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 1938
INTRODUCER:	Senator Constantine
SUBJECT:	Cardiology services
DATE:	April 6, 2009
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Wilson	HR	**Unfavorable**
2.			HA	
3.				
4.				
5.				
6.				

I. Summary:

The bill assigns responsibilities to the Agency for Health Care Administration (Agency), the Department of Health (DOH), Emergency Medical Services (EMS) providers and directors, and hospitals to develop and implement protocols for the assessment, treatment, and transportation of patients experiencing an ST-elevation myocardial infarction (STEMI) heart attack to appropriate medical facilities.

This bill creates three undesignated sections of law.

II. Present Situation:

Hospitals

Hospitals are licensed and regulated by the Agency under ch. 395, F.S., the general licensure provisions of part II, ch. 408, F.S., and administrative rules in Chapter 59A-3, Florida Administrative Code (F.A.C.)

Certificate of Need (CON) Exemption

A 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.[1] Currently, a CON is required for the establishment of a hospice, skilled nursing facility (currently under a moratorium), intermediate care facility for the developmentally disabled,

[1] s. 408.032(3), F.S.

hospital, and certain in-patient hospital services. A CON issued by the Agency is not required prior to the purchase of major medical equipment.

Upon request to the Agency, certain projects are exempt from review and filing an application for a CON.[2] One of the exemptions, found in s. 408.036(3)(o), F.S., is for the provision of percutaneous coronary intervention (PCI)[3] for patients presenting with emergency myocardial infarctions in a hospital without an approved adult open-heart surgery program. A request for exemption under this provision requires certification that the applicant will meet and continuously comply with the rules adopted by the Agency for the provision of PCIs in hospitals without adult open-heart services. This rule became effective on January 8, 2009, under the Level I program for adult cardiovascular services described more fully below. The statute requires the rules to contain certain elements, including but not limited to: formalized written transfer agreements with a hospital that has an adult open-heart surgery program; ensuring safe and efficient transfer of a patient within 60 minutes; and the submission of a quarterly report to the Agency detailing patient characteristics, treatment, and outcomes for all patients receiving emergency PCIs.

Level I and Level II Adult Cardiovascular Services
Section 408.0361, F.S., requires each provider of adult cardiovascular services to comply with rules adopted by the Agency, which establish licensure standards that govern the provision of adult cardiovascular services. These rules must address, at a minimum, staffing, equipment, physical plant, operating protocols, the provisions of services to Medicaid and charity care patients, accreditation, licensure period and fees, and enforcement of minimum standards. Further, the rules must provide for two hospital program licensure levels:

- Level I program, authorizing the performance of adult percutaneous cardiac intervention without onsite cardiac surgery, and
- Level II program, authorizing the performance of percutaneous cardiac intervention with onsite cardiac surgery.

A hospital seeking a Level I program must demonstrate that, for the most recent 12-month period, as reported to the agency, it has:

- Provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations, or
- Discharged or transferred at least 300 inpatients with the principal diagnosis of ischemic heart disease and that has a formalized, written transfer agreement with a hospital that has a Level II program, including written transport protocols to ensure safe and efficient transfer of a patient within 60 minutes.

A hospital seeking a Level II program must demonstrate that, for the most recent 12-month period, as reported to the agency, it has:

- Performed a minimum of 1,100 adult inpatient and outpatient cardiac cathertizations, of which at least 400 must be therapeutic cathertizations, or
- Discharged at least 800 patients with the principal diagnosis of ischemic heart disease.

[2] s. 408.036(3), F.S.
[3] PCI is commonly known as angioplasty and is used to open blocked blood vessels.

The statute requires these programs to comply with the most recent guidelines of the American College of Cardiology and American Heart Association guidelines for staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety. In addition, hospitals licensed for Level I or Level II adult cardiovascular services must participate in clinical outcome reporting systems operated by the American College of Cardiology and the Society for Thoracic Surgeons.

The Agency has adopted rules,[4] which became final on January 8, 2009, that provide criteria for designation of hospital programs as a Level I program or a Level II program.

The Agency has posted a listing of designated adult cardiovascular services hospitals on its website. Hospitals are included in these listings on the basis of providing an attestation that the adult cardiovascular services meet the criteria in rule. As of March 13, 2009, there were 20 Level I adult cardiovascular services hospitals listed[5] and as of March 5, 2009, 73 Level II adult cardiovascular services hospitals were listed.[6] Hospitals providing the required attestation will have the appropriate Level I or Level II designation added to the hospital license for the current licensure period. Existing Level I and Level II adult cardiovascular services programs must renew their licenses at the time of the hospital license renewal by submitting an updated attestation.

Emergency Medical Services (EMS)

EMS providers are licensed and regulated by the DOH under part III of ch. 401, F.S., and administrative rules in Chapter 64J-1, F.A.C. EMS providers might be private businesses or part of local government. The DOH is responsible, at a minimum, for the improvement and regulation of basic and advanced life support programs. The DOH must develop and biennially revise a comprehensive state plan for basic and advanced life support services, the emergency medical services grants program, trauma centers, the injury control program, and medical disaster preparedness.[7] The state plan must include, but need not be limited to:

- Emergency medical systems planning, including the prehospital and hospital phases of patient care, and injury control effort and unification of such services into a total delivery system to include air, water, and land services;
- Requirements for the operation, coordination, and ongoing development of emergency medical services, which includes: basic life support or advanced life support vehicles, equipment, and supplies; communications; personnel; training; public education; state trauma system; injury control; and other medical care components; and
- The definition of areas of responsibility for regulating and planning the ongoing and developing delivery service requirements.

---

[4] Rule 59A-3.2085(13), (16), (17), and (18), F.A.C.
[5] The list is available at: http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/forms/Level_I_ACS_Listing.pdf (Last visited on April 4, 2009).
[6] This list is available at: <http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/forms/Level_II_ACS_Listing.pdf> (Last visited on April 4, 2009).
[7] s. 401.24, F.S.

The DOH Bureau of EMS regulates approximately 266 EMS provider agencies and the Office of Trauma regulates approximately 20 trauma centers.[8] Protocols are handled at the local level and are developed by the EMS provider's medical director. Currently there are approximately 145 EMS medical directors, some of whom provide direction to multiple EMS providers.[9] The local EMS protocols provide the emergency service personnel with the information needed to transport patients to the medical facility that is appropriate for the patient's medical conditions.[10]

ST-Elevated Myocardial Infarction (STEMI)

STEMI is the most serious and deadly type of heart attack, characterized by a complete blockage of a coronary artery. The American Heart Association estimates that between 200,000 and 400,000 STEMI heart attacks occur annually.[11]

The American Heart Association conducted a survey during October – December 2008 of more than 5,400 EMS system or agency directors and asked questions about staffing, funding, training, and existing processes for handling patients who have experienced a STEMI.[12] The most significant findings were:

- Only half of EMS systems have 12-lead electrocardiograms[13] (ECGs), used to detect STEMI, on 75 percent or more of their vehicles;
- Of EMS systems with 12-lead ECGs, most of those lacked a standard method for EMS to communicate the 12-lead ECG results to the hospital;
- EMS field personnel remotely activate hospital cathertization labs only 40 percent of the time, which can significantly delay evaluation and treatment (the cathertization lab performs procedures like angioplasty and stenting);
- Destination protocols are only used a third of the time to enable EMS to take STEMI patients directly to a hospital capable of providing angioplasty/stenting 24 hours a day, seven days a week. Instead many EMS departments take patients to the closest hospital, which can cause significant delays to appropriate care; and
- Only about 20 percent of hospitals are able to perform procedures like angioplasty and stenting for STEMI patients 24 hours a day, seven days a week.

---

[8] A trauma center is a hospital that has been verified by the DOH to be in substantial compliance with the requirements in s. 395.4025, F.S., related to criteria for selection of trauma centers, and has been approved by the DOH to operate as a Level I trauma center, Level II trauma center, or pediatric trauma center. A trauma victim is a person who has incurred a single or multisystem injury due to blunt or penetrating means or burns and who requires immediate medical intervention or treatment. See part II of ch. 395, F.S.

[9] Department of Health Bill Analysis, Economic Statement and Fiscal Note for SB 1938, dated March 16, 2009.

[10] Agency for Health Care Administration 2009 Bill Analysis and Economic Impact Statement for SB 1938.

[11] Pre-hospital ECGs save critical time for heart attack patients, published August 13, 2008, available at: <http://americanheart.mediaroom.com/index.php?s=43&item=493&printable> (Last visited on April 4, 2009).

[12] American Heart Association EMS Survey Uncovers Deficiencies in Response, Treatment and Transfer of Patients with Most Deadly Heart Attacks, media release published on February 16, 2009, available at: <http://americanheart.mediaroom.com/index.php?s=43&item=677> (Last visited on April 4, 2009).

[13] A 12-lead ECG is a device that measures the electrical activity of the heartbeat and can help medical personnel determine if a heart attack has occurred and whether the heart attack was a STEMI or non-STEMI event. See the Mission Lifeline Glossary by the American Heart Association found at: <http://www.americanheart.org/print_presenter.jhtml?identifier=3061532> (Last visited on April 4, 2009).

One strategy in the EMS care of acute STEMI is to bypass the nearest community hospital in favor of a more distant specialty center able to perform primary percutaneous coronary intervention (PCI). A study[14] recently released in the Annuals of Emergency Medicine looked at whether EMS transport of out-of-hospital STEMI patients directly to more distant specialty PCI centers alters the 30-day survival compared with transport to the nearest community hospital for fibrinolytic therapy.[15] The study considered the use of ground transportation only and excluded situations with fibrinolytic therapy contraindications. The study concluded that the EMS transport of acute STEMI patients directly to PCI centers may offer small but uncertain survival benefits over nearest community hospital fibrinolytic therapy.

III. Effect of Proposed Changes:

The bill provides Legislative findings regarding certain heart attack victims and the state of emergency treatment for persons experiencing life-threatening heart attacks.

The bill provides additional Legislative findings regarding STEMI, in particular. Rapid identification and treatment can significantly improve outcomes and a strong emergency system is necessary to support survival, therefore the Legislature strongly encourages local emergency medical providers to establish a STEMI system of care. A STEMI system of care is defined as a local agreement between EMS providers and local hospitals to deliver patients identified as having a STEMI to appropriate medical facilities.

The Agency is required to:

- Post on its website a list of the licensed PCI centers by December 1, 2009, and by June 1 of each year thereafter. Note: this list is currently available on the Agency's website; and
- Direct each hospital to participate in coordinating a local STEMI system of care composed of hospitals, primary PCI centers with and without open-heart centers onsite, stand-alone PCI centers, and those hospitals not equipped to provide services related to PCI.

DOH is required to:

- Send a list of the *licensed* PCI centers to each EMS provider and EMS director by June 1, 2010, or 6 months after the Agency adopts a rule governing the *certification* of PCI centers under s. 408.036(3)(o), F.S., whichever occurs later, and by each June 1 thereafter. (See the comment under Related Issues);
- Develop sample assessment criteria related to cardiac triage, post the criteria on its website, and provide a copy of the criteria to each EMS provider and EMS director by July 1, 2010. This sample assessment must be based on the American Heart Association's advanced cardiovascular life support chest pain algorithm for prehospital assessment, triage, and treatment of patients suspected of having STEMI, a substantially similar program, or a program that uses evidence-based guidelines. EMS providers are encouraged to use assessment criteria relating to cardiac triage which are substantially similar to the sample assessment criteria developed by the DOH;

[14] The study is available at: <http://www.ncbi.nlm.nih.gov/pubmed/18801596> (Last visited on April 4, 2009).
[15] Fibrinolytic therapy involves the use of drugs to dissolve blood clots. There are contraindications for fibrinolytic use in certain STEMI patients. See <http://emedicine.medscape.com/article/811234-overview> (Last visited on April 4, 2009).

- Develop and provide to each EMS provider and EMS director: technical support, equipment recommendations, and necessary training for the effective identification of patients who have acute STEMI;
- Conduct a biennial survey of all applicable EMS providers to develop an inventory of their equipment and identify their equipment needs, training requirements, and performance regarding the practical application of protocols and the identification of acute STEMI in the field;
- Report the survey findings and provide a copy of the survey to EMS providers, EMS directors, the Emergency Medical Services Advisory Council, and other stakeholders;
- After implementation of the assessment criteria, convene stakeholders at least once a year, if necessary, to facilitate the sharing of experiences and best practices;
- Post assessment criteria best practices on its website;
- Adopt rules necessary to administer this section; and
- Redesignate the Office of Trauma to the Office of Trauma/STEMI.

The DOH is encouraged to identify and provide to all EMS providers opportunities, partnerships, and resources for securing appropriate equipment for identifying STEMI in the field.

Each EMS medical director is required to:

- Develop and implement protocols for the assessment, treatment, and transportation of cardiac patients, and transport STEMI patients to the most appropriate hospital. These protocols must include use of a community plan to address the transport of cardiac patients to appropriate facilities in a manner that addresses community-specific resources and needs; and
- Comply with this law by July 1, 2010, or 6 months after the date it receives the list of certified PCI centers sent pursuant this law, whichever occurs later. (See the comment under Related Issues).

The hospital portion of the STEMI system of care shall deliver detailed, time-stamped documentation of each step in the patient-care process to the EMS medical director for quality-improvement purposes.

The bill is to take effect July 1, 2009.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

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

B. Public Records/Open Meetings Issues:

The provisions of 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:

There may be an indeterminate fiscal impact to the extent this bill requires revisions to existing protocols between EMS providers and hospitals dealing with STEMI patients. Of the 266 licensed EMS providers, 22.5 percent of these agencies are private. It is not known at this point whether these agencies have the necessary equipment to appropriately utilize the criteria that might be developed.

C. Government Sector Impact:

The DOH estimates a fiscal impact of $198,063 in the first year and $119,680 thereafter. The first year costs include two staff, $70,000 for biennial training, and $21,273 for the stakeholder meeting. There will also be a cost to cities and counties that operate EMS providers to the extent this bill requires revisions to existing protocols between EMS providers and hospitals.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Lines 115-117, refer to the Agency adopting rules to certify PCI centers under s. 408.036(3)(o), F.S. Section 408.036(3)(o), F.S., addresses an exemption from the requirement of a CON and does not require any type of certification. The Agency indicates that it has no intention of certifying PCI centers since they are currently licensed as Level I or Level II adult cardiovascular services programs.

On lines 188-189, the term “stand-alone PCI centers” is used. Under the current regulatory scheme, a PCI center must be located in a hospital with a licensed Level I or Level II adult cardiovascular services programs.

The bill requires duplicative activities without an apparent benefit, such as:

- Requiring the Agency to adopt a rule to certify PCI centers, which would cover providers already licensed as Level I or Level II adult cardiovascular services providers;
- Requiring the Agency to post a list of PCI centers on its website by December 1, 2009 and by June 1 of each year thereafter. The Agency currently posts this information on its hospital

web page, under the heading Adult Cardiovascular Services, Level I and Level II Programs. The list is currently being updated monthly, but will be updated less frequently based on the infrequent changes to the list;[16]

- Requiring the DOH to send a list of licensed PCI centers to each EMS provider and EMS director when this information is posted on the Agency's website; and
- Requiring the DOH to post sample assessment criteria relating to cardiac triage on its website *and* provide a copy of it to each EMS provider and EMS director.

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.

[16] Agency for Health Care Administration 2009 Bill Analysis and Economic Impact Statement for SB 1938.