Requires the DOH and the AHCA to provide notice to interested persons via email of any rulemaking notices, if requested.
- Exempts the DOH and the AHCA from the requirement to hold public workshops in various regions of the state.
- Authorizes the DOH and the AHCA to schedule a workshop 7 days after notice of a rule development workshop has been prominently displayed on its website, if a toll-free conference call telephone number has been provided to the public to access the workshop.
- Authorizes a DOH or an AHCA deputy secretary or agency head's designee to approve the agency's intended action on a proposed rule.
- Authorizes the DOH or the AHCA to include in the notice of proposed rulemaking a short sentence summarizing the conclusion reached in the agency's statement of estimated regulatory costs (SERC).
- Authorizes the DOH or the AHCA to base a SERC on good faith cost estimates and provides that these agencies are not required to hire an economic expert to prepare a SERC.
- Authorizes the DOH or the AHCA to provide the Joint Administrative Procedures Committee (JAPC) access to copies of certain documents via an electronic link.
- Prohibits the DOH or the AHCA from suspending a rulemaking proceeding to convene a substantial interest hearing.
- Permits a rule to be modified or withdrawn after adoption and before the rule becomes effective only in response to the Legislature during the rule ratification process or to an objection by the JAPC.
- Requires the DOH and the AHCA to proceed with the rulemaking process after a challenge to the proposed rule has been made.
- Creates a presumption that a person is not a substantially affected person, if the person making a rule challenge has not participated in the rulemaking process, unless the rule challenge is based on a change in the proposed rule.

This proposed committee bill substantially amends the following sections of the Florida Statutes: 120.52, 120.525, 120.54, 120.541, and 120.56.

This proposed committee bill creates an undesignated section of law.

II. Present Situation:

The Administrative Procedure Act

Because administrative agencies have been granted extensive investigative, rulemaking, and adjudicating powers, statutes such as the Florida Administrative Procedure Act (APA)[1] have been adopted to provide parties in administrative proceedings with procedural protection and due process.[2] The APA allows individuals who feel that their interests are being, or will be affected, by the preliminary decisions of agencies to challenge those decisions.[3] The central purpose of the APA is to provide the basic fairness that should surround all governmental activity, such as:

[1] Chapter, 120, F.S.
[2] 2 FLA. JUR 2D *Administrative Law* s. 1 (2011).
[3] Judge Linda M. Rigot, *Administrative Law: A Meaningful Alternative to Circuit Court Litigation*, 75 FLA. B.J. 14, 14 (2001); *see also* 2 FLA. JUR 2D *Administrative Law* s. 5 (2011).

- The opportunity for adequate and full notice of agency activities;
- The right to present viewpoints and to challenge the views of others;
- The right to develop a record which is capable of court review;
- The right to locate precedent and have it applied; and
- The right to know the factual bases and policy reasons for agency action.[4]

In protecting such rights, the APA establishes specific procedures and timelines for such procedures during the rulemaking process. Currently, all notices are required to be published in the Florida Administrative Weekly (FAW). Materials to be published in the FAW are due to the Secretary of State by 12:00 p.m. on Wednesday of the week prior to the publication in the FAW. The FAW is published on Fridays.[5]

Generally, but not in every instance, a proposed rule goes through the following process before it is formally adopted by an agency:

1) The agency publishes a notice of proposed rule development.[6]
2) The agency schedules and provides notice of a rule development workshop, upon request by an affected person or at the election of the agency.[7]
3) The agency publishes a notice of proposed rulemaking.[8]
4) The agency prepares a statement of estimated regulatory costs (SERC).[9]
5) The agency schedules and notices a public hearing on the proposed rule, upon request by an affected person or at the election of the agency.[10]
6) The agency changes the proposed rule and publishes notice of the change after a hearing or after receiving a letter from the JAPC outlining concerns.[11]
7) The agency adopts the rule by filing with the Department of State three certified copies of the rule it proposes to adopt; one copy of any material incorporated by reference in the rule, certified by the agency; a summary of the rule; a summary of any hearings held on the rule; and a detailed written statement of the facts and circumstances justifying the rule.[12]

Agencies are required to formally propose rules to implement an act enacted by the Legislature within 180 days after the effective date of the act, unless the act provides otherwise.[13]

Any person substantially affected by a rule or a proposed rule may seek an administrative determination of the invalidity of the rule on the ground that the rule is an invalid exercise of delegated legislative authority.[14] The petition seeking an administrative determination must state

[4] 2 FLA. JUR 2D *Administrative Law* s. 5 (2011) (*quoting Singer Island Civic Ass'n, Inc. v. State Dep't of Environmental Regulation*, 636 So. 2d 723, 725 (Fla. 4th DCA 1994)).
[5] When Friday is observed as a holiday, as designated by s. 110.117, F.S., publication is on the last working day of the week in which the holiday is observed. All materials to be published in the FAW must be received by 12:00 p.m. on Monday, the week prior to publication. *See* Rule 1B-30.003, F.A.C.
[6] Section 120.54(2)(a), F.S.
[7] Section 120.54(2)(c), F.S.
[8] Section 120.54(3)(a), F.S.
[9] Section 120.54(3)(b)1., F.S. *See also* s. 120.541, F.S.
[10] Section 120.54(3)(c), F.S.
[11] Section 120.54(3)(d)1., F.S.
[12] Section 120.54(3)(e), F.S.
[13] Section 120.54(1)(b), F.S.
[14] Section 120.56(1), F.S.

with particularity the provisions alleged to be invalid with sufficient explanation of the facts or grounds for the alleged invalidity and facts sufficient to show that the person challenging a rule is substantially affected by it, or that the person challenging a proposed rule would be substantially affected by it.[15]

The Division of Administrative Hearings (DOAH), which consists of an independent group of administrative law judges (ALJs), conducts hearings on rule challenges by substantially affected persons.[16] Proceedings by DOAH are conducted like nonjury trials and are governed by ch. 120, F.S.[17]

Analysis of Regulatory Costs

An agency is encouraged to prepare a SERC prior to the adoption, amendment, or repeal of any rule other than an emergency rule. The SERC must include:[18]

- Whether the proposed 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 implementation of the rule; have an adverse impact on business competitiveness, productivity, or innovation in excess of $1 million in the aggregate within 5 years after the implementation of the rule; or increase regulatory costs in excess of $1 million in the aggregate within 5 years after implementation of the rule;
- 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;
- An analysis of the impact on small businesses, small counties, and small cities;
- Additional information that the agency determines may be useful; and
- If applicable, a description of any good-faith written proposal submitted for a lower cost regulatory alternative to a proposed rule that substantially accomplishes the objective of the law being implemented, and the agency's response to the alternative.

However, an agency must prepare a SERC of the proposed rule, if:[19]

- A lower cost regulatory alternative to the proposed rule has been submitted to the agency;
- The proposed rule will have an adverse impact on small business; or
- The proposed rule 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.

[15] *Id.*
[16] Rigot, *supra* note 3, at 14.
[17] *Id.*
[18] Section 120.541(2), F.S.
[19] Sections 120.541(1)(a) and 120.54(3)(b), F.S.

If the SERC shows that the proposed rule will 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; have an adverse impact on business competitiveness, productivity, or innovation in excess of $1 million in the aggregate within 5 years after the implementation of the rule; or increase regulatory costs, including any transactional costs, in excess of $1 million in the aggregate within 5 years after the implementation of the rule, the proposed rule must be submitted to the Legislature no later than 30 days prior to the next regular legislative session, and it may not take effect until it is ratified by the Legislature.[20]

On January 4, 2011, Governor Rick Scott signed Executive Order No. 11-01, which suspended rulemaking for all agencies under the direction of the Governor and established the Office of Fiscal Accountability and Regulatory Reform (Office). The executive order requires, among other things, the Office to review all rules prior to promulgation as well as agency practices and contracts.[21]

Joint Administrative Procedures Committee

Within the APA, the responsibility of the Legislature's JAPC is delineated.[22] As a check on legislatively created authority, JAPC examines every proposed rule, unless exempted by law, and may examine existing rules. JAPC examines such rules to determine whether:

- The rule is an invalid exercise of delegated legislative authority;
- The statutory authority for the rule has been repealed;
- The rule reiterates or paraphrases statutory material;
- The rule is in proper form;
- Proper notice was given prior to the rule's adoption and adequate notice was provided of the purpose and effect of the rule;
- The rule is consistent with expressed legislative intent;
- The rule is necessary to accomplish the apparent or expressed objectives of the specific provision of law which the rule implements;
- The rule is a reasonable implementation of the law as it affects persons impacted;
- The rule could be made less complex or more easily comprehensible to the general public;
- A SERC is prepared as required by law and regulatory costs on the regulated persons, county, or city impacted by the rule could be reduced by adoption of a less costly alternative;
- The rule requires additional appropriations; and
- If an emergency rule, is the emergency status justified.[23]

If after review of a proposed rule and any information required from an agency, JAPC objects to the rule, it has 5 days to certify the objection to the agency along with its detailed concerns.

[20] Section 120.541(3), F.S.
[21] The Office of the 45th Governor of Florida Rick Scott, *Governor Rick Scott Fulfills First Campaign Promises to Hold Government Accountable*, available at http://www.flgov.com/2011/01/04/governor-rick-scott-fulfills-first-campaign-promises-to-hold-government-accountable/ (Last visited on March 4, 2011). Executive Order No. 11-01 is available at http://www.flgov.com/wp-content/uploads/2011/01/scott.eo_.one_.pdf (Last visited on March 4, 2011).
[22] Section 120.545, F.S.
[23] *See* s. 120.545(1), F.S.

JAPC also notifies the President of the Senate and the Speaker of the House of Representatives of its concerns.[24]

Within 30 to 45 days of receipt of the objection, an agency, depending upon its structure, must do the following:

- If the rule is not in effect, it must notice modifications of the rule that address JAPC's concerns or withdrawal of the rule, or notify JAPC that it refuses to do either.
- If the rule is in effect, it must notice to amend the rule to address JAPC's concerns or to repeal the rule, or to notify JAPC that it refuses to do either.
- If the objection is with the SERC, the agency must prepare a corrected SERC, notice it, and send a copy to JAPC, or notify JAPC that it will not comply.[25]

If an agency refuses to respond within timeframes required for a proposed rule, the rule is considered withdrawn. Any other lack of response is considered a refusal to take action by the agency.[26]

If JAPC objects to a rule, or portion of a rule, and the agency does not begin administrative action consistent with the objection within 60 days after objection or fails to proceed in good faith to complete the action, JAPC makes recommendations to the Legislature for changes in the law, if determined necessary.[27]

An agency is notified of JAPC's vote to introduce legislation. JAPC may request the agency to temporarily suspend the rule or its adoption, pending consideration of proposed legislation during the next regular session of the Legislature.[28]An agency has up to 45 days to respond to JAPC's request to suspend the rule or its adoption. Failure of the agency to respond is considered a refusal to act. Nothing prevents an agency from refusing to take action as requested by JAPC.[29]

If legislation addressing the objections fails to become law, the temporary rule suspensions by an agency expire.[30]

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

[24] *See* s. 120.545(2), F.S.
[25] *See* s. 120.545(3)(c), F.S.
[26] *See* s. 120.545(4), (5), and (6), F.S.
[27] *See* s. 120.545(8), F.S.
[28] *See* s. 120.545(8)(b)1., F.S.
[29] Section 120.545(8)(b)2., F.S.
[30] Section 120.545(8)(d), F.S.

and the community.[31] The State Surgeon General is the State Health Officer and the head of the DOH.

As of February 2011, the DOH's divisions, programs, and offices with rulemaking responsibilities, have approximately 978 rules. The DOH's Medical Quality Assurance Boards, which are separate rulemaking agencies, have approximately 1,490 rules.[32]

An example of a lengthy rulemaking procedure within the DOH is demonstrated by promulgation of Rule 64B16-26.1032, Florida Administrative Code. Council substitute for House Bill 543 (HB 543) became effective on July 1, 2007. HB 542 requires a pharmacist seeking to administer influenza virus immunizations to adults to be certified to administer influenza virus immunizations pursuant to a certification program approved by the Board of Pharmacy. Rule 64B16-26.1032, Florida Administrative Code, which provides for the "Immunization Administration Certification Application," did not become effective until September 21, 2010, more than 38 months after the law became effective.

The Agency for Health Care Administration

Section 20.42, F.S., creates the AHCA. The AHCA is the chief health policy and planning entity for the state. The AHCA is responsible for health facility licensure, inspection, and regulatory enforcement; investigation of consumer complaints related to health care facilities and managed care plans; the implementation of the certificate of need program; the operation of the Florida Center for Health Information and Policy Analysis; the administration of the Medicaid program; the administration of the contracts with the Florida Healthy Kids Corporation; the certification of health maintenance organizations and prepaid health clinics as set forth in part III of chapter 641; and any other duties prescribed by statute or agreement.[33] The head of the AHCA is the Secretary of Health Care Administration.

As of February 2011, the AHCA has promulgated 625 rules.[34]

An example of a lengthy rulemaking process within AHCA pertains to the development of proposed rule 59A-26.003. In 1999, the Legislature enacted committee substitute for Senate Bill 2214 (SB 2214), which became effective May 7, 1999. SB 2214 created, among other sections of law, s. 400.967(2), F.S., to require the AHCA to develop rules regarding specific criteria, including facility requirements, minimum standards of program development, and quality of care, for Intermediate Care Facilities for Developmentally Disabled Persons. To date, proposed rule 59A-26.003, which is being developed to meet the rulemaking requirements under s. 400.967(2), F.S., has yet to become effective.

[31] Section 381.001, F.S.
[32] Professional committee staff of the Senate Health Regulation Committee received an email from a DOH representative on February 18, 2011, providing these statistics. A copy of the email is on file with the committee.
[33] Section 20.42, F.S.
[34] Professional committee staff of the Senate Health Regulation Committee received this information via telephone interview with an AHCA representative on February 18, 2011.

III. Effect of Proposed Changes:

This proposed committee bill seeks to streamline the rulemaking process for the DOH and AHCA. This bill does not change the requirement for the DOH and the AHCA to publish initial notice of rule development in the FAW.

Section 1 creates an undesignated section of law to declare that it is the Legislature's intent to expedite the rulemaking process within the DOH and the AHCA by requiring a date certain for rules to become effective, by authorizing the use of websites to meet publication requirements under the APA, and by encouraging early and timely participation in the rulemaking process.

Section 2 amends s. 120.52, F.S., to define the term "prominent display" to mean text in a font larger than, and in a different color than, the surrounding text.

Section 3 amends s. 120.525, F.S., to require the DOH and the AHCA to provide notice of public meetings, hearings, or workshops by prominent display on the home page of the DOH or the AHCA website, instead of in the FAW. However, the DOH and the AHCA may also elect to provide such notice in the FAW.

Section 4 amends s. 120.54, F.S., to require the DOH or the AHCA to submit a written report to the Governor, President of the Senate, and Speaker of the House of Representatives if the agency has not adopted a rule to implement an act enacted by the Legislature within 30 days prior to the next general legislative session or within 6 months after the effective date of the act requiring adoption of the rule if the next general session is less than 6 months from the effective date of the act, unless the rule has not become effective because of the Legislature's refusal to ratify the rule. The report must be submitted within 30 days of the required deadline and identify the number and dates of workshops and hearings that have been conducted during the rulemaking process; explain why the rule has not become effective within the required time, including any protests to the proposed rule, or any other relevant information regarding the lack of timeliness of the rule's adoption; and recommend any legislative changes that might be appropriate.

In addition, this section:

- Requires the DOH and the AHCA to provide a mailing address, telephone number, or email address on its notice of rule development in order to allow a person to request rulemaking updates via email.
- Requires the DOH and the AHCA to provide notice to interested persons via email of any rulemaking notices that have been made available to the public, if such persons have requested updates of those notices and provided a current email address. The requirement in s. 120.54(3)(a)3., F.S., that agencies provide notification by mail to anyone who requests notification in that manner, remains unchanged for these two agencies.
- Exempts the DOH and the AHCA from the requirement that each agency must hold public workshops in various regions of the state, which is currently required if a person makes such a request.
- Authorizes the DOH and the AHCA to schedule a workshop 7 days after notice of a rule development workshop has been prominently displayed on its website, if a toll-free conference call telephone number has been provided to the public to access the workshop.

- Authorizes a DOH or an AHCA agency head's designee to approve the agency's intended action on a proposed rule.
- Authorizes the DOH or the AHCA to include in the notice of proposed rulemaking a short sentence summarizing the conclusion reached in the agency's SERC.
- Requires the DOH or the AHCA to provide a notice of proposed rulemaking by display on its website, but not less than 28 days prior to the intended action, and such notice is required to remain on the website until the rule becomes effective or is withdrawn.
- Requires the DOH or the AHCA to provide the Department of State with an electronic link to the website where the notice of proposed rulemaking is displayed and requires the Department of State to maintain a copy of the notice displayed on the website, which must be made available for public inspection.
- Authorizes the DOH or the AHCA to provide notice of the proposed rulemaking via email to persons who request such notice by email and have provided the DOH or the AHCA with a current email address.
- Authorizes the DOH or the AHCA to provide the JAPC access to a copy of the proposed rule and copies of other documents pertaining to the proposed rule via an electronic link.
- Prohibits the DOH or the AHCA from suspending a rulemaking proceeding to convene a substantial interest hearing. As a result, these agencies must proceed with the steps in the rulemaking process, except the rule may not become effective until after an ALJ has issued a decision under s. 120.56(2), F.S.
- Authorizes the DOH or the AHCA to provide a notice of change of the proposed rule via email to persons who request such notice by email and have provided the DOH or the AHCA with a current email address.
- Requires the DOH or the AHCA to display a notice of change on its website at least 21 days prior to the filing of the rule for adoption and such notice is required to be displayed on the website until the rule becomes effective or is withdrawn.
- Requires the DOH or the AHCA to provide the Department of State with an electronic link to the website where the notice of change is displayed and requires the Department of State to maintain a copy of the notice displayed on the website, which must be made available for public inspection.
- Permits a rule to be modified or withdrawn after adoption and before the rule becomes effective only in response to the Legislature during the rule ratification process or to an objection by the JAPC.
- Authorizes a deputy secretary of the DOH or the AHCA to approve of the filing of certain documents with the Department of State, which are required for final adoption of the rule.
- Requires the DOH or the AHCA to provide notice of its withdrawal of a rule by display of the notice on its website.
- Requires the DOH or the AHCA to provide notice of its intent to adopt a rule that is substantively identical to regulations adopted pursuant to federal law in order for the state to implement a federal program by display on its website at least 21 days prior to filing the rule with the Department of State.

This section also makes several technical and conforming changes.

Section 5 amends s. 120.541, F.S., to authorize the DOH or the AHCA to base a SERC on good faith cost estimates by applying common sense and logic to readily available or obtainable facts.

This section also provides that the DOH or the AHCA is not required to use or hire an economic expert to prepare a SERC, but the involved subject matter experts are to use their best judgment under the circumstances.

Section 6 amends s. 120.56, F.S., to require the DOH and the AHCA to proceed with the rulemaking process after a petition for administrative determination has been filed to challenge a proposed rule. This section also creates a legal presumption that a person is not a substantially affected person, which is required for standing to challenge a rule, if the person making a rule challenge has not participated in the rulemaking process, unless the rule challenge is based on a change in the proposed rule. A presumption is not created if the person can provide documentary evidence that he or she has attended at least one workshop either in person or electronically or provided written comments or concerns to the DOH or the AHCA during the rulemaking process, or the DOH or the AHCA has determined that the person participated in the rulemaking process prior to the date of the rule challenge.

Section 7 provides an effective date of July 1, 2011.

Other Potential Implications:
At a minimum, the bill, should it become law, would save 32 days during the rulemaking process. Additional time may be saved depending on the number of workshops and hearings that are conducted on the proposed rule and the number of changes that are made to the proposed rule during the rulemaking process.

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:

Persons interested in proposed rules may save on travel expenses by attending workshops via telephone conference calls.

C. Government Sector Impact:

The DOH or the AHCA may incur some administrative costs associated with displaying notices on their respective websites, compiling lists of interested persons to send email updates to concerning notices of rulemaking processes, and submitting written reports to the Governor and Legislature if the rulemaking deadlines provided for in the bill are missed.

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.