HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1033 Emergency Cardiology Services
SPONSOR(S): Renuart and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1938

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee		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 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. This bill establishes a system of care requiring emergency medical service providers to deliver individuals experiencing cardiac emergencies to appropriate medical facilities that are certified by the Agency for Health Care Administration as a percutaneous coronary intervention center (“PCI center”). The proposed statutory placement of these provisions is in Part I, Chapter 395, Florida Statutes (F.S.), the part that governs hospital licensure.

The bill will have a significant negative fiscal impact on the Emergency Medical Services Trust Fund within the Department of Health of approximately of $119,000 to $198,000 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]

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[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.

- Florida Hospital Association,
- 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 mandate 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.

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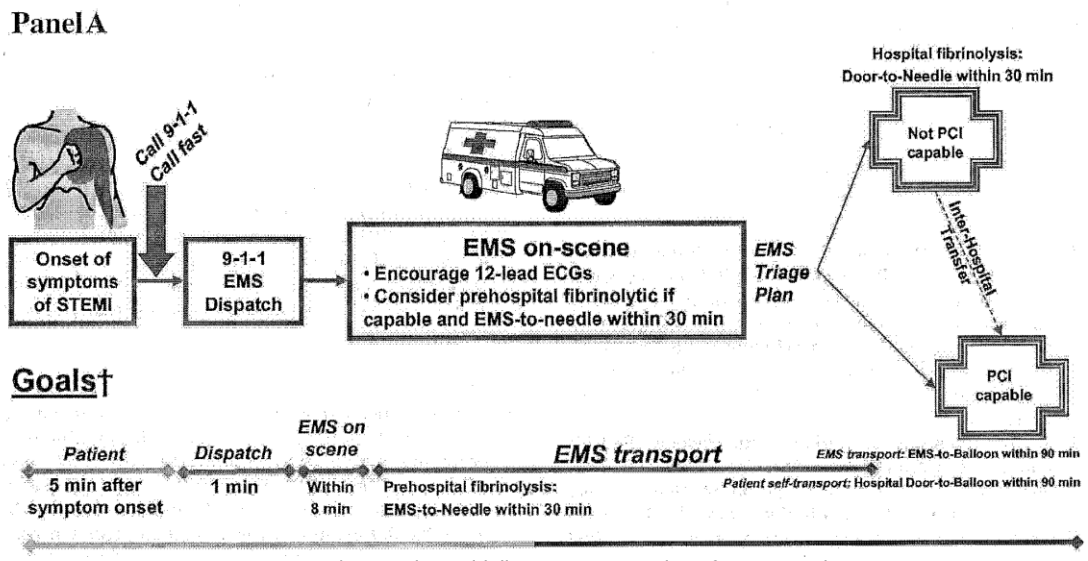
[11] Section 408.0361(5)(a), F.S.
[12] *Ibid.*
[13] Agency for Health Care Administration Bill Analysis and Economic Impact Statement for HB 1033 (2009) and 59A-3.2085, F.A.C
[14] American Heart Association, Mission: Lifeline. Available online at: http://www.americanheart.org/presenter.jhtml?identifier=3050213 (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 percutaneous coronary intervention 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 percutaneous coronary intervention centers may offer small but uncertain survival benefits over nearest community hospital fibrinolytic therapy.[20]

The Effects of the Bill

The bill creates a new section of law that provides cardiac assessment criteria and treatment protocols for emergency medical services providers in the state. The bill requires the agency to certify percutaneous coronary intervention centers ("PCI center"). According to the bill, a PCI center is a licensed provider of adult interventional cardiology services as provided in s. 408.0361, F.S. Currently, the agency licenses PCI centers as either a Level I or Level II adult cardiovascular service provider. Since, the agency already licenses hospitals according to the level of PCI services they may provide (Level I or Level I facilities), it is unclear what additional certification of "PCI centers" would add to the current regulatory scheme.

The bill requires the agency to direct all licensed hospitals under chapter 395, F.S., to participate in the coordination of local STEMI systems of care. However, the bill does not provide any enforcement authority to the agency. According to the bill, entities in the STEMI systems of care, include but are not limited to: hospitals with or without open-heart surgery programs on site; stand-alone PCI centers; and hospitals that are not equipped with PCI centers. The bill mentions "stand-alone PCI centers" but this facility may conflict with the definition of a licensed level I or Level II adult cardiovascular services program in part because the facility may not be located in a hospital. According to the bill, each hospital that is part of the STEMI system of care is required to provide detailed documentation of the patient care process, to include, the length of time each step of the patient care process. Additionally, the bill requires the hospital to provide the documentation to the emergency medical services (EMS) director for the purpose of quality improvement.

[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.*

The bill states that by June 1, 2010, or 6 months after the agency adopts a rule governing the certification of PCI centers, whichever is later, the Department of Health ("department") is required to send a list of each PCI center and its address to each licensed emergency medical services provider[21] and director in the state. However, the bill also requires the agency to post a list of the licensed PCI centers on its internet website by December 1, 2009. It is unclear why both the agency and the department need to provide lists and the timelines appear to conflict. Both the agency and the department are required to either post or send the lists by June 1 annually thereafter.

The bill requires the department to develop sample cardiac triage assessment criteria. The criteria must be posted on the departments' internet website and a copy of the criteria must be provided to each licensed EMS provider and EMS director no later than July 10, 2010. The bill requires every EMS provider licensed under chapter 401, F.S., to comply with the provisions of the bill by July 1, 2010 or 6 months after it receives the list of certified PCI centers, whichever is later. Depending upon when the list of certified PCI centers is posted, there may be a problem with the time period between the creation of the criteria and implementation. If the criteria is posted on the departments' internet website on July 10 , 2010, then EMS providers may not have sufficient time to implement the protocol. Moreover, the bill encourages each licensed EMS provider to use the cardiac triage assessment criteria provided by the department or one that is substantially similar.

The bill requires each medical director of a licensed EMS provider to develop and implement assessment, treatment, and transportation protocols for cardiac patients. The protocols must be employed to assess, treat, and transport STEMI patients to the most appropriate hospital. In addition the protocols must include the use of a community plan to address transport of cardiac patients to an appropriate facility in a manner that addresses community-specific resources and needs. The bill does not reference the use of the American College of Cardiology and the American Heart Association adopted joint guidelines as a basis for the development or implementation of protocols for cardiac patients.

The bill requires the department to develop and provide technical support, equipment recommendations, and necessary training for the effective identification of acute STEMI for each licensed EMS provider and emergency medical services director. The department is required to use the American Heart Association's advanced cardiac life support chest pain algorithm, a substantially similar program, or a program with evidence-based guidelines as a model. Furthermore, the bill requires the department to conduct a biannual survey to develop an equipment inventory, equipment standards, training requirements, and performance standards in applying the protocols for all licensed EMS providers in the state. A report of the survey findings must be provided to all EMS providers, EMS directors, the Emergency Medical Services Advisory Council, and other stakeholders. It is unclear how the information collected in the survey will be used by the department or stakeholders and many years the survey should be conducted.

The bill encourages the department to help identify and provide opportunities, partnerships, and resources for licensed EMS providers to secure appropriate STEMI equipment. Furthermore, the bill provides that the department may annually convene stakeholders to facilitate the sharing of experiences and best practices following the implementation of the assessment criteria. The bill requires the department to post best practices on their website.

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.

[21] Emergency medical services providers are regulated under part III of chapter 401, F.S.

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.

   Inventory of Equipment
   Staff time will also be required to administer a biennial survey of the 266 licensed EMS provider agencies to develop an inventory of their equipment, identify their equipment needs, training requirements, and performance regarding the practical application of protocols and the identification of acute STEMI in the field.

   Annual Meeting
   A recent cost analysis of other annual meeting revealed an average cost of $21,274 per meeting. The cost includes meeting space rental at a central location and travel reimbursement for approximately 25 stakeholders and DOH staff. Using this rationale, the department could incur an annual cost of $21,273.23 per year to convene a stakeholder meeting. This estimate does not include staff preparation time for the stakeholder meetings.

   Website
   The department, Bureau of EMS, currently has a Emergency Medical Services for Children program. The duties of this program are to improve statewide communication and education by regularly updating a website, strengthening partnerships with other state agencies, conducting surveys, and managing stakeholders, organizations and consumer groups regarding children affected by emergencies. The program has 1 FTE-Community/Social Services Specialist. Using this rationale, the addition of 1 FTE is provided. The Community Planner for Children Program often finds it necessary to use administrative support staff from other sections to meet deadlines, process surveys, and collaborate with stakeholders. An Administrative Assistant 1 is provided to increased workload that is required.

Estimated Expenditures	1st Year	2nd Year (Annualized/Recurr.)
Salaries		
1.0 FTE – Community Planner, Pay Grade 22 (Annual salary $36, 468 w/ 29% fringe)	$47,044	$47,044
1.0 FTE – Administrative Assistant I, Pay Grade 15 (Annual salary $25,479 w/ 29% fringe)	$32,868	$32,868
Other Personal Services		
Biennial Training Cost	$70,000	
Expense		
Stakeholder meeting cost	$21,273	$21,273
Standard Expense Package with Limited Travel – 1.0 FTE	$15,680	$12,268
Standard Expense Package - 1.0 FTE	$8,397	$5,426
Operating Capital Outlay		
2.0 FTE Operating Capital Outlay *(OCO) Package*	$2,000	
Human Resources	*$801*	*$801*
Total Estimated Expenditures to the Emergency Medical Services Trust Fund:	$198,063	$119,680

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.

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 suppose 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:

The agency currently provides a list of PCI centers to emergency medical providers and currently posted on the Agency website. According to the agency, EMS providers currently use the information on the website in developing their protocols for determining appropriate medical facilities. The fiscal impact to the agency would be insignificant since most of the activity required in the bill is already taking place under existing regulatory requirements.

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 provides sufficient rule making authority to the agency to adopt rules for governing the certification of PCI centers. The department has sufficient rule making authority in s. 401.35, F.S.

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 does not include a sanction for hospitals that do not participate in the coordination of local STEMI systems of care. The bill identifies the participants in a STEMI system to include hospitals with PCI centers, hospitals without PCI centers and "stand-alone PCI centers". The term "stand-alone PCI centers" is not identified elsewhere in the bill, and would not meet the definition of a PCI center if not a hospital with a licensed Level I or Level II adult cardiovascular services program.
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.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

[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.