HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1033 Emergency Cardiology Services
SPONSOR(S): Health Care Regulation Policy Committee, Renuart and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1938

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee	7 Y, 0 N, As CS	Holt	Calamas
2)	Health & Family Services Policy Council			
3)	Health Care Appropriations Committee			
4)	Full Appropriations Council on General Government & Health Care			
5)				

SUMMARY ANALYSIS

The bill requires the establishment of a specific local system of care, to be identified as a "STEMI system of care". STEMI is identified in the bill as "an ST elevated myocardial infarction", an emergency cardiac condition commonly referred to as a heart attack. Specifically, the bill:

- Provides legislative findings;
- Requires hospitals to participate in the coordination of a local STEMI system of care;
- Requires hospitals to submit certain documentation to the National Cardiovascular Data Registry, and provide copies to EMS medical directors;
- Permits EMS medical directors to access the National Cardiovascular Data Registry for a certain purpose;
- Requires the department to develop sample assessment criteria for cardiac triage, to post it on the department website and provide copies to EMS providers;
- Requires EMS medical directors to implement a protocol for the assessment, treatment and transportation of certain cardiac patients to the most appropriate hospital, and requires the protocols to include the use of a community plan and data-sharing with hospitals;
- Requires the department to provide technical support and recommendations for equipment and training to EMS providers;
- Requires the department to biennially survey all EMS providers to identify their equipment and training needs, and performance, and provide copies of the survey findings to certain parties;
- Requires the department to provide EMS providers with opportunities, partnerships and resources for securing appropriate equipment;
- Encourages local STEMI systems to meet semi-annually;
- Requires the department to convene an annual meeting of local STEMI system stakeholders for certain purposes, as necessary, and requires the department to post best practices shared at those meetings on its website; and
- Authorizes rulemaking for the department and the Agency for Health Care Administration.

The bill will have a significant negative fiscal impact on the Emergency Medical Services Trust Fund within the Department of Health of approximately of $70,000 for training and a potential insignificant fiscal impact to local governments for the purchase of STEMI equipment (see fiscal impact).

The bill takes effect July 1, 2009.

HOUSE PRINCIPLES

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

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background:

Society of Chest Pain Centers

The Society of Chest Pain Centers (SCPC) is a non-profit international society dedicated to the belief that heart disease can be eliminated as the number one cause of death worldwide.[1] Currently, there are 40 licensed hospitals in Florida that are accredited by the Society of Chest Pain Centers.[2] The accreditation process helps the facility define and actualize its strengths, identify and improve weaknesses, and recognize opportunities to enhance processes. The review process provides a road map to indentify gaps, sets standards, and starts the journey to improve cardiac patient care.[3]

The accreditation process considers eight elements or areas that a facility must demonstrate expertise include:

1. Emergency Department Integration with the Emergency Medical System
2. Emergency Assessment of Patients with Symptoms of Possible Asymptomatic Carotid Stenosis (ACS)[4] - Timely Diagnosis and Treatment of ACS
3. Assessment of Patients with Low Risk for ACS and No Assignable Cause for their Symptoms
4. Process Improvement
5. Personnel, Competencies, and Training
6. Organizational Structure and Commitment
7. Functional Facility Design
8. Community Outreach

Facilities that meet or exceed these criteria are assigned one of three possible designations:

- **Accredited Chest Pain Center** is the designation earned by a healthcare facility, having met the standards for accreditation.

[1] Society of Chest Pain Centers. Available online at: http://www.scpcp.org/dnn/ (last viewed March 22, 2009).
[2] Society of Chest Pain Centers, List of CPC Accredited Facilities. (2009) Available online at: http://www.scpcp.org/dnn/Accreditation/ChestPainCenter/ListofCPCAccreditedFacilities/tabid/210/Default.aspx (last viewed March 22, 2009).
[3] *Ibid.*
[4] ACS is a condition in which the main vessels supplying blood to the brain are narrowed but the patient has no stroke symptoms.

- **Accredited Chest Pain Center with Percutaneous Coronary Intervention (PCI)**[5] is the designation earned by a healthcare facility that meets the standards accreditation and uses primary PCI as the facility's reperfusion[6] strategy of first choice for STEMI.

- **Provisionally Accredited Chest Pain Center** is the designation given to a healthcare facility that has met the majority of standards, but some items remain incomplete and has completed a site visit. A provisionally accredited facility may not call itself an "Accredited Chest Pain Center" or use the seal of accreditation. A provisionally accredited facility may call itself only a "Provisionally Accredited Chest Pain Center".[7]

Cardiovascular Services

Section 408.0361, F.S., provides that each provider of diagnostic cardiac catheterization services shall comply with rules adopted by the Agency for Health Care Administration ("agency") to establish licensure standards governing the operation of adult inpatient diagnostic cardiac catheterization programs. The rules ensure that the programs:

- Comply with the most recent guidelines of the American College of Cardiology and American Heart Association Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories.
- Perform only adult inpatient diagnostic cardiac catheterization services and will not provide therapeutic cardiac catheterization or any other cardiology services.
- Maintain sufficient appropriate equipment and health care personnel to ensure quality and safety.
- Maintain appropriate times of operation and protocols to ensure availability and appropriate referrals in the event of emergencies.
- Demonstrate a plan to provide services to Medicaid and charity care patients.

The agency created licensure standards establishing two hospital cardiac program licensure levels:

- **Level I** program authorizes the performance of adult percutaneous cardiac intervention *without* onsite cardiac surgery; a hospital must demonstrate it has provide a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations or treated patients with a diagnosis of ischemic heart disease in the past 12-months.
- **Level II** program authorizes the performance of percutaneous cardiac intervention *with* onsite cardiac surgery; a hospital must demonstrate it has provide a minimum of 1,100 adult inpatient and outpatient cardiac catheterizations, of which at least 400 must be therapeutic catheterizations, or discharged at least 800 patients with the principal diagnosis of ischemic heart disease within the past 12-months.

All 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.[8]

In addition, the agency created a technical advisory panel that developed recommendations that the agency used to develop and adopt rules for cardiology services and the licensure of Level I and II cardiac programs.[9] Members of the panel[10] included representatives from:[11]

- Florida Hospital Association,

[5] Commonly known as coronary angioplasty or simply angioplasty, PCI is used to open blocked blood vessels that cause heart attacks.
[6] The restoration of blood flow to an organ, after it was cut off.
[7] Society of Chest Pain Centers, What is Chest Pain Center Accreditation? (2009) Available online at: http://www.scpcp.org/dnn/Accreditation/ChestPainCenter/WhatisChestPainCenterAccreditation/tabid/61/Default.aspx (last viewed March 22, 2009).
[8] Section 408.0361(5)(b), F.S.
[9] 59A-3.2085, F.A.C.
[10] The panel was disbanded in December 2008 following the conclusion of the rule promulgation process.
[11] Section 408.0361(5)(a), F.S.

- Florida Society of Thoracic and Cardiovascular Surgeons,
- Florida Chapter of the American College of Cardiology,
- Florida Chapter of the American Heart Association; and
- Any other entities with experience in statistics and outcome measurement.

The agency adopted rules dealing with the following for adult cardiovascular services:[12]

- A risk adjustment procedure that accounts for the variations in severity and case mix found in hospitals in this state;
- Outcome standards specifying expected levels of performance in Level I and Level II adult cardiovascular services. Such standards may include, but shall not be limited to, in-hospital mortality, infection rates, nonfatal myocardial infarctions, length of stay, postoperative bleeds, and returns to surgery; and
- Specific steps to be taken by the agency and licensed hospitals that do not meet the outcome standards within specified time periods, including time periods for detailed case reviews and development and implementation of corrective action plans.

According to the agency, a rule was enacted to deal with adult cardiovascular services after four years of painstaking and often contentious effort, culminating in a protracted proposed rule challenge.[13]

ST-Elevation Myocardial Infarction (STEMI)

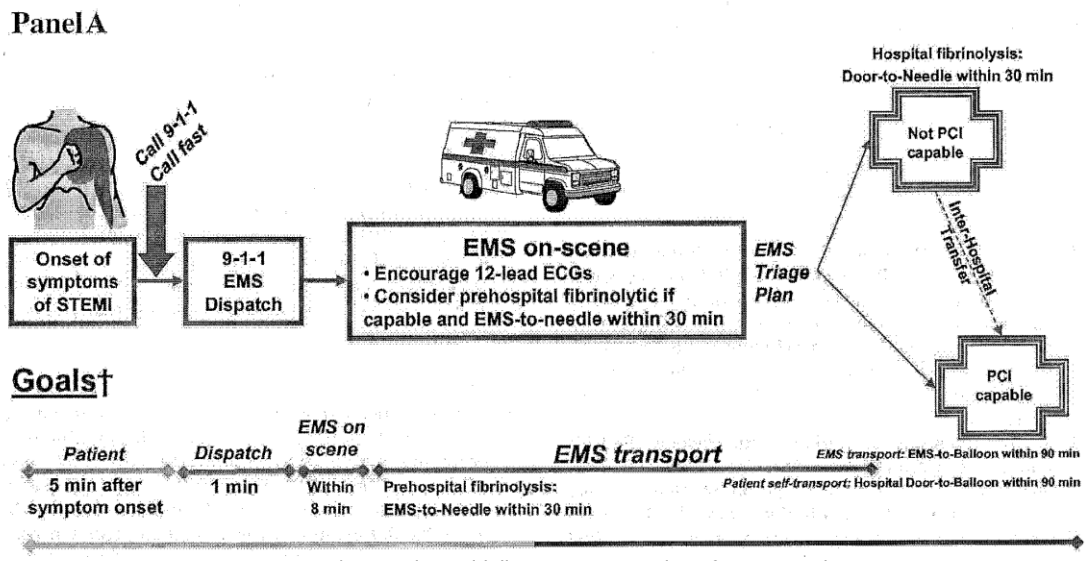
A STEMI is commonly referred to as a heart attack. According to the American Heart Association, every year, almost 400,000 people experience a STEMI, the deadliest type of heart attack.[14]

According to a article in Circulation, there are several barriers that limit the rapid transport of patients with STEMI to the most appropriate facility: a minority (10%) of EMS systems have 12-lead ECG capabilities, which is needed to recognize a STEMI event; a minority (4% to 5%) of EMS patients with chest pain have STEMI; a directive exists to deliver the patient to the nearest facility even when fibrinolysis[15] may be contraindicated and the facility does not provide PCI; and transport times may be long in rural areas.[16] If a patient is brought to a non–PCI-capable facility and primary PCI is necessary, it is not unusual for the patient to wait for the next available ambulance to gain access to PCI. Furthermore, critically ill patients often require stabilization before transport, which could hamper the response and treatment timeline.[17]

In 1999, the American College of Cardiology and the American Heart Association adopted joint guidelines on the management of patients with STEMI.[18] The purpose of the guidelines was to focus on the numerous advances in the diagnosis and management of patients with STEMI. The guidelines specifically discuss pre-hospital issues with emergency medical services systems to ensure that patients receive quick, appropriate care in route to a hospital. If the hospital is not a PCI capable facility then the patient is usually transferred via inter-hospital transfer to a PCI capable facility. Below is a diagram of a recommended Emergency Medical Services (EMS) provider transport and care process.

---

[12] *Ibid.*
[13] Agency for Health Care Administration Bill Analysis and Economic Impact Statement for HB 1033 (2009) and 59A-3.2085, F.A.C
[14] American Heart Association, Mission: Lifeline. Available online at: http://www.americanheart.org/presenter.jhtml?identifier=3050213 (last viewed March 22, 2009).
[15] Drugs used to dissolve blood clots.
[16] Circulation. *Recommendation to Develop Strategies to Increase the Number of ST-Segment–Elevation Myocardial Infarction Patients With Timely Access to Primary Percutaneous Coronary Intervention*. (2006) Available online at: http://circ.ahajournals.org/cgi/content/full/113/17/2152 (last viewed March 22, 2009).
[17] *Ibid.*
[18] Circulation. *A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 1999 Guidelines for the Management of Patients with Acute Myocardial Infarction)*. (2004;110).



ACC/AHA Joint Guidelines: Transportation of STEMI patient

Recently, a study was released in the Annuals of Emergency Medicine that looked at the practice of bypassing the nearest community hospital for STEMI patients in favor of a more distant specialty center able that is a PCI capable facility.[19] The study tried to determine whether EMS transport of out-of-hospital STEMI patients directly to more distant specialty PCI centers will alter 30-day survival compared with transport to the nearest community hospital fibrinolytic therapy. The findings in the study determined that in select out-of-hospital STEMI care scenarios, EMS transport of acute STEMI patients directly to PCI centers may offer small but uncertain survival benefits over going to the nearest community hospital for fibrinolytic therapy.[20]

The American College of Cardiology National Cardiovascular Data Registry is a set of trademarked registries established by the American College of Cardiology Foundation to assist providers in measuring the quality of cardiovascular care. The registry is accessible through certified software vendors certified by the registry.[21]

The Effects of the Bill

The bill creates two new unnumbered sections of law. The bill states legislative findings that rapid identification and treatment of serious heart attacks, known as a STEMI, can significantly improve outcomes by reducing death and disability by rapidly restoring blood flow to the heart. Additionally, the bill finds that a strong emergency system that supports the survival from life-threatening heart attacks is needed in this state in order to treat victims in a timely manner, improve outcomes and the overall care of the heart attack victims.

The bill requires all hospitals licensed under chapter 395, F.S., to participate in the coordination of a local STEMI system of care. The bill defines a "STEMI system of care" as a local agreement between EMS providers and local hospitals to deliver patients that are identified as having a STEMI to an appropriate medical facility. The bill states that the participants in the STEMI system of care should include but not be limited to: hospitals, primary PCI centers with or without open-heart centers onsite, facilities designated as chest pain centers and hospitals not equipped to provide services related to PCI. The bill defines a PCI center as a provider of adult interventional cardiology services licensed by the agency under s. 408.0361, F.S.

[19] Annuals of Emergency Medicine. *Direct paramedic transport of acute myocardial patients to percutaneous coronary intervention centers: a decision analysis.* (Feb 2009). Available online at: http://www.ncbi.nlm.nih.gov/pubmed/18801596 (last viewed March 22, 2009).
[20] *Ibid.*
[21] *See*, National Cardiovascular Data Registry http://www.ncdr.com/WebNCDR/COMMON/DEFAULT.ASPX.

The bill requires each hospital that is part of the STEMI system of care to submit detailed documentation of the patient care process for all STEMI patients to the American College of Cardiology-National Cardiovascular Data Registry in accordance with the timetables, procedures, data elements, definitions, and transmission format established by the registry. The bill specifies that the hospital reports must include, at a minimum: door to reperfusion time, door to cardiac cauterization laboratory time, emergency department arrival time, and emergency department exit time. The bill requires hospitals to provide a copy of the reporting data to the EMS medical directors for each suspected STEMI patient treated by their respective EMS teams, and permits the medical directors to access the American College of Cardiology National Cardiovascular Data Registry within 30 days of patient discharge for the exclusive purpose of determining quality improvement of the entire STEMI system.

The bill requires the Department of Health ("department") to develop a sample assessment criteria relating to cardiac triage. The sample must be posted in the departments' website and a copy must be provided to each licensed EMS provider licensed under chapter 401, F.S., by July 1, 2010. The department is required to base the sample assessment criteria on the most recent version of the advanced cardiovascular life support chest pain algorithm that uses evidence-based guidelines such as those developed by the American Heart Association or a substantially similar program. In addition, the bill requires each licensed EMS provider to submit their existing cardiac triage protocols or to develop an assessment criteria relating to cardiac triage that specifically addresses transportation and treatment plans for acute STEMI patients.

The bill requires the medical director for each licensed EMS provider to submit, implement and employ either an existing protocol or develop a new protocol for the assessment, treatment, and transportation of cardiac patients having a STEMI to the most appropriate hospital. However, the bill requires that the medical directors of EMS providers must determine the most appropriate transport destination for suspected STEMI patients. The bill requires that the protocols incorporate the 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. In addition, the community plan must also address a data-sharing agreement between hospitals and EMS.

The bill requires the department to develop and provide technical support, equipment recommendations, and necessary training recommendations to EMS providers and EMS medical directors for the effective identification of patients who are having an acute STEMI. The department is also required to conduct a biannual survey of all applicable licensed EMS providers to develop an inventory of their equipment that will be used to assist in identifying their equipment needs, training requirements, and performance regarding the practical application of protocols and the identification of acute STEMI in the field. The bill requires that a copy of the survey findings be provided to EMS providers, the medical directors of EMS providers, the Emergency Medical Services Advisory Council and other stakeholders.

The bill requires the department to assist in identifying and providing all licensed EMS providers with opportunities, partnerships, and resources for securing appropriate equipment for identifying STEMI in the field. The sources may include the Emergency Medical Services Grant fund pursuant to ss. 401.101-401.121, F.S. The expected June 30, 2009, the cash balance of the EMS Trust Fund is $485,000.

The bill encourages local STEMI systems to meet semi-annually, following the implementation of the assessment criteria, to assess quality improvement measures. The bill requires the department to convene stakeholders at least once a year, if necessary, to facilitate the sharing of experiences and best practices. The stakeholder meetings may take place at the one of the annual EMS meetings, via teleconference, web conference or other methods appropriate to distribute and share information. The bill requires the department to post best practices shared at the annual meeting on its website.

The bill authorizes the department to adopt rules necessary to administer the provisions of the bill related to EMS providers. The bill authorizes the department and the Agency for Health Care Administration to adopt rules to implement the provisions of the bill related to data sharing.

The bill requires that all EMS providers licensed under chapter 401, F.S. must comply with the provisions in the bill by July 1, 2010.

The bill provides an effective date of July 1, 2009.

B. SECTION DIRECTORY:

Section 1. Creates s. 395.1042, F.S., relating to emergency medical services providers and cardiac assessment criteria and protocols.

Section 2. Provides an effective date of July 1, 2009.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The fiscal impact to the department:

Training & Technical Support
According to the department, the technical support and training that must be provided to the 266 licensed EMS provider agencies and directors is projected to cost $70,000. The extent of the technical support is difficult to quantify at this time. However, the cost of training can be estimated from previous training efforts provided by DOH. A course for Ambulance Strike Team training cost approximately $10,000 per course with an unlimited number of participants. The training was provided in a train-the-trainer format, which the department has deemed the most efficient use of funds. There is an undetermined turnover rate among licensed EMS providers, therefore, it is anticipated that this training would need to be completed on a biennial basis.

Program Evaluation
According to the department, staff time will be required to determine what programs were substantially similar to the chest pain algorithm for pre-hospital assessment, triage, and treatment of patients with suspected STEMI.

Estimated Expenditures	**1st Year**	**2nd Year** (Annualized/Recurr.)
Other Personal Services		
Biennial Training Cost	$70,000	
Total Estimated Expenditures to the Emergency Medical Services Trust Fund:	$70,000	

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

Local governments may have to support the purchase of a 12-lead EKG machine for each ambulance or emergency response vehicle.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The provisions in the bill would, in effect, require all EMS providers to have a 12-lead EKG/ECG machine aboard all ambulances or emergency response vehicles. A 12-lead EKG is supposed to be the best instrument to use in the detection of a STEMI event. Not all ambulances currently utilize a 12-lead EKG. A broadband all-digital system such as the LIFEPAK 12 defibrillator or monitor enables paramedics to transmit 12-lead ECGs in the field to a secure web-based system. The system relays the information securely via the Internet to hospital care teams and catheterization labs, or directly to a cardiologist's handheld device.[22] The LIFEPAK 12 defibrillator/monitor series from Medtronic Physio-Co can range from $7,500 to $13,495.[23]

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to: require the counties or cities to spend funds or take an action requiring the expenditure of funds; reduce the authority that cities or counties have to raise revenues in the aggregate; or reduce the percentage of a state tax shared with cities or counties.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill authorizes the Department of Health to adopt rules necessary to administer the provisions of the bill related to EMS providers. The bill authorizes the department and the Agency for Health Care Administration to adopt rules to implement the provisions of the bill related to data sharing.

C. DRAFTING ISSUES OR OTHER COMMENTS:

There are emergency service providers that only provide inter-facility transfers and do not perform emergency services. It may be advantageous to provide an exemption for providers that do not perform emergency services.

The bill requires all licensed EMS providers to have a 12-lead EKG or STEMI equipment aboard all ambulances or emergency response vehicles. Current law[24] requires that each licensed hospital with an emergency department have a two-way radio that is capable interfacing with designated municipal aid channels and communicating with all ground basic life support service vehicles, advanced life support service vehicles, and rotorcraft air ambulances that operate within the hospitals service area under state permit. It is not clear how a web-based system would transmit the EKG in transport to the hospitals and it is not known whether most EMS providers have a cell phone or computer with blue tooth technology available, especially in the rural areas of the state.

---

[22] Pre-hospital 12-Lead ECGs Help Reduce EMS-to-Balloon Times. Available online at: www.monoc.org/admin/docs/news/general/Physio-Control%20STEMI%20Case%20Study% *(last viewed March 21, 2009).*

[23] Dixie Medical Equipment, Lifepak 12 Biphasic defibrillator/monitor. Available online at: http://www.dixiemed.com/proddetail.php?prod=LP123BiPA&_s_ref=G56mfU0dS&kw="lifepak%2012"&creative=2989213848&gclid=CKejy-WauZkCFRBhnAodf2Bv_g (last viewed March 22, 2009).

[24] Section 395.1031, F.S.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

On March 25, 2009, the Health Regulation Policy Committee adopted a strike-all amendment and reported the fill favorably as a committee substitute. The amendment:

- Provides legislative findings;
- Requires hospitals to participate in the coordination of a local STEMI system of care;
- Requires hospitals to submit certain documentation to the National Cardiovascular Data Registry, and provide copies to EMS medical directors;
- Permits EMS medical directors to access the National Cardiovascular Data Registry for a certain purpose;
- Requires the department to deelop sample assessment criteria for cardiac triage, to post it on the department website and proide copies to EMS providers;
- Requires EMS medical directors to implement a protocol for the assessment, treatment and transportation of certain cardiac patients to the most appropriate hospital, and requires the protocols to include the use of a community plan and data-sharing with hospitals;
- Requires the department to provide technical support and recommendations for equipment and training to EMS providers;
- Requires the department to biennially survey all EMS providers to identify their equipment and training needs, and performance, and provide copies of the survey findings to certain parties;
- Requires the department to provide EMS providers with opportunities, partnerships and resources for securing appropriate equipment;
- Encourages local STEMI systems to meet semi-annually;
- Requires the department to convene an annual meeting of local STEMI system stakeholders for certain purposes, as necessary, and requires the department to post best practices shared at those meetings on its website; and
- Authorizes rulemaking for the department and the Agency for Health Care Administration.

The analysis is drafted to the committee substitute.