The Florida Senate

PROFESSIONAL STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

Prepared By: Health Regulation Committee

BILL:	CS/SB 1938
INTRODUCER:	Health Regulation Committee and Senator Joyner
SUBJECT:	Cardiology Services
DATE:	March 23, 2007 REVISED:

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

I. Summary:

The bill requires the Agency for Health Care Administration (AHCA or agency) to post on its website a list of the percutaneous intervention centers and open-heart surgery programs licensed by the agency. The bill requires the Department of Health (DOH or department) to send a list of percutaneous intervention centers and open-heart surgery programs to emergency medical services (EMS) providers and EMS directors in the state. The bill requires the department to develop sample cardiac triage assessment criteria and post them on the DOH website. The assessment criteria must be sent to each EMS provider and EMS director. Each EMS provider must use assessment criteria that are substantially similar to the sample criteria provided by the department.

The bill requires the medical director of each licensed EMS provider to develop and implement assessment, treatment, and transportation protocols for serious heart attack patients. The bill requires the DOH to develop and provide technical support, equipment recommendations, and necessary training to each licensed EMS provider and EMS medical director. The bill requires the DOH to conduct a biennial survey of all licensed EMS providers to develop an inventory of their equipment and identify their equipment needs, their training requirements, and their performance regarding the application of protocols and the identification of severe heart attacks in the field. The DOH is also required to convene stakeholders once a year, after implementation of the assessment criteria, to facilitate the sharing of experiences and best practices. The bill requires each EMS provider to comply with the specified mandates by July 1, 2009.

This bill creates one undesignated section of law.

II. Present Situation

Heart Attacks

A heart attack, or acute myocardial infarction, occurs when one of the arteries that supply the heart muscle becomes blocked. The ST elevation myocardial infarction (STEMI) is a severe heart attack in which an artery is completely blocked. Emergency treatment for acute myocardial infarction includes thrombolitics—the use of drugs to break up the clot—or percutaneous coronary intervention—the use of angioplasty or the insertion of a stent into the artery. *Angioplasty* is the dilatation of an obstructed artery, which is most commonly achieved by the passage of a balloon catheter through the vessel to the area of disease. Inflation of the catheter compresses the plaque against the vessel wall. A *stent* is a short narrow metal or plastic tube that is inserted into the artery to keep a previously blocked passageway open. For patients with a STEMI, treating this type of heart attack requires fast action because if blood flow is not restored to the heart within 20 minutes permanent damage will occur. While some heart muscle can be saved if patients are treated later, more muscle is lost with every minute treatment is delayed. Speedy treatment not only means the difference between life and death, but also between disability and a return to an active lifestyle after a heart attack.

One of the most crucial decisions when treating a patient with a STEMI is whether to open the blocked artery with a clot-busting drug or by using stents that prop open blocked arteries. The decision is based on four issues:

- How much time has passed since the onset of symptoms?
- How great is the risk of dying?
- How great is the risk of bleeding in the brain if clot-busting drugs are used?
- Realistically, how much time will it take to get the patient into a cardiac catheterization lab for stenting?

In an August 2003 article in *The New England Journal of Medicine*, Henning R. Andersen, et. al., compared coronary angioplasty with fibrinolytic therapy in acute myocardial infarction. Danish researchers randomly assigned 1,572 patients with acute myocardial infarction to treatment with angioplasty or accelerated treatment with intravenous alteplase. The patients who were treated with angioplasty were less likely to die or suffer reinfarction or a stroke than the patients who were treated with fibrinolytic therapy (8.5 percent of the patients in the angioplasty group as compared with 14.2 percent of patients in the fibrinolysis group). This research indicates that treatment with angioplasty within 60 minutes of the onset of the heart attack is preferable to treatment with intravenous drugs, and the researchers suggested changing the existing triage procedure accordingly. Instead of taking a patient to the nearest hospital, a better emergency procedure would be to take the patient to a center where angioplasty could be performed.

There are clear instructions about medical treatments after heart attack. For example, it is recommend that patients should take aspirin daily and receive beta-blockers (to reduce the risk of irregular heart rhythm) after heart attack. It is also strongly recommended that angiotensin-converting enzyme (ACE) inhibitors be used for all patients to improve heart function. For those

patients who cannot tolerate an ACE inhibitor, an angiotensin receptor blocker (ARB) is suggested.

Hospital Licensure

Florida hospitals are licensed by the Agency for Health Care Administration (AHCA or agency) under ch. 395, F.S. The law requires the AHCA to inspect hospitals, or to cause inspections to be made, to ensure compliance with licensure and safety requirements. Surveys or inspections of accrediting organizations such the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) are accepted as licensure surveys by the state.

Rule 59C-1.032(6)(b), F.A.C., prohibits therapeutic cardiac catheterization and therefore also prohibits the provision of emergency percutaneous coronary intervention in a hospital without an open-heart-surgery program. Therapeutic cardiac catheterization is a general term that applies to angioplasty, stent insertion, and related procedures that are generally performed in cardiac catheterization laboratories. This term is distinguished from diagnostic cardiac catheterization, in which cardiac catheterization procedures are used to establish the patient's diagnosis.

There is a certificate-of-need (CON) exemption in s. 408.036(3)(o), F.S., for the provision of percutaneous coronary intervention for patients presenting with emergency myocardial infarctions in a hospital that does not have an approved adult open-heart-surgery program. In addition to any other documentation required by the AHCA, a request for an exemption submitted under this paragraph must comply with the following:

- The applicant must certify that it will meet and continuously maintain the requirements adopted by the agency for the provision of these services. These licensure requirements must be adopted by rule pursuant to ss. 120.536(1) and 120.54, F.S., and must be consistent with the guidelines published by the American College of Cardiology and the American Heart Association for the provision of percutaneous coronary interventions in hospitals without adult open-heart services. At a minimum:
    - Cardiologists must be experienced interventionalists who have performed a minimum of 75 interventions within the previous 12 months.
    - The hospital must provide a minimum of 36 emergency interventions annually in order to continue to provide the service.
    - The hospital must offer sufficient physician, nursing, and laboratory staff to provide the services 24 hours a day, 7 days a week.
    - Nursing and technical staff must have demonstrated experience in handling acutely ill patients requiring intervention based on previous experience in dedicated interventional laboratories or surgical centers.
    - Cardiac care nursing staff must be adept in hemodynamic monitoring and Intra-aortic Balloon Pump (IABP) management.
    - Formalized written transfer agreements must be developed with a hospital with an adult open-heart surgery program, and written transport protocols must be in place to ensure safe and efficient transfer of a patient within 60 minutes. Transfer and transport agreements must be reviewed and tested, with appropriate documentation maintained at least every 3 months.

- Hospitals implementing the service must first undertake a training program of 3 to 6 months, which includes establishing standards and testing logistics, creating quality assessment and error management practices, and formalizing patient-selection criteria.

- The applicant must certify that it will use at all times the patient-selection criteria for the performance of primary angioplasty at hospitals without adult open-heart surgery programs issued by the American College of Cardiology and the American Heart Association. At a minimum, these criteria would provide for the:
  - Avoidance of interventions in hemodynamically stable patients who have identified symptoms or medical histories.
  - Transfer of patients who have a history of coronary disease and clinical presentation of hemodynamic instability.

- The applicant must agree to submit a quarterly report to the agency detailing patient characteristics, treatment, and outcomes for all patients receiving emergency percutaneous coronary interventions pursuant to this paragraph. This report must be submitted within 15 days after the close of each calendar quarter.
- The exemption from CON review for percutaneous coronary intervention does not apply unless the AHCA determines that the hospital has taken all necessary steps to be in compliance with all requirements of the bill, including the training program.
- Failure of the hospital to continuously comply with the requirements for round-the-clock availability, staff qualifications, transfer agreements, adherence to the criteria of the American College of Cardiology and the American Heart Association referenced above, and submission of reports to the AHCA will result in the immediate expiration of this exemption.
- Failure of the hospital to meet the volume requirements within 18 months after the program begins offering the service will result in the immediate expiration of the exemption.

If the exemption for this service expires, the AHCA may not grant another exemption for this service to the same hospital for two years, and then only upon a showing that the hospital will remain in compliance with the requirements of this paragraph through a demonstration of corrections to the deficiencies that caused expiration of the exemption.

Currently, Florida has 72 approved operational adult open-heart surgery programs; one approved non-operational adult open-heart surgery program, and eight operational emergency percutaneous coronary intervention programs without an adult open-heart program. Based on guidelines published by the American College of Cardiology and the American Heart Association for the Emergency, percutaneous coronary intervention for patients presenting with emergency myocardial infarctions should be performed at these hospitals with open adult open-heart surgery programs or these centers with experienced percutaneous coronary interventionalists.

Emergency Medical Services

Part III, ch. 401, F.S., provides for the regulation of emergency medical services by the department. Section 401.23, F.S., provides definitions. "Advanced life support" is defined to mean treatment of life-threatening medical emergencies through the use of specified techniques by a qualified person, pursuant to the department rules. "Basic life support" is defined to mean treatment of medical emergencies by a qualified person through the use of specified techniques and other techniques described in the Emergency Medical Technician Basic Training Course Curriculum of the United States Department of Transportation. "Basic life support" also includes other techniques that have been approved and are performed under conditions specified by rules of the department. "Basic life support service" is defined to mean any emergency medical service, which uses only basic life support techniques. "Advanced life support service" is defined to mean any emergency medical transport or nontransport service, which uses advanced life support techniques. "Air ambulance" is defined to mean any fixed-wing or rotary-wing aircraft used for, or intended to be used for, air transportation of sick or injured persons requiring or likely to require medical attention during transport. "Air ambulance service" is defined to mean any publicly or privately owned service, licensed in accordance with the provisions of this part, which operates air ambulances to transport persons requiring or likely to require medical attention during transport. The department:

- Regulates, by licensure, permit, and certification, ground and air ambulance providers and vehicles, and emergency medical technicians and paramedics and their training programs;
- Provides grant funds to organizations to improve and expand Florida's EMS systems; and
- Oversees injury prevention programs, statewide trauma systems development, and trauma center verification.

Section 401.265, F.S., requires that each basic life support transportation service or advanced life support service must employ or contract with a medical director. The medical director must be a licensed physician; a corporation, association, or partnership composed of physicians; or physicians employed by any hospital that delivers in-hospital emergency medical services and employs or contracts with physicians specifically for that purpose. One physician from any of these groups must be designated as the medical director at any given time. Each medical director will establish a quality assurance committee to provide for quality assurance review of all technicians and paramedics working under his or her supervision. The department adopts and enforces all rules necessary to administer this section pertaining to medical directors.

The department does not currently regulate emergency medical services protocols. Emergency medical services protocols are developed by the medical directors who contract with or are employed by emergency medical services providers. Protocols are developed on the local level to address the needs of the emergency medical services system and the skills of the emergency medical technicians and paramedics who assess, treat, and determine the appropriate location to transport a patient who suffers a medical emergency.

III. Effect of Proposed Changes:

Section 1. *Subsection (1)* provides legislative findings and intent, including the following:

- That rapid identification and treatment of ST elevation myocardial infarction (serious heart attacks) can significantly improve outcomes;
- A strong emergency system is needed in order to treat victims in a timely manner; and
- The Legislature intends to establish a statewide emergency cardiac system to help improve outcomes for heart attack victims.

Subsection (2) provides definitions for agency, department, open-heart surgery program, and percutaneous intervention center.

Subsection (3) requires the agency to post on its website a list of the percutaneous intervention centers and the open-heart surgery programs licensed by the agency. The list must be posted by December 1, 2007, and by June 1, each year thereafter.

Subsection (4) requires the department to send a list of the names and addresses of each percutaneous intervention center and open-heart surgery program licensed by the agency to each licensed EMS provider and EMS director in the state by June 1, 2008, or six months after the agency adopts a rule governing the certification of percutaneous intervention centers under s. 408.036(3)(o), F.S., whichever is later and by June 1, of each year thereafter.

Subsection (5) requires the department to develop sample cardiac triage assessment criteria, post the assessment criteria on the DOH website, and send the assessment criteria to each licensed EMS provider and EMS director by December 1, 2008. Each licensed EMS provider must use assessment criteria that are substantially similar to the sample criteria provided by the department.

Subsection (6) requires the medical director of each licensed EMS provider to develop and implement assessment, treatment, and transportation protocols and employ these protocols to assess, treat and transport ST elevation myocardial infarction patients to the most appropriate hospital. These protocols may address community-specific resources and needs.

Subsection (7) requires the department to develop and provide technical support, equipment recommendations, and necessary training to each licensed EMS provider and EMS medical director for the identification of acute ST elevation myocardial infarction patients. The sample cardiac triage assessment criteria must be modeled on the American Heart Association's advanced cardiovascular life support chest pain algorithm or a substantially similar program or a program with evidence-based guidelines. The DOH must conduct a biennial survey of all applicable licensed EMS providers to develop an inventory of their equipment and identify their equipment needs, their training requirements, and their performance regarding the application of protocols and the identification of acute ST elevation myocardial infarction patients in the field. The DOH is also required to report the survey findings and make the results of the survey available to the EMS providers, EMS directors, the Emergency Medical Services Advisory Council, and other stakeholders.

Subsection (8) encourages the DOH to identify and provide opportunities, partnerships, and resources to secure equipment for the identification of acute ST elevation myocardial infarction in the field to all licensed EMS providers.

Subsection (9) requires the DOH to convene stakeholders, at least once a year, after implementation of the assessment criteria, to facilitate the sharing of experiences and best practices. Best practices must be made available on the department's website.

Subsection (10) requires each emergency medical services provider, licensed under ch. 401, F.S., to comply with this section by July 1, 2009, or 6 months after the date it receives the list of percutaneous intervention centers, whichever is later.

Section 2. Provides an effective date of July 1, 2007.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The bill requires medical directors of licensed emergency medical services providers to develop and implement assessment, treatment, and transportation protocols for cardiac patients. The fiscal impact of this requirement has not yet been determined, however, if the bill requires local governments to spend in the aggregate $1.8 million, then pursuant to Article VII, Section 18 of the Florida Constitution, the Legislature must formally determine that the bill fulfills an important state interest and the bill must pass by two-thirds vote of the membership of each house of the Legislature.

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. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The public will benefit from improved responses to emergencies involving ST elevation myocardial infarction.

C. Government Sector Impact:

To complete the tasks required in the bill, the DOH will need one FTE who is a Florida certified paramedic or registered nurse. The estimated expense to the department for the first year is $77,982.00 and for the second year, it is $74,958.00. There is not a fiscal impact to the agency.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Section 1, subsection (10), requires each EMS provider licensed under ch. 401, F.S., to comply with the section by July 1, 2009. The DOH's role is unclear regarding the enforcement of this mandate.

The DOH, Bureau of EMS, is currently developing the Emergency Medical Services Tracking and Reporting System (EMSTARS). This data collection and analysis system has the ability to identify operational and clinical benchmarks, trends, and the number of patients transported to percutaneous intervention centers versus the number who are transported to non-percutaneous intervention hospitals. The EMSTARS system will provide information that may eventually eliminate the need for a survey.

On page 4, lines 4 through 9, the bill requires the DOH to send a list of the names and addresses of every percutaneous intervention center and every open-heart surgery program in the state. It is unclear why local EMS providers would need statewide information.

VIII. Summary of Amendments:

None.