# Volume 37, Number 24 Pages 2093-2294 December 17, 2012 Part II

# SALUS POPULI SUPREMA LEX ESTO

"The welfare of the people shall be the supreme law."



# ROBIN CARNAHAN

SECRETARY OF STATE

MISSOURI

REGISTER



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# SECRETARY OF STATE

# **ROBIN CARNAHAN**

Administrative Rules Division James C. Kirkpatrick State Information Center 600 W. Main Jefferson City, MO 65101 (573) 751-4015

> DIRECTOR WAYLENE W. HILES

> > **EDITORS**

CURTIS W. TREAT

SALLY L. REID

Associate Editor Delane Jacquin

PUBLICATION TECHNICIAN JACQUELINE D. WHITE

> • Specialist

MICHAEL C. RISBERG

# Administrative Assistant

# Alisha Dudenhoeffer

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# Missouri



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December 17, 2012

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Vol. 37 No. 24 Pages 1885-2346

# IN THIS ISSUE:

# PART I

# **PROPOSED RULES**

Department of Health and Senior Services Division of Regulation and Licensure	.1889
PART II Department of Health and Senior Services	

Division of Regulation and Licensure	.2097
Department of Insurance, Financial Institutions and	
Professional Registration	
State Board of Pharmacy	.2286
•	

# PART III

Department of Insurance, Professional Registration	Financial Institutions and
Real Estate Appraisers	

# **ORDERS OF RULEMAKING**

Department of Agriculture	
State Milk Board	2320
Weights and Measures	2322
Department of Social Services	
MO HealthNet Division	2324

Department of Insurance, Financial Institutions and	
Professional Registration	
Missouri State Board of Accountancy	
Missouri Board for Architects, Professional Engineers,	
Professional Land Surveyors, and Landscape Architects2325	
Division of Professional Registration	
Missouri Real Estate Commission	
CONTRACTOR DEBARMENT LIST	
DISSOLUTIONS	
SOURCE GUIDES	
<b>RULE CHANGES SINCE UPDATE</b>	
EMERGENCY RULES IN EFFECT	
<b>EXECUTIVE ORDERS</b>	

Register	Register	Code	Code
Filing Deadlines	Publication Date	Publication Date	Effective Date
August 1, 2012	September 4, 2012	September 30, 2012	October 30, 2012
August 15, 2012	September 17, 2012	September 30, 2012	October 30, 2012
September 4, 2012	October 1, 2012	October 31, 2012	November 30, 2012
September 17, 2012	October 15, 2012	October 31, 2012	November 30, 2012
October 1, 2012	November 1, 2012	November 30, 2012	December 30, 2012
October 15, 2012	November 15, 2012	November 30, 2012	December 30, 2012
November 1, 2012	December 3, 2012	December 31, 2012	January 30, 2013
November 15, 2012	December 17, 2012	December 31, 2012	January 30, 2013
December 3, 2012	January 2, 2013	January 29, 2013	February 28, 2013
December 17, 2012	January 15, 2013	January 29, 2013	February 28, 2013
January 2, 2013	February 1, 2013	February 28, 2013	March 30, 2013
January 15, 2013	February 15, 2013	February 28, 2013	March 30, 2013
February 1, 2013	March 1, 2013	March 31, 2013	April 30, 2013
February 15, 2013	March 15, 2013	March 31, 2013	April 30, 2013
March 1, 2013	April 1, 2013	April 30, 2013	May 30, 2013
March 15, 2013	April 15, 2013	April 30, 2013	May 30, 2013
April 1, 2013	May 1, 2013	May 31, 2013	June 30, 2013
April 15, 2013	May 15, 2013	May 31, 2013	June 30, 2013
May 1, 2013	June 3, 2013	June 30, 2013	July 30, 2013
May 15, 2013	June 17, 2013	June 30, 2013	July 30, 2013

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The rules are codified in the <i>Code of State Regulations</i> in this system—				
Title	Code of State Regulations	Division	Chapter	Rule
1	CSR	10-	1.	010
Department		Agency, Division	General area regulated	Specific area regulated

They are properly cited by using the full citation, i.e., 1 CSR 10-1.010.

Each department of state government is assigned a title. Each agency or division within the department is assigned a division number. The agency then groups its rules into general subject matter areas called chapters and specific areas called rules. Within a rule, the first breakdown is called a section and is designated as (1). Subsection is (A) with further breakdown into paragraph 1., subparagraph A., part (I), subpart (a), item I. and subitem a.

RSMo-The most recent version of the statute containing the section number and the date.

## Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES Division 30—Division of Regulation and Licensure Chapter 40—Comprehensive Emergency Medical Services Systems Regulations

## **PROPOSED RULE**

#### **19** CSR **30-40.760** Standards for ST-Segment Elevation Myocardial Infarction (STEMI) Center Designation

PURPOSE: This rule establishes standards for level I, II, III, and IV STEMI center designation.

#### AGENCY NOTE:

*I-R, II-R, III-R, or IV-R after a standard indicates a requirement for level I, II, III, or IV STEMI centers respectively.* 

I-IH, II-IH, III-IH, or IV-IH after a standard indicates an in-house requirement for level I, II, III, or IV STEMI centers respectively. I-IA, II-IA, III-IA, or IV-IA indicates an immediately available requirement for level I, II, III, or IV STEMI centers respectively. I-PA, II-PA, III-PA, or IV-PA indicates a promptly available requirement for level I, II, III, or IV STEMI centers respectively.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome and expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) General Standards for STEMI Center Designation.

(A) The STEMI center board of directors, administration, medical staff, and nursing staff shall demonstrate a commitment to quality STEMI care. Methods of demonstrating the commitment shall include, but not be limited to, a board resolution that the hospital governing body agrees to establish policy and procedures for the maintenance of services essential for a STEMI center; assure that all STEMI patients will receive medical care at the level of the hospital's designation; commit the institution's financial, human, and physical resources as needed for the STEMI program; and establish a priority admission for the STEMI patient to the full services of the institution. (I-R, II-R, III-R, IV-R)

(B) STEMI centers shall agree to accept all STEMI patients appropriate for the level of care provided at the hospital, regardless of race, sex, creed, or ability to pay. (I-R, II-R, III-R, IV-R)

(C) The STEMI center shall demonstrate evidence of a STEMI program. The STEMI program shall be available twenty-four (24) hours a day, seven (7) days a week to treat and evaluate STEMI patients. (I-R, II-R, III-R, IV-R)

1. The STEMI center shall maintain a STEMI team that at a minimum consists of—

A. A core team which provides administrative oversight and includes the following:

(I) A physician experienced in diagnosing and treating cardiovascular disease and STEMI (usually the STEMI medical director); and (I-R, II-R, III-R, IV-R)

(II) At least one (1) other health care professional or qualified individual credentialed in STEMI care (usually the STEMI program manager/coordinator); (I-R, II-R, III-R, IV-R)

B. A STEMI call roster that provides twenty-four (24) hours a day, seven (7) days a week cardiology service coverage. The call roster identifies the physicians or qualified individuals on the schedule that are available to manage and coordinate emergent, urgent, and routine assessment, diagnosis, and treatment of the STEMI patients. A level I and level II STEMI call roster shall include, but not be limited to, the emergency department physician, interventional cardiologist, and others as appropriate. The level III STEMI center call roster shall include, but not be limited to, the emergency department physician and others as appropriate. A level IV STEMI center call roster shall include, but not be limited to, the emergency department physician and other qualified individuals as appropriate. (I-R, II-R, III-R, IV-R)

(I) Level I and II STEMI centers shall have this coverage promptly available from notification of STEMI patients. (I-R, II-R)

(II) Level III and IV STEMI centers shall have a regional networking agreement with a level I or level II STEMI center for telephone consult or telemedicine consultation promptly available from notification of STEMI patients; and (I-R, II-R, III-R, IV-R)

C. A clinical team appropriate to the center level designation that may include, but not be limited to, cardiologists, interventional cardiologists, clinical perfusionists, members of the STEMI call roster, members of the cardiac catheterization team, cardiothoracic surgeons, anesthesiologists, emergency department physicians, intensivists, and other STEMI center clinical staff as applicable. (I-R, II-R, III-R, IV-R)

2. The STEMI center shall have a peer review system to review STEMI cases respective of the STEMI center's designation. (I-R, II-R, III-R, IV-R)

3. The STEMI team shall have appropriate experience to maintain skill and proficiency to care for STEMI patients. The STEMI center shall maintain evidence that it meets the following requirements by documenting the following:

A. A list of all STEMI team members; (I-R, II-R, III-R, IV-R)

B. Position qualifications and completion of continuing education requirements by STEMI team members as set forth in sections (1), (2), and (4) of this rule; (I-R, II-R, III-R, IV-R)

C. Management of sufficient numbers of STEMI patients by the STEMI team members in order to maintain their STEMI skills; (I-R, II-R, III-R, IV-R)

D. Participation by the core team and members of the STEMI call roster in at least half of the regular, ongoing STEMI program peer review system meetings as shown in meeting attendance documents. The STEMI medical director shall disseminate the information and findings from the peer review system meetings to the STEMI call roster members and the core team and document such dissemination; (I-R, II-R, IV-R)

E. Participation by STEMI team members in at least half of the regular ongoing STEMI program performance improvement and patient safety meetings and documentation of such attendance in the meeting minutes and/or meeting attendance documents. The STEMI medical director shall disseminate the information and findings from the performance improvement and patient safety meetings to the STEMI team members and document such dissemination. If a STEMI team member is unable to attend a STEMI program performance improvement and patient safety meeting, then the STEMI team member shall send an appropriate representative in his/her place; (I-R, II-R, III-R, IV-R)

F. Maintenance of skill levels in the management of STEMI patients by the STEMI team members as required by the STEMI center and the STEMI medical director and documentation of such continued experience; and (I-R, II-R, III-R, IV-R)

G. Review of regional outcome data on the quality of patient care by STEMI team members as part of the STEMI center's performance improvement and patient safety process. (I-R, II-R, III-R, IV-R)

4. The STEMI center shall maintain a multidisciplinary team, in addition to the STEMI team, to support the care of STEMI patients. (I-R, II-R, IV-R)

A. The multidisciplinary team shall include a suitable representative from hospital units as appropriate for care of each STEMI patient. The units represented on the multidisciplinary team may include, but not be limited to: administration, emergency medical services, intensive care unit, cardiac catheterization lab, pharmacy, laboratory, intermediate care unit, cardiac rehabilitation, and discharge planning. (I-R, II-R, III-R, IV-R)

B. The multidisciplinary team members or their representatives shall attend at least half of the STEMI program performance improvement and patient safety meetings which shall be documented in meeting minutes and/or meeting attendance documents. (I-R, II-R, III-R, IV-R)

(D) The STEMI center shall provide the services of a cardiac catheterization laboratory staffed twenty-four (24) hours a day, seven (7) days a week. The staff of the cardiac catheterization laboratory, referred to as the cardiac catheterization laboratory team, shall consist of at least the following:

1. An interventional cardiologist. The STEMI center credentialing committee shall document that the interventional cardiologist has completed appropriate training and conducted sufficient coronary interventional procedures. In addition, the interventional cardiologist shall annually conduct a sufficient number of percutaneous coronary interventions (PCIs). It is recommended that interventional cardiologist(s) perform seventy-five (75) or more elective percutaneous coronary interventions per interventional cardiologist per year and eleven (11) or more primary percutaneous coronary interventions per interventional cardiologist per year; and (I-R/PA, II-R/PA)

2. Other health care professional as deemed necessary. (I-R/PA, II-R/PA)  $\,$ 

(E) A level I STEMI center shall meet the following criteria:

1. It is recommended that the cardiac catheterization laboratory perform—

A. At least an average of four hundred (400) or more elective percutaneous coronary interventions per year over three (3) consecutive preceding years per STEMI center; and

B. At least an average of forty-nine (49) or more primary percutaneous coronary interventions per year over three (3) consecutive preceding years per STEMI center; and

2. On-site emergency cardiothoracic surgical services as needed twenty-four (24) hours a day, seven (7) days a week. (I-R/PA)

(F) A level II STEMI center shall meet one (1) of the two (2) options outlined below to qualify for a level II STEMI center designation—

1. Option one-

A. It is recommended that the cardiac catheterization laboratory perform—

(I) An average of two hundred (200) or more elective percutaneous coronary interventions per year over three (3) consecutive preceding years per STEMI center; and

(II) An average of thirty-six (36) or more primary percutaneous coronary interventions per year over three (3) consecutive preceding years per STEMI center; and

B. On-site emergency cardiothoracic surgical services or have a written plan that has been shown to be effective, a transfer agreement, and expedited transfer process for cardiothoracic surgery back-up in a nearby STEMI center with appropriate hemodynamic support capability for transfer. The written plan shall ensure that once a potential need for cardiothoracic intervention is identified, the STEMI patient can be evaluated by cardiothoracic surgery and in the operating room (OR) of the receiving hospital as expeditiously as possible; or (II-R)

2. Option two is a level II STEMI center that performs less than a recommended average of two hundred (200) elective percutaneous coronary interventions per year and a recommended average of thirty-six (36) or more primary percutaneous coronary interventions per year over three (3) consecutive preceding years or a recommended average of two hundred (200) elective percutaneous coronary interventions per year or more and less than a recommended average of thirty-six (36) primary percutaneous coronary interventions per year over three (3) consecutive preceding years. The following requirements for option two shall be met to qualify for a level II center designation:

A. If a STEMI center performs less than an annual recommended average of thirty-six (36) primary percutaneous coronary interventions over three (3) consecutive preceding years, it is recommended that the STEMI center perform an annual average of two hundred (200) or more elective percutaneous coronary interventions over three (3) consecutive preceding years, and it is recommended that all operators shall perform seventy-five (75) or more elective percutaneous coronary interventions and eleven (11) or more primary percutaneous coronary interventions per year. If an operator does not perform a recommended eleven (11) or more primary percutaneous coronary interventions per year, he or she shall have a mentoring relationship defined by written agreement with a highly experienced operator. This mentor may be a member of the same institution or belong to another institution. This relationship, established by a written agreement, may include, but not be limited to, on-site supervision and observation of performance during primary and elective percutaneous coronary interventions per year, review of mentee's patient encounters, review of mentee's outcomes, evaluation of mentee and hospital's process pertaining to elective and primary percutaneous coronary interventions, and guidance on methods to improve process, performance, and outcomes; or

B. If a STEMI center performs less than an annual recommended average of two hundred (200) elective percutaneous coronary interventions over three (3) consecutive preceding years, it is recommended that the STEMI center perform an annual average of thirtysix (36) primary percutaneous coronary interventions over three (3) consecutive preceding years, and it is recommended that all operators perform seventy-five (75) or more elective percutaneous coronary interventions and eleven (11) or more primary percutaneous coronary interventions per year or have a mentoring relationship defined by a written agreement with a highly experienced operator. This mentor may be a member of the same institution or belong to another institution. This relationship, established by a written agreement, may include, but not be limited to, on-site supervision and observation of performance during primary and elective percutaneous coronary interventions, review of mentee's patient encounters, review of mentee's outcomes, evaluation of mentee and hospital's process pertaining to elective and primary percutaneous coronary interventions, and guidance on methods to improve process, performance, and outcomes; and

C. Be able to provide on-site emergency cardiothoracic surgical services or have a written plan that has been shown to be effective, a transfer agreement, and expedited transfer process for cardiothoracic surgery back-up in a nearby STEMI center with appropriate hemodynamic support capability for transfer. The written plan shall ensure that once a potential need for cardiothoracic intervention is identified, the STEMI patient can be evaluated by cardiothoracic surgery and in the operating room of the receiving hospital as expeditiously as possible; and (II-R)

D. Provide cardiac intensive care capability; and (II-R)

E. Provide evidence of a written plan shown to be effective, a transfer agreement, and expedited transfer process for STEMI patients to higher level care in a nearby STEMI center with appropriate hemodynamic support capability for transfer; and (II-R)

F. The STEMI center shall collect, document, maintain for at least five (5) years and make available for review by the department the following:

(I) The STEMI center's average time from the STEMI center door to percutaneous coronary interventions device inflation time (i.e., door-to-balloon (D2B) times) is no more than ninety (90) minutes at least seventy-five percent (75%) of the time; and (II-R)

(II) The STEMI center tracks and compares the time from the first medical contact to balloon times; and (II-R)

G. The STEMI center shall document that it collects and trends its past and current risk-adjusted outcome and process measures. (II-R)

(G) The STEMI center shall appoint a physician to serve as the STEMI medical director with appropriate qualifications, experience,

and training. A STEMI medical director shall be appointed at all times with no lapses. (I-R, II-R, III-R, IV-R)

1. Level I and II STEMI center medical directors shall be cardiologists or interventional cardiologists. It is recommended that the cardiologist or interventional cardiologist be board-certified or board-admissible in interventional cardiology or cardiology. (I-R, II-R)

2. Level III and IV STEMI center medical directors shall be physicians. A board-certified or board-admissible physician is recommended. (III-R, IV-R)

3. The STEMI center shall have a job description and organization chart depicting the relationship between the STEMI medical director and other services. (I-R, II-R, III-R, IV-R)

4. Level I and II STEMI medical directors are recommended to be members of the catheterization lab team call roster. (I-R, II-R)

5. The STEMI medical director shall meet the continuing medical education (CME) requirements as described in section (4) of this rule. (I-R, II-R, III-R, IV-R)

6. The STEMI medical director shall be responsible for oversight of the education and training of the medical and clinical staff in STEMI care. This includes a review of the appropriateness of the education and training for the practitioner's level of responsibility. (I-R, II-R, III-R, IV-R)

7. Level I STEMI medical directors shall participate in the STEMI center's research and publication projects. (I-R)

(H) The STEMI center shall have a STEMI program coordinator/manager who is a registered nurse, other clinical staff, or qualified individual. The STEMI center shall have a STEMI program coordinator/manager at all times with no lapses. (I-R, II-R, III-R, IV-R)

1. The STEMI center shall have a job description and organization chart depicting the relationship between the STEMI program coordinator/manager and other services. (I-R, II-R, III-R, IV-R)

2. The STEMI coordinator/manager shall meet continuing education requirements as described in section (4) of this rule. (I-R, II-R, III-R, IV-R)

3. The STEMI program coordinator/manager shall participate in the formal STEMI center performance improvement and patient safety program. (I-R, II-R, III-R, IV-R)

(I) The STEMI center shall document a plan for and utilization of a specific and well-organized system as appropriate to center level designation for the emergency department to rapidly notify and activate the STEMI team or STEMI/cardiac catheterization lab team at the time the emergency department identifies STEMI on electrocardiogram (ECG) or verifies emergency medical services (EMS) STEMI electrocardiogram identification. (I-R, II-R, III-R, IV-R)

(J) The STEMI center shall have a protocol detailing a one- (1-) call cardiac catheterization lab activation by emergency medical services at the time emergency medical services identifies a STEMI patient and as appropriate to the hospital's process. (I-R, II-R)

(K) The STEMI center shall have a one- (1-) call STEMI team activation protocol or a STEMI/cardiac catheterization lab team activation protocol as appropriate for center level designation that establishes the following:

1. The criteria used to triage STEMI patients; (I-R, II-R, III-R, IV-R)

2. The person authorized to notify STEMI team or STEMI team/cardiac catheterization lab team members when a suspected STEMI patient is in route or when a suspected STEMI patient has arrived at the STEMI center; and (I-R, II-R, III-R, IV-R)

3. The method for immediate notification and the response requirements for STEMI team or STEMI/cardiac catheterization lab team members when a suspected STEMI patient is in route to the STEMI center. (I-R, II-R, III-R, IV-R).

(L) All members of the STEMI team or STEMI/cardiac catheterization lab team call roster shall comply with the availability and response requirements. If not on STEMI center premises, then STEMI/cardiac catheterization lab team members who are on call shall carry electronic communication devices at all times to permit contact by the STEMI center and shall be promptly available. (I-R, II-R, III-R, IV-R)

(M) The STEMI centers shall have a fibrinolysis protocol for instances when percutaneous coronary intervention is not achievable within an appropriate designated time frame and for when fibrinolysis is achievable within an appropriate designated time frame. It is recommended that the designated time frame follow nationally acceptable standards, for example as set forth in Appendix A number eight (8) entitled "Time to Fibrinolytic Therapy" included in the article entitled "ACC/AHA Clinical Performance Measures for Adults with ST-Elevation and Non-ST-Elevation Myocardial Infarction: A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures (Writing Committee to Develop Performance Measures on ST-Elevation and Non-ST-Elevation Myocardial Infarction)" as published by the Journal of the American College of Cardiology in 2006, volume 47, pages 236-265 which is incorporated by reference in this rule and is available at the Journal of the American College of Cardiology, Reprint Department Elsevier Inc., 360 Park Avenue South, New York, NY 10010-1710 or on the Journal of the American College of Cardiology website at http://content.onlineJACC.org. This rule does not incorporate any subsequent amendments or additions. (I-R, II-R, III-R, IV-R)

(N) STEMI centers shall have transfer agreements between referring and receiving facilities. (II-R, III-R, IV-R)

1. The STEMI center shall have a one- (1-) call transfer protocol to a level I or level II designated STEMI center that establishes the criteria used to triage STEMI patients and identifies the persons authorized to notify the designated STEMI center. (II-R, III-R, IV-R)

2. The STEMI center shall have a rapid transfer process in place to transport a STEMI patient to a higher level of STEMI care when needed. (II-R, III-R, IV-R)

(O) STEMI centers shall have cardiac rehabilitation services directed by a physician experienced in cardiac rehabilitation. (I-R, II-R)

(P) The STEMI centers shall demonstrate that there is a plan for adequate post-discharge and post-transfer follow-up on STEMI patients, including cardiac rehabilitation and repatriation if indicated. (I-R, II-R, III-R, IV-R)

(Q) The STEMI center shall maintain a STEMI patient log, keep this log for a period of five (5) years, and make this log readily retrievable during a review by the department. This patient log shall include all STEMI patients and shall contain the following information:

1. Response times; (I-R, II-R, III-R, IV-R)

2. Patient diagnosis; (I-R, II-R, III-R, IV-R)

3. Treatment/actions; (I-R, II-R, III-R, IV-R)

4. Outcomes; (I-R, II-R, III-R, IV-R)

5. Number of patients; and (I-R, II-R, III-R, IV-R)

6. Benchmark indicators. (I-R, II-R, III-R, IV-R)

(R) Level I, II, and III STEMI centers shall have a lighted designated helicopter landing area at the STEMI center to accommodate incoming medical helicopters. (I-R, II-R, III-R)

1. The landing area shall serve solely as the receiving and takeoff area for medical helicopters and shall be cordoned off at all times from the general public to assure its continual availability and safe operation. (I-R, II-R, III-R)

2. The landing area shall be on the hospital premises no more than three (3) minutes from the emergency room. (I-R, II-R, III-R)

(S) Level IV STEMI centers shall have a lighted designated helicopter landing area that meets the following requirements:

1. Accommodates incoming medical helicopters; (IV-R)

2. Serves as the receiving and take-off area for medical helicopters; (IV-R)

3. Cordoned off from the general public when in use; (IV-R)

4. Managed to assure its continual availability and safe operation; and (IV-R)

5. It is recommended the landing area shall be no more than three (3) minutes from the emergency department. (IV-R)

(T) STEMI centers shall enter data into the Missouri STEMI registry as follows:

1. All STEMI centers shall submit data into the department's Missouri STEMI registry on each STEMI patient who is admitted to the STEMI center, transferred out of the STEMI center, or dies as a result of the STEMI (independent of hospital admission or hospital transfer status). The data required to be submitted into the Missouri STEMI registry by the STEMI centers is listed and explained in the document entitled "Time Critical Diagnosis ST-Segment Elevation Myocardial Infarction (STEMI) Center Registry Data Elements" dated March 1, 2012, which is incorporated by reference in this rule and is available at the Missouri Department of Health and Senior Services, PO Box 570, Jefferson City, MO 65102-0570 or on the department's website at www.health.mo.gov. This rule does not incorporate any subsequent amendments or additions; (I-R, II-R, III-R, IV-R)

2. The data required in paragraph (1)(T)1. above shall be submitted electronically into the Missouri STEMI registry via the department's website at www.health.mo.gov; (I-R, II-R, III-R, IV-R)

3. This data required in paragraph (1)(T)1. above shall be submitted electronically into the Missouri STEMI registry on at least a quarterly basis for that calendar year. STEMI centers have ninety (90) days after the quarter ends to submit the data electronically into the Missouri STEMI registry; (I-R, II-R, III-R, IV-R)

4. The data submitted by the STEMI centers shall be complete and current; and (I-R, II-R, III-R, IV-R)

5. The data submitted by the STEMI centers shall be managed in compliance with the confidentiality requirements and procedures contained in section 192.067, RSMo. (I-R, II-R, III-R, IV-R)

(U) A STEMI center shall maintain a diversion protocol for the STEMI center that is designed to allow best resource management within a given area. The STEMI center shall create criteria for diversion in this diversion protocol and shall detail a performance improvement and patient safety process in the diversion protocol to review and validate the criteria for diversion created by the STEMI center. The STEMI center shall also collect, document, and maintain diversion information that includes at least the date, length of time, and reason for diversion. This diversion information shall be readily retrievable by the STEMI center during a review by the department and shall be kept by the STEMI center for a period of five (5) years. (I-R, II-R, II-R, IV-R)

(2) Medical Staffing Standards for STEMI Center Designation.

(A) There shall be a delineation of privileges for the cardiologists, cardiothoracic surgeons, and interventional cardiologists made by the medical staff credentialing committee in each STEMI center. (I-R, II-R)

(B) The STEMI center shall credential and have different types of physicians available as listed below—

1. A cardiologist; (I-R/PA, II-R/PA)

2. An interventional cardiologist; (I-R/PA, II-R/PA)

3. A cardiothoracic surgeon as follows:

A. A cardiothoracic surgeon and back-up coverage shall be available for level I STEMI centers and for those level II STEMI centers which provide cardiothoracic surgery; or (I-R/PA, II-R/PA)

B. A cardiothoracic surgeon and back-up coverage arrangements with a level I STEMI center or a level II STEMI center which provides cardiothoracic surgery shall be available for those level II STEMI centers that do not provide cardiothoracic surgery to ensure that the STEMI patient is in the operating room of the receiving STEMI center as expeditiously as possible, recommended within sixty (60) minutes of the time surgery is determined needed; (II-R) 4. An emergency department physician; (I-R/IH, II-R/IH, III-

4. An emergency department physician, (I-K/IH, II-K/IH, II-R/IH, IV-R/IA)

5. An internal medicine physician; (I-R/PA, II-R/PA, III-R/PA)

6. A diagnostic radiologist; and (I-R/IA, II-R/IA, III-R/IA, IV-R/PA)

7. An anesthesiologist. (I-PA, II-PA)

A. Anesthesiology staffing requirements may be fulfilled by anesthesiology residents or certified registered nurse anesthetists (CRNA), or anesthesia assistants capable of assessing emergent situations in STEMI patients and of providing any indicated treatment including induction of anesthesia. When anesthesiology residents or CRNA's are used to fulfill availability requirements, the staff anesthesiologist on call will be advised and be promptly available and present for all operative interventions and emergency airway conditions. The CRNA may proceed with life preserving therapy while the anesthesiologist is in route under the direction of the cardiologist/cardiovascular surgeon, including induction of anesthesia. An anesthesiologist assistant shall practice only under the direct supervision of an anesthesiologist who is physically present or immediately available as this term is defined in section 334.400, RSMo. (I-PA, II-PA)

(3) Standards for Hospital Resources and Capabilities for STEMI Center Designation.

(A) The STEMI center shall meet emergency department standards listed below.

1. The emergency department staffing shall meet the following requirements:

A. The emergency department in the STEMI center shall provide immediate and appropriate care of the STEMI patient; (I-R, II-R, III-R, IV-R)

B. A level I STEMI center shall have a medical director of the emergency department who shall be a board-certified or boardadmissible physician in emergency medicine by the American Board of Medical Specialties, the Bureau of Osteopathic Specialties and Boards of Certification, or the Royal College of Physicians and Surgeons of Canada; (I-R)

C. A level II STEMI center shall have a medical director of the emergency department who shall be a board-certified or boardadmissible physician; (II-R)

D. A level III and IV STEMI center shall have a medical director of the emergency department who is recommended to be a board-certified or board-admissible physician; (III-R, IV-R)

E. There shall be an emergency department physician credentialed for STEMI care covering the emergency department twenty-four (24) hours a day, seven (7) days a week; (I-R/IH, II-R/IH, III-R/IH, IV-R/IA)

F. The emergency department physician who provides coverage shall be current in continuing medical education (CME) in the area of cardiovascular disease as set forth in section (4) of this rule; (I-R, II-R, III-R, IV-R)

G. There shall be a written policy defining the organizational relationship of the emergency department physicians to other physician members of the STEMI team; (I-R, II-R, III-R, IV-R)

H. Registered nurses in the emergency department shall be current in continuing education requirements as set forth in section (4) of this rule; (I-R, II-R, III-R, IV-R)

I. At a minimum, all registered nurses assigned to the emergency department shall be determined to be credentialed in the care of the STEMI patient by the STEMI center within one (1) year of assignment in the emergency department, and these registered nurses shall remain current in continuing education requirements as set forth in section (4) of this rule; and (I-R, II-R, III-R, IV-R)

J. The emergency department in STEMI centers shall have written care protocols for identification, triage, and treatment of acute STEMI patients that are available to emergency department personnel, reviewed annually, and revised as needed. (I-R, II-R, III-R, IV-R)

2. Nursing documentation for the STEMI patient shall be on a STEMI flow sheet approved by the STEMI medical director and the STEMI program manager/coordinator. (I-R, II-R, III-R, IV-R)

3. The emergency department shall have at least the following equipment for resuscitation and life support available to the unit:

A. Airway control and ventilation equipment including:

(I) Laryngoscopes; (I-R, II-R, III-R, IV-R)

(II) Endotracheal tubes; (I-R, II-R, III-R, IV-R)

(III) Bag-mask resuscitator; (I-R, II-R, III-R, IV-R)

(IV) Sources of oxygen; and (I-R, II-R, III-R, IV-R)

(V) Mechanical ventilator; (I-R, II-R, III-R)

B. Suction devices; (I-R, II-R, III-R, IV-R)

C. Electrocardiograph, cardiac monitor, and defibrillator; (I-R, II-R, III-R, IV-R)

D. Central line insertion equipment; (I-R, II-R, III-R)

E. All standard intravenous fluids and administration devices including intravenous catheters and intraosseous devices; (I-R, II-R, III-R, IV-R)

F. Drugs and supplies necessary for STEMI emergency care; (I-R, II-R, III-R, IV-R)

G. Two- (2-) way communication link with emergency medical service (EMS) vehicles; (I-R, II-R, III-R, IV-R)

H. Equipment necessary to communicate with emergency medical services regarding pre-hospital ECG STEMI findings; (I-R, II-R, III-R, IV-R)

I. End-tidal carbon dioxide monitor; (I-R, II-R, III-R, IV-R) J. Temperature control devices for patient and resuscitation

fluids; (I-R, II-R, III-R, IV-R) K. External pacemaker; and (I-R, II-R, III-R, IV-R)

L. Transvenous pacemaker. (I-R/IA, II-R/IA, III-R/IA)

4. The STEMI center emergency department shall maintain all equipment according to the hospital preventive maintenance schedule and document when the equipment is checked. (I-R, II-R, III-R, IV-R)

(B) The STEMI center shall have a designated intensive care unit (ICU). (I-R, II-R)

1. The STEMI center intensive care unit shall ensure staffing to provide appropriate care of the STEMI patient. (I-R, II-R)

A. The STEMI center intensive care unit shall have a designated medical director who has twenty-four (24) hours a day, seven (7) days a week access to a physician knowledgeable in STEMI care who meets the STEMI call roster continuing education requirements as set forth in section four (4) of this rule. (I-R, II-R)

B. The STEMI center intensive care unit shall have a physician on duty or available twenty-four (24) hours a day, seven (7) days a week in the STEMI center who is not the emergency department physician. This physician shall have access to a physician on the STEMI call roster. (I-R, II-R)

C. The STEMI center intensive care unit shall have a one to one (1:1) or one to two (1:2) registered nurse/patient ratio used for critically ill patients requiring intensive care unit level care. (I-R, II-R)

D. Registered nurses in the STEMI center intensive care unit shall annually maintain core competencies in the care of the STEMI patient and remain current in continuing education requirements as set forth in section (4) of this rule. (I-R, II-R)

2. The STEMI center intensive care unit shall have written care protocols for identification and treatment of acute STEMI patients which are available to intensive care unit personnel, reviewed annually, and revised as needed. (I-R, II-R)

3. The STEMI center intensive care unit shall have intensive care unit beds for STEMI patients or, if space is not available in the intensive care unit, the STEMI center shall make arrangements to provide the comparable level of care until space is available in the intensive care unit. (I-R, II-R)

4. The STEMI center intensive care unit shall have equipment available for resuscitation and to provide life support for the STEMI patient. This equipment shall include at least the following:

A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes, bag-mask resuscitator, and a mechanical ventilator; (I-R, II-R)

B. Oxygen source with concentration controls; (I-R, II-R)

C. Cardiac emergency cart, including medications:

(I) External pacemaker; and (I-R, II-R)

(II) Transvenous pacemaker; (I-R, II-R)

D. Telemetry, electrocardiograph, cardiac monitor, and defibrillator; (I-R, II-R)

E. Electronic pressure monitoring and pulse oximetry; (I-R, II-R)

F. End-tidal carbon dioxide monitor; (I-R, II-R)

G. Patient weighing devices; and (I-R, II-R)

H. Drugs, intravenous fluids, and supplies. (I-R, II-R)

5. The STEMI center intensive care unit shall check all equipment according to the hospital preventive maintenance schedule and document when it is checked. (I-R, II-R)

(C) The STEMI center shall have a cardiac catheterization lab. (I-R, II-R)

1. The STEMI center cardiac catheterization lab shall have angiography with interventional capability available twenty-four (24) hours a day, seven (7) days a week. (I-R/PA, II-R/PA)

2. All members of the STEMI center catheterization lab and team shall maintain core competencies annually as required by the STEMI center. (I-R, II-R)

3. Resuscitation equipment shall be readily available in the STEMI center catheterization lab. (I-R, II-R)

4. The following diagnostic equipment shall be readily available in the STEMI center cardiac catheterization lab:

A. Sheaths; (I-R, II-R)

B. Diagnostic wires; (I-R, II-R)

C. Diagnostic catheters; (I-R, II-R)

D. Manifold or contrast injector/delivery system; and (I-R,

II-R)

E. Pressure tubing. (I-R, II-R)

5. The following interventional equipment shall be readily available in the STEMI center cardiac catheterization lab:

A. Sheaths; (I-R, II-R)

B. Interventional guide wires; (I-R, II-R)

C. Interventional guide catheters; (I-R, II-R)

D. Balloon catheters-

(I) Compliant; and (I-R, II-R)

(II) Non-compliant; (I-R, II-R)

E. Stents-

(I) Bare metal stents; and (I-R, II-R)

(II) Drug eluting stents; (I-R, II-R)

F. Balloon pump catheters; and (I-R, II-R)

G. Thrombectomy aspiration catheters or mechanical thrombectomy device. (I-R, II-R)

6. The following equipment shall be readily available to the STEMI center cardiac catheterization lab:

A. Balloon pump; (I-R, II-R)

B. The level I STEMI center cardiac catherization labs shall have percutaneous or surgically implanted circulatory assist devices (i.e., left ventricular assistive device (LVAD)). It is also recommended that the level II STEMI center cardiac catherization labs have left ventricular assistive devices; and (I-R)

C. Emboloic protection device. (I-R, II-R)

7. The cardiac catheterization laboratory shall maintain equipment according to the STEMI center's preventive maintenance schedule and document when the equipment is checked. (I-R, II-R)

(D) The STEMI center shall have an intermediate care unit (e.g., step down unit). (I-R, II-R, III-R)

1. The STEMI center shall have a designated medical director for the STEMI center intermediate care unit who has access to a physician knowledgeable in STEMI care and who meets the STEMI call roster continuing medical education requirements as set forth in section (4) of this rule. (I-R, II-R, III-R)

2. The STEMI center intermediate care unit shall have a physician on duty or available twenty-four (24) hours a day, seven (7) days a week who is not the emergency department physician. This physician shall have access to a physician on the STEMI call roster. (I-R/IA, II-R/IA, III-R/IA)

3. The STEMI center intermediate care unit shall have registered nurses and other essential personnel on duty twenty-four (24) hours a day, seven (7) days a week. (I-R, II-R, III-R)

4. The STEMI center intermediate care unit registered nurses shall remain current in continuing education requirements as set forth in section (4) of this rule. (I-R, II-R, III-R)

5. The STEMI centers shall annually credential registered nurses that work in the intermediate care unit. (I-R, II-R, III-R)

6. The STEMI center intermediate care unit shall have written care protocols for identification and treatment of STEMI patients which are available to the cardiac unit personnel, reviewed annually, and revised as needed. (I-R, II-R, III-R)

7. The STEMI center intermediate care unit shall have equipment to support the care and resuscitation of the STEMI patient that includes at least the following:

A. Airway control and ventilation equipment including:

(I) Laryngoscopes, endotracheal tubes of all sizes; (I-R, II-R, III-R)

(II) Bag-mask resuscitator and sources of oxygen; and (I-R, II-R, III-R)

(III) Suction devices; and (I-R, II-R, III-R)

B. Telemetry, electrocardiograph, cardiac monitor, and defibrillator; (I-R, II-R, III-R)

C. All standard intravenous fluids and administration devices and intravenous catheters; and (I-R, II-R, III-R)

D. Drugs and supplies necessary for emergency care. (I-R, II-R, III-R,  $\ensuremath{\text{II-R}}\xspace$ 

8. The STEMI center intermediate care unit shall maintain equipment according to the STEMI center's preventive maintenance schedule and document when the equipment is checked. (I-R, II-R, III-R)

(E) The STEMI center shall have the following radiological and diagnostic capabilities:

1. The STEMI center radiological and diagnostic capabilities shall include a mechanism for timely interpretation to aid in the management of STEMI patients; (I-R, II-R, III-R, IV-R)

2. Resuscitation equipment shall be readily available in the radiology department; (I-R, II-R, III-R, IV-R)

3. The STEMI center radiology department shall have adequate physician and nursing personnel available with monitoring equipment to fully support the STEMI patient and provide documentation of care during the time the patient is physically present in the radiology department and during transportation to and from the radiology department; (I-R, II-R, III-R, IV-R)

4. The STEMI center radiology department shall have x-ray capability with twenty-four (24) hours a day, seven (7) days a week coverage; (I-R/IH, II-R/IA, IV-R/PA)

5. The STEMI center radiology department shall have a radiological technician; (I-R/IH, II-R/IH, III-R/IA, IV-R/PA)

6. The STEMI center radiology department shall have in-house computerized tomography; (I-R, II-R)

7. The STEMI center radiology department shall have a computerized tomography technician; and (I-R/IH, II-R/IA)

8. The STEMI center shall maintain all radiology and diagnostic equipment according to the hospital preventive maintenance schedule and document when the equipment is checked. (I-R, II-R, III-R, IV-R)

(F) All level I STEMI centers and level II STEMI centers with cardiothoracic surgery capability shall have operating room personnel, equipment and procedures that meet the following requirements:

1. The STEMI center operating room staff shall be available twenty-four (24) hours a day, seven (7) days a week; (I-R/PA, II-R/PA with cardiothoracic surgery capability)

2. Registered nurses in the STEMI center operating room shall maintain core competencies annually as required by the STEMI center; (I-R/PA, II-R/PA with cardiothoracic surgery capability)

3. The STEMI center shall provide twenty-four (24) hours a day, seven (7) days a week heart team coverage. This heart team includes physicians, perfusionists, and qualified individuals on call

and available to provide cardiothoracic surgery; (I-R/PA, II-R/PA with cardiothoracic surgery capability)

4. The STEMI center operating rooms shall have at least the following equipment:

A. Thermal control equipment for patient and resuscitation fluids; (I-R/PA, II-R/PA with cardiothoracic surgery capability)

B. X-ray capability; (I-R/PA, II-R/PA with cardiothoracic surgery capability)

C. Instruments and equipment necessary for cardiothoracic surgical services; (I-R/PA, II-R/PA with cardiothoracic surgery capability)

D. Patient monitoring equipment; and (I-R/PA, II-R/PA with cardiothoracic surgery capability)

E. Resuscitation equipment readily available to the operating room; and (I-R/PA, II-R/PA with cardiothoracic surgery capability)

5. The STEMI center operating room shall maintain all equipment according to the STEMI center's preventive maintenance schedule and document when the equipment is checked. (I-R/PA, II-R/PA with cardiothoracic surgery capability)

(G) All level I STEMI centers shall meet post-anesthesia recovery room (PAR) requirements as set out below. Those level II STEMI centers with cardiothoracic surgery capability shall also have a postanesthesia recovery room and meet the requirements as set out below. (I-R/PA, II-R/PA with cardiothoracic surgery capability)

1. The STEMI center post-anesthesia recovery rooms shall have registered nurses and other essential personnel on call and available within sixty (60) minutes twenty-four (24) hours a day, seven (7) days a week. (I-R, II-R with cardiothoracic surgery capability)

2. Registered nurses who work in the STEMI center post-anesthesia recovery room shall maintain core competencies annually as required by the STEMI center. (I-R, II-R with cardiothoracic surgery capability)

3. The STEMI center post-anesthesia recovery rooms shall have at least the following equipment for resuscitation and to provide life support for the STEMI patient:

A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes of all sizes, bag-mask resuscitator, sources of oxygen, and mechanical ventilator; (I-R, II-R with cardiothoracic surgery capability)

B. Suction devices; (I-R, II-R with cardiothoracic surgery capability)

C. Telemetry, electrocardiograph, cardiac monitor, and defibrillator; (I-R, II-R with cardiothoracic surgery capability)

D. All standard intravenous fluids and administration devices, including intravenous catheters; and (I-R, II-R with cardio-thoracic surgery capability)

4. Drugs and supplies necessary for emergency care. (I-R/PA, II-R/PA with cardiothoracic surgery capability)

5. The STEMI center post-anesthesia recovery room shall maintain all equipment according to the STEMI center's preventive maintenance schedule and document when the equipment is checked. (I-R, II-R with cardiothoracic surgery capability)

(H) The STEMI center shall have clinical laboratory services available twenty-four (24) hours a day, seven (7) days a week. (I-R, II-R, III-R, IV-R)

1. The STEMI center's clinical laboratory services shall have a written protocol to provide timely availability of results. (I-R, II-R, III-R, IV-R)

2. The STEMI center's clinical laboratory services shall be able to conduct standard analyses of blood, urine, and other body fluids. (I-R, II-R, III-R, IV-R)

3. The STEMI center's clinical laboratory services shall be able to conduct blood typing and cross-matching. (I-R, II-R, III-R)

4. The STEMI center's clinical laboratory services shall be able to conduct coagulation studies. (I-R, II-R, III-R, IV-R)

5. Clinical laboratory services at level I, II, and III STEMI centers shall include a comprehensive blood bank or access to a community central blood bank and adequate hospital blood storage facilities. (I-R, II-R, III-R) 6. Clinical laboratory services at level IV STEMI centers shall include a blood bank or access to a community central blood bank and adequate hospital blood storage facilities. (IV-R)

7. The STEMI center's clinical laboratory services shall be able to perform blood gases and pH determinations. (I-R, II-R, III-R, IV-R)

8. The STEMI center's clinical laboratory services shall be able to perform blood chemistries. (I-R, II-R, III-R, IV-R)

9. The STEMI center's clinical laboratory services shall have a written protocol for prioritization of the STEMI patient in comparison to other time critical patients. (I-R, II-R, III-R, IV-R)

(I) The STEMI center shall have support services to assist the STEMI patient's family from the time of entry into the facility to the time of discharge or transfer, and the support services that were provided shall be documented. (I-R, II-R, III-R, IV-R)

(J) The STEMI center shall have cardiac rehabilitation or a written network agreement for the provision of cardiac rehabilitation. (I-R, II-R, III-R)

1. Level I and level II STEMI centers shall have Phase I cardiac rehabilitation on site. (I-R, II-R)

(4) Continuing Medical Education (CME) and Continuing Education Standards for STEMI Center Designation.

(A) The STEMI center shall ensure that staff providing services to STEMI patients receive continued medical education and continuing education as set forth in section (4) of this rule and document this education for each staff member. The department shall allow up to one (1) year from the date of the STEMI center's initial STEMI center designation for STEMI center staff members to complete all of the required continuing medical education and/or continuing education requirements if the STEMI center staff documents that at least half of the required continuing medical education and continuing education hours have been completed for each STEMI center staff at the time of the on-site initial application review. The STEMI center shall submit documentation to the department within one (1) year of the initial designation date that all continued medical education and continuing education requirements for STEMI center staff members have been met in order to maintain the STEMI center's designation. (I-R, II-R, III-R, IV-R)

(B) The STEMI call roster members shall complete the following continuing education requirements:

1. Core team members of the STEMI call roster in level I and level II STEMI centers shall document a minimum of ten (10) hours every year of continuing education in the area of acute coronary syndrome. All other members of the STEMI call roster shall document a minimum of ten (10) hours every year of continuing education in the area of cardiovascular disease. This continuing education shall be reviewed by the STEMI center medical director for appropriateness to the practitioner's level of responsibility; and (I-R, II-R)

2. All members of the STEMI call roster in level III and level IV STEMI centers shall document a minimum of eight (8) hours every two (2) years of continuing education in the area of cardiovascular disease. This continuing education shall be reviewed by the STEMI center medical director for appropriateness to the practitioner's level of responsibility. (III-R, IV-R)

(C) The STEMI center medical director shall complete the following continuing medical education requirements:

1. Level I and II STEMI medical directors shall document a minimum average of ten (10) hours every year in the area of acute coronary syndrome; (I-R, II-R)

2. The level III and IV STEMI medical directors that are boardcertified or board-eligible shall document a minimum average of eight (8) hours every other year of continuing medical education in the area of cardiovascular disease; and (III-R, IV-R)

3. The level III and IV STEMI medical directors who are not board-certified or board-eligible shall document:

A. A minimum average of ten (10) hours every two (2) years of continuing medical education in the area of cardiovascular disease

with a focus on acute coronary syndrome; and (III-R, IV-R)

B. Attend one (1) national, regional, or state meeting every three (3) years in cardiovascular disease. Continuing medical education earned at these meetings can count toward the ten (10) continuing medical education hours required. (III-R, IV-R)

(D) The STEMI center's STEMI program manager/coordinator shall complete the following continuing education requirements:

1. A level I STEMI program coordinator/manager shall complete and document the following:

A. A minimum average of ten (10) hours every year of continuing education in the area of cardiovascular disease. This continuing education shall be reviewed for appropriateness by the STEMI center medical director to the STEMI program manager's/coordinator's level of responsibility; and (I-R)

B. Attend one (1) national, regional, or state meeting every two (2) years focused on cardiovascular disease. If the national, regional, or state meeting provides continuing education, that continuing education may count towards the annual requirement; (I-R)

2. A level II STEMI program coordinator/manager shall complete and document the following:

A. A minimum average of eight (8) hours every year of continuing education in the area of cardiovascular disease. This continuing education shall be reviewed by the STEMI center medical director for appropriateness to the STEMI program manager's/coordinator's level of responsibility; and (II-R)

B. Attend one (1) national, regional, or state meeting every three (3) years focused on cardiovascular disease. If the national, regional, or state meeting provides continuing education, that continuing education may count toward the annual requirement; and (II-R)

3. The level III and IV STEMI program coordinator/manager shall complete and document a minimum average of eight (8) hours every other year of continuing education in the area of cardiovascular disease. This continuing education shall be reviewed for appropriateness by the STEMI center medical director to the STEMI program manager's/coordinator's level of responsibility. (III-R, IV-R)

(E) STEMI center emergency department personnel shall complete the continuing education requirements for STEMI centers that are detailed below.

1. The emergency department physician(s) shall be current in cardiovascular continuing medical education. (I-R, II-R, III-R, IV-R)

A. Emergency department physicians in level I and II STEMI centers shall complete and document a minimum average of four (4) hours every year of continuing medical education in the area of cardiovascular disease. (I-R, II-R)

B. Emergency department physicians in level III and IV STEMI centers shall complete and document a minimum average of six (6) hours every two (2) years of continuing medical education in the area of cardiovascular disease. (III-R, IV-R)

2. Registered nurses assigned to the emergency department shall complete the following requirements:

A. Registered nurses assigned to the emergency department at level I and II STEMI centers shall complete and document a minimum of four (4) hours of continuing education every year in the area of cardiovascular disease; (I-R, II-R)

B. Registered nurses assigned to the emergency department at level III and IV STEMI centers shall complete and document a minimum of six (6) hours of continuing education every two (2) years in the area of cardiovascular disease; and (III-R, IV-R)

C. Registered nurses assigned to the emergency department at STEMI centers shall maintain core competencies in the care of the STEMI patient annually as determined by the STEMI center. Continuing education earned in training to maintain these competencies may count toward continuing education requirements. (I-R, II-R, III-R, IV-R) (F) Registered nurses assigned to the intensive care unit who provide care to STEMI patients shall complete the following continuing education requirements:

1. Registered nurses in the intensive care unit shall complete and document a minimum of eight (8) hours every year of continuing education in the area of cardiovascular disease. This continuing education shall be reviewed for appropriateness by the STEMI center medical director to the practitioner's level of responsibility. (I-R, II-R).

(G) Registered nurses and clinical staff assigned to the cardiac catheterization lab shall complete the following continuing education requirements:

1. Registered nurses and clinical staff shall complete and document a minimum of eight (8) hours of continuing education every year in the area of acute coronary syndrome. This continuing education shall be reviewed for appropriateness by the STEMI center medical director to the practitioner's level of responsibility. (I-R, II-R)

(H) Registered nurses assigned to the intermediate care unit shall complete the following continuing education requirements:

1. Intermediate care unit registered nurses in level I and level II STEMI centers shall complete and document a minimum of eight (8) hours every year of continuing education in the area of cardiovascular disease. This continuing education shall be reviewed for appropriateness by the STEMI center medical director to the practitioner's level of responsibility; and (I-R, II-R)

2. Intermediate care unit registered nurses in level III STEMI centers shall complete and document a minimum of eight (8) hours of continuing education every two (2) years in the area of cardiovascular disease. This continuing education shall be reviewed for appropriateness by the STEMI center medical director to the practitioner's level of responsibility. (III-R)

(5) Standards for Hospital Performance Improvement, Patient Safety, Outreach, Public Education, and Training Programs for STEMI Center Designation.

(A) The STEMI center shall maintain an ongoing performance improvement and patient safety program designed to objectively and systematically monitor, review, and evaluate the quality, timeliness, and appropriateness of patient care, to resolve problems, and to improve patient care. (I-R, II-R, III-R, IV-R)

1. The STEMI center shall collect, document, trend, maintain for at least five (5) years, and make available for review by the department at least the following data elements:

A. Any STEMI center that performs percutaneous coronary interventions shall report all percutaneous coronary interventionrelated data, including the time from first medical contact or pre-hospital electrocardiogram STEMI identification to hospital door time and the time from first medical contact to balloon or device time. The percutaneous coronary intervention-related data is set forth and identified in the columns labeled "Level I & II STEMI Centers" and "Only for Level III STEMI Centers which are Performing Percutaneous Coronary Interventions (PCIs) (Only on Patients Receiving Percutaneous Coronary Interventions (PCIs))" in the document entitled "Time Critical Diagnosis ST-Segment Elevation Myocardial Infarction (STEMI) Center Registry Data Elements" dated March 1, 2012, which is incorporated by reference in this rule and is available at the Missouri Department of Health and Senior Services, PO Box 570, Jefferson City, MO 65102-0570 or on the department's website at www.health.mo.gov. This rule does not incorporate any subsequent amendments or additions; (I-R, II-R, III-R)

B.Thrombolytic administration time which is the time from first medical contact or pre-hospital electrocardiogram STEMI identification to hospital door time and the time from hospital door to needle time; (I-R, II-R, III-R, IV-R)

C. Number of STEMI patients presenting within the treatment window for percutaneous coronary interventions and/or thrombolytic administration; (I-R, II-R, III-R, IV-R) D. Number of eligible STEMI patients treated with percutaneous coronary intervention and/or thrombolytic administration; and (I-R, II-R, III-R, IV-R)

E. Time from when STEMI patient presents at the receiving STEMI center to time STEMI patient is in the operating room at the receiving STEMI center. (I-R, II-R if cardiac surgical capability)

2. The STEMI center shall at least quarterly conduct a regular morbidity and mortality review. (I-R, II-R, III-R, IV-R)

3. The STEMI center shall conduct a review of the reports generated by the department from the Missouri STEMI registry. (I-R, II-R, III-R, IV-R)

4. The STEMI center shall conduct a monthly review of its prehospital STEMI care including inter-facility transfers. (I-R, II-R, III-R, IV-R)

5. The STEMI center shall participate in the emergency medical services regional system of STEMI care. (I-R, II-R, III-R, IV-R)

6. The STEMI center shall review cases of STEMI patients remaining greater than thirty (30) minutes at the referring hospital prior to transfer as a part of its performance improvement and patient safety program. (I-R, II-R, III-R, IV-R)

7. The STEMI center shall review and monitor the core competencies of its physicians, practitioners, and nurses. (I-R, II-R, III-R, IV-R)

(B) It is recommended that level I and II STEMI centers establish a cardiology outreach program that provides physicians in the outlying areas with telephone access to the cardiology program. (I-R, II-R)

(C) STEMI centers shall establish a patient and public education program to promote STEMI prevention and awareness of signs and symptoms. (I-R, II-R, III-R, IV-R)

(D) Level I, II, and III STEMI centers shall establish a professional education outreach program in catchment areas to provide training and other supports to improve care of STEMI patients. (I-R, II-R, III-R)

(E) Each STEMI center shall establish a training program on caring for STEMI patients for professionals in the STEMI center that includes at least the following:

1. A procedure for training nurses and clinical staff to be credentialed in STEMI care; (I-R, II-R, III-R, IV-R)

2. A mechanism to assure that all nurses providing care to STEMI patients complete a minimum of required continuing education to become credentialed in STEMI care; and (I-R, II-R, III-R, IV-R)

3. The content and format of any STEMI continuing education courses developed and offered by the STEMI center shall be developed with the oversight of the STEMI center medical director. (I-R, II-R, II-R, IV-R)

(F) STEMI centers shall provide and monitor timely feedback to the emergency medical services providers and referring hospital(s), if involved. This feedback shall include, at least, diagnosis, treatment and referring hospital, if involved. It is recommended that the feedback be provided within seventy-two (72) hours of admission to the hospital. When emergency medical services does not provide patient care data on patient arrival or in a timely fashion (recommended within three (3) hours of patient delivery), this time frame shall not apply. (I-R, II-R, IV-R)

(G) The STEMI centers shall be actively involved in local and regional emergency medical services systems by providing training and clinical educational resources. (I-R, II-R, III-R, IV-R)

(6) Standards for the Programs in STEMI Research for STEMI Center Designation.

(A) The STEMI center and its staff shall support an ongoing research program in STEMI as evidenced by any of the following:

1. Production of evidence based reviews of the STEMI program's process and clinical outcomes; (I-R)

2. Publications in peer-reviewed journals; (I-R)

3. Reports of findings presented at regional or national meetings; (I-R)

- 4. Receipt of grants for study of STEMI care; (I-R)
- 5. Participation in multi-center studies; or (I-R)
- 6. Epidemiological studies and individual case studies. (I-R)

(B) The STEMI center shall agree to cooperate and participate with the department for the purpose of developing prevention programs. (I-R, II-R, III-R, IV-R)

AUTHORITY: sections 190.185 and 190.241, RSMo Supp. 2012. Original rule filed Nov. 15, 2012.

PUBLIC COST: This proposed rule will cost state agencies or political subdivisions \$288,097,913 for the initial three- (3-) year period and (\$92,714,624) annually thereafter.

*PRIVATE COST: This proposed rule will cost private entities* \$568,174,457 for the initial three- (3-) year period and \$192,915,622 annually thereafter.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with Teresa Generous, Director, Department of Health and Senior Services, Division of Regulation and Licensure, PO Box 570, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.

# FISCAL NOTE PUBLIC COST

# I. Department Title: Missouri Department of Health and Senior Services Division Title: Division of Regulation and Licensure Chapter Title: Chapter 40-Comprehensive Emergency Medical Services System

Rule Number and	19 CSR 30-40.760 Standards for ST Segment Elevation Myocardial
Name:	Infarction (STEMI) Center Designation.
Type of Rulemaking:	Proposed

# II. SUMMARY OF FISCAL IMPACT

Affected Agency or Political Subdivision	Estimated Cost of Compliance in the Aggregate
18 public hospitals	
1 Level I STEMI Center	\$56,507,551 for the first 3 year period and
	\$18,024,283 for annually thereafter
Level II STEMI Centers	\$102,648,322 for the first 3 year period and
	\$32,586,306 for annually thereafter
Level III STEMI Centers	\$74,856,912 for the first 3 year period and
	\$24,461,991 for annually thereafter
Level IV STEMI Centers	\$54,046,528 for the first 3 year period and
	\$17,635,244 for annually thereafter
Department of Health and Senior	\$38,600 for the first 3 year period and
Services' Costs	\$6,800 for annually thereafter
Total	\$288,097,913 for the first 3 year period and
	\$92,714,624 for annually thereafter

# III. WORKSHEET

It is anticipated that most if not all of the STEMI centers voluntarily applying to be designated as STEMI centers will have the staff and equipment required to be the level of STEMI center for which they are applying to be designated. However, the list of required staff and equipment has been detailed below, even if it is assumed the hospital currently meets these requirements.

- 1. Level I STEMI center.
  - A. Salary Costs for medical professionals.
    - 1) A physician experienced in diagnosing and treating cardiovascular disease - \$359,000 annually X one level I STEMI center = \$359,000 X

3 years = \$1,077,000 for the first 3 year period and \$359,000 annually X one level I STEMI center X 1 year = \$359,000 annually thereafter.

- 2) At least 1 other health care professional or qualified individual credentialed in STEMI care - \$126,046 annually X one level I STEMI center = \$126,046 X 3 years = \$378,138 for the first 3 year period and \$126,046 annually X one level I STEMI center X 1 year = \$126,046 annually thereafter.
- 3) Interventional Cardiologist \$359,000 annually X one level I STEMI center for the first 3 year period = \$359,000 X 3 years = \$1,077,000 for the first 3 year period and \$359,000 X one level 1 STEMI center X 1 year = \$359,000 annually thereafter.
- 4) Other health care professional as deemed necessary in the cardiac catheterization laboratory \$59,750 annually X one level I STEMI center = \$59,750 X 3 years = \$179,250 for the first 3 year period and \$59,750 annually X one level I STEMI center X 1 year = \$59,750 annually thereafter.
- 5) STEMI center medical director who shall be a cardiologist or interventional cardiologist - \$359,000 annually X one level I STEMI center = \$359,000 X 3 years = \$1,077,000 for the first 3 year period and \$359,000 annually X one level I STEMI center X 1 year = \$359,000 annually thereafter.
- 6) STEMI program manager/coordinator who is a registered nurse or a qualified individual \$126,046 annually X one level I STEMI center = \$126,046 X 3 years = \$378,138 for the first 3 year period and \$126,046 annually X one level I STEMI center X 1 year = \$126,046 annually thereafter.
- 7) Physician to direct cardiac rehabilitation services trained in cardiac rehabilitation \$200,339 annually X one level I STEMI center = \$200,339 X 3 years = \$601,017 for the first 3 year period and \$200,339 annually X one level I STEMI center X 1 year = \$200,339 annually thereafter.
- 8) Cardiologist \$359,000 annually X one level I STEMI center = \$359,000 X 3 years = \$1,077,000 for the first 3 year period and \$359,000 X one level I STEMI center X 1 year = \$359,000 annually thereafter.
- 9) Cardiothoracic surgeon \$403,993 annually X one level I STEMI center = \$403,993 X 3 years = \$1,211,979 for the first 3 year period and \$403,993 annually X one level I STEMI center X 1 year = \$403,993 annually thereafter.
- 10) An internal medicine physician \$181,823 annually X one level I STEMI center = \$181,823 X 3 years = \$545,469 for the first 3 year period and \$181,823 annually X one level I STEMI center X 1 year = \$181,823 annually thereafter.
- 11) A diagnostic radiologist \$402,539 annually X one level I STEMI center = \$402,539 X 3 years = \$1,207,617 for the first 3 year period and \$402,539 annually X one level I STEMI center X 1 year = \$402,539 annually thereafter.
- 12) An anesthesiologist \$331,932 annually X one level I STEMI center for the first 3 year period = \$331,932 X 3 years = \$995,796 for the

first 3 year period and \$331,932 annually X one level I STEMI center X 1 year = \$331,932 annually thereafter.

- 13) Anesthesiology resident \$61,000 annually X one level I STEMI center = \$61,000 X 3 years = \$183,000 for the first 3 year period and \$61,000 annually X one level I STEMI center X 1 year = \$61,000 annually thereafter.
- 14) Certified nurse anesthetists \$155,095 annually X one level I STEMI center = \$155,095 X 3 years = \$465,285 for the first year 3 year period and \$155,095 annually X one level I STEMI center X 1 year = \$155,095 annually thereafter.
- 15) Anesthesia assistants \$120,000 annually X one level I STEMI center = \$120,000 X 3 years = \$360,000 for the first 3 year period and \$120,000 X one level I STEMI center X 1 year = \$120,000 annually thereafter.
- 16) Emergency department physician credentialed for STEMI care by the STEMI center 24 hours a day, 7 days a week \$244,973 annually X 3 emergency department physicians X one level I STEMI center = \$734,919 X 3 years = \$2,204,757 for the first 3 year period and \$244,973 annually X 3 physicians X one level I STEMI center X 1 year = \$734,919 annually thereafter.
- 17) Registered nurses in the emergency department \$64,533 annually X 5 registered nurses in the emergency department X one level I STEMI center = \$322,665 X 3 years = \$967,995 for the first 3 year period and \$322,665 X one level I STEMI center X 1 year = \$322,665 annually thereafter.
- 18) Medical director of the emergency department \$199,038 annually X one level I STEMI center = \$199,038 X 3 years = \$597,114 for the first 3 year period and \$199,038 X one level I STEMI center X 1 year = \$199,038 annually thereafter.
- 19) A medical director for a designated intensive care unit \$177,560 annually X one level I STEMI center = \$177,560 X 3 years = \$532,680 for the first 3 year period and \$177,560 annually X one level I STEMI center X 1 year = \$177,560 annually thereafter.
- 20) A physician on duty or available 24 hours a day 7 days a week in the designated intensive care unit \$244,553 annually X 3 STEMI center intensive care unit physicians X one level I STEMI center = \$733,659 X 3 years = \$2,200,977 for the first 3 year period and \$244,553 annually X 3 STEMI center intensive care unit physicians = \$733,659 annually X one level I STEMI center X 1 year = \$733,659 annually X one level I STEMI center X 1 year = \$733,659 annually thereafter.
- 21) The designated intensive care unit shall have a 1 to 1 or 1 to 2 registered nurse/patient ratio used for critically ill patients requiring intensive care unit level of care \$67,623 annually X 5 registered nurses in the designated intensive care unit X one level I STEMI center = \$338,115 X 3 years = \$1,014,345 for the first 3 year period and \$67,623 X 5 registered nurses = \$338,115 annually X one level I STEMI center X 1 year = \$338,115 annually thereafter.
- 22) Intermediate care unit medical director \$177,560 annually X one level I STEMI center = \$177,560 X 3 years = \$532,680 for the first 3

year period and \$177,560 annually X one level I STEMI center X 1 year = \$177,560 annually thereafter.

- 23) Physician on duty or available 24 hours a day, 7 days a week in the intermediate care unit \$177,560 annually X 3 physicians in the intermediate unit X one level I STEMI center = \$532,680 X 3 years = \$1,598,040 for the first 3 year period and \$177,560 annually X 3 physicians = \$532,680 annually X one level I STEMI center X 1 year = \$532,680 annually thereafter.
- 24) The intermediate care unit shall have registered nurses and other essential personnel on duty 24 hours a day 7 days a week \$65,097 annually for the registered nurse X 4 registered nurses in the intermediate care unit X one level I STEMI center = \$260,388 X 3 years = \$781,164 for the first 3 year period and \$65,097 X 4 registered nurses = \$260,338 annually X one level I STEMI center X 1 year = \$260,388 annually thereafter.
- 25) Certified Nursing Technician \$30,000 annually X one level I STEMI center = \$30,000 X 3 years = \$90,000 for the first 3 year period and \$30,000 annually X one level I STEMI center X 1 year = \$30,000 annually thereafter.
- 26) The STEMI center post-anesthesia recovery room shall have registered nurses and other essential personnel on call and available within 60 minutes 24 hours a day 7 days a week \$65,097 annually X 4 registered nurses X one level I STEMI center = \$260,388 X 3 years = \$781,164 for the first 3 year period and \$65,097 X 4 registered nurses = \$260,388 annually X one level I STEMI center X 1 year = \$260,388 annually thereafter.
- 27) Computerized tomography technician \$58,895 annually X 4 computerized tomography technicians X one level I STEMI center = \$235,580 X 3 years = \$706,740 for the first 3 year period and \$58,895 X 4 computerized tomography technicians = \$235,580 X one level I STEMI center X 1 year = \$235,580 annually thereafter.
- 28) Radiologist average \$300,000 annually X 3 neurologist/radiologists X one level I STEMI center = \$900,000 X 3 years = \$2,700,000 for the first 3 year period and \$300,000 X 3 neurologists/radiologists = \$900,000 annually X one level I STEMI center X 1 year = \$900,000 annually thereafter.
- 29) Transport nurse average \$62,000 annually X one level I STEMI center = \$62,000 X 4 transport nurses = \$248,000 X 3 years = \$744,000 for the first 3 year period and \$62,000 annually X 4 transport nurses X one level I STEMI center X 1 year = \$248,000 annually thereafter.
- 30) Radiology technician average \$62,000 annually X 4 radiology technicians X one level I STEMI center = \$248,000 X 3 years = \$744,000 for the first 3 year period and \$62,000 annually X 4 radiology technicians X one level I STEMI center X 1 year = \$248,000 annually thereafter.
- 31) Scrub nurse \$68,655 annually X 4 scrub nurses X one level I STEMI center = \$274,620 X 3 years = \$823,860 for the first 3 year period and \$68,655 X 4 scrub nurses = \$274,620 annually X one level I STEMI center X 1 year = \$274,620 annually thereafter.

- 32) Clinical perfusionist \$111,420 annually X one level I STEMI center = \$111,420 X 3 years = \$334,260 for the first 3 year period and \$111,420 annually X one level I STEMI center X 1 year = \$111,420 annually thereafter.
- 33) Nurse educator/supervisor to ensure staff are trained on core competencies \$78,500 annually X one level I STEMI center = \$78,500 X 3 years = \$235,500 for the first 3 year period and \$78,500 annually X one level I STEMI center X 1 year = \$78,500 annually thereafter.

Total cost for salaries for medical professionals for the first 3 year period - \$1,077,000 (#1 above) + \$378,138 (#2 above) + \$1,077,000 (#3 above) + \$179,250 (#4 above) + \$1,077,000 (#5 above) + \$378,138 (#6 above) + \$601,017 (#7 above) + \$1,077,000 (#8 above) + \$1,211,979 (#9 above) + \$545,469 (#10 above) + \$1,207,617 (#11 above) + \$995,796(#12 above) + \$183,000 (#13 above) + \$465,285 (#14 above) + \$360,000(#15 above) + \$2,204,757 (#16 above) + \$967,995 (#17 above) + \$597,114 (#18 above) + \$532,680 (#19 above) + \$2,200,977 (#20 above) + \$1,014,345 (#21 above) + \$532,680 (#22 above) + \$1,598,040 (#23 above) + \$781,164 (#24 above) + \$90,000 (# 25 above) + \$781,164 (#26 above) + \$706,740 (#27 above) + \$2,700,000 (#28 above) + \$744,000(#29 above) + \$744,000 (#30 above) + \$823,860 (#31 above) + \$334,260(#32 above) + \$235,500 (#33 above) = \$28,402,965 for the first 3 year period.

Total cost for the salaries for the medical professionals for annually thereafter - \$359,000 (#1 above) + \$126,046 (#2 above) + \$359,000 (#3 above) + \$59,750 (#4 above) + \$359,000 (#5 above) + \$126,046 (#6 above) + \$200,339 (#7 above) + \$359,000 (#8 above) + \$126,046 (#6 above) + \$200,339 (#7 above) + \$359,000 (#8 above) + \$126,046 (#6 above) + \$181,823 (#10 above) + \$359,000 (#8 above) + \$403,993 (#9 above) + \$181,823 (#10 above) + \$402,539 (#11 above) + \$331,932 (#12 above) + \$61,000 (#13 above) + \$155,095 (#14 above) + \$120,000 (#15 above) + \$734,919 (#16 above) + \$322,665 (#17 above) + \$199,038 (#18 above) + \$177,560 (#19 above) + \$733,659 (#20 above) + \$338,115 (#21 above) + \$177,560 (#22 above) + \$532,680 (#23 above) + \$260,388 (#24 above) + \$30,000 (# 25 above) + \$260,388 (#26 above) + \$235,580 (#27 above) + \$900,000 (#28 above) + \$111,420 (#32 above) + \$78,500 (#33 above) = \$9,467,655 for annually thereafter.

B. Continuing education costs for level I STEMI center staff.

- Level I core team members of the STEMI call roster shall complete a minimum of 10 hours of continuing education in the area of acute coronary syndrome every year – average of \$10.00 per hour for online training X 10 hours = \$100 X one level I STEMI center = \$100 X 3 years = \$300 for the first 3 year period and \$100 X one level I STEMI center X 1 year = \$100 annually thereafter.
- 2) Level I core team member of the STEMI call roster shall complete a minimum of 10 hours of continuing education in the area of acute

coronary syndrome every year - average of \$39.99 annually for online training - \$39.99 X one level I STEMI center = \$39.99 X 3 years = \$119.97 for the first 3 year period and \$39.99 X one level I STEMI center X 1 year = \$39.99 annually thereafter.

- 3) Level I STEMI call roster member (emergency department physician) shall complete a minimum average of 10 hours of continuing education in cardiovascular disease every year average of \$10.00 per hour for online training X 10 hours X one level I STEMI center = \$100 X 3 years = \$300 for the first 3 year period and \$100 X one level I STEMI center X 1 year = \$100 annually thereafter.
- 4) Level I STEMI call roster member (interventional cardiologist) shall complete a minimum average of 10 hours of continuing education in the area of cardiovascular disease every year - average of \$10.00 per hour for online training x 10 hours X one level I STEMI center = \$100 X 3 years = \$300 for the first 3 year period and \$100 X one level I STEMI center X 1 year = \$100 annually thereafter.
- 5) Level I STEMI call roster member (others as appropriate) shall complete a minimum average of 10 hours of continuing education in the area of cardiovascular disease every year average of \$10.00 per hour for online training X 10 hours X one level I STEMI center = \$100 annually X 3 others as appropriate = \$300 X 3 years = \$900 for the first 3 year period and \$300 X one level I STEMI center X 1 year = \$300 annually thereafter.
- 6) A level I STEMI center medical director shall complete a minimum of 10 hours of continuing medical education every year in the area of acute coronary syndrome average of \$10.00 per hour for online training X 10 hours X one level I STEMI center = \$100 X 3 years = \$300 for the first 3 year period and \$100 X one level I STEMI center X 1 year = \$100 annually thereafter.
- 7) A level I program coordinator/ manager shall complete a minimum of 10 hours of continuing education every year in the area of cardiovascular disease average of \$39.99 annually for online training = \$39.99 X one level I STEMI center = \$39.99 X 3 years = \$119.97 for the first 3 year period and \$39.99 X one level I STEMI center X 1 year = \$39.99 annually thereafter.
- 8) Emergency department physicians in level I STEMI centers shall complete a minimum average of 4 hours of continuing medical education in cardiovascular disease every year - average of \$10.00 per hour for online training X 3 physicians in the emergency room X 4 hours X one level I STEMI center = \$120 X 3 years = \$360 for the first 3 year period and \$10.00 X 3 physicians X 4 hours X one level I STEMI center X 1 year = \$120 annually thereafter.
- 9) Registered nurses assigned to the emergency departments in level I STEMI centers shall complete a minimum of 4 hours of continuing education in the area of cardiovascular disease every year - average of \$39.99 annually for online training = \$39.99 X 5 registered nurses in the emergency room X one level I STEMI center X 3 years = \$599.85 for the first 3 year period and \$39.99 X 5 registered nurses in the emergency room X one level I STEMI center X 1 year = \$199.95 annually thereafter.

- 10) Registered nurses assigned to the intensive care unit in level I STEMI centers who care for STEMI patients shall complete a minimum of 8 hours of continuing education in the area of cardiovascular disease every year - average of \$39.99 annually for online training X 5 registered nurses in the intensive care unit X one level I STEMI center X 3 years = \$599.85 for the first 3 year period and \$39.99 annually X 5 registered nurses in the intensive care unit X one level I STEMI center X 1 year = \$199.95 annually thereafter.
- 11) Registered nurses and clinical staff assigned to the cardiac catheterization laboratory shall complete a minimum of eight hours of continuing education every year in the area of acute coronary syndrome average of \$39.99 annually for online training X 5 staff in the catheterization laboratory X one level I STEMI center X 3 years = \$599.85 for the first 3 year period and \$39.99 annually X 5 staff in the catheterization laboratory X one level I STEMI center X 1 year = \$199.95 annually thereafter.
- 12) Registered nurses assigned to the intermediate care unit in level I STEMI centers shall complete a minimum of 8 hours of continuing education in the area of cardiovascular disease every year - average of \$39.99 annually X 4 intermediate unit registered nurses X one level I STEMI center X 3 years = \$479.88 for the first 3 year period and \$39.99 X 4 registered nurses X one level I STEMI center X 1 year = \$159.96 annually thereafter.

Total cost for continuing education for level I STEMI center staff for the first 3 year period - 300 (#1 above) + 119.97 (#2 above) + 300 (#3 above) + 300 (#4 above) + 1900 (#5 above) + 300 (#6 above) + 19.97 (#7 above) + 360 (#8 above) + 5599.85 (#9 above) + 5599.85 (#10 above) + 5599.85 (#11 above) + 5479.88 (#12 above) = 54,979.37 for the first 3 year period.

Total cost for continuing education for level I STEMI center staff for annually thereafter - \$100 (#1 above) + \$39.99 (#2 above) + \$100 (#3 above) + \$100 (#4 above) + \$300 (#5 above) + \$100 (#6 above) + \$39.99(#7 above) + \$120 (#8 above) + \$199.95 (#9 above) + \$199.95 (#10 above) + \$199.95 (#11 above) + \$159.96 (#12 above) = \$1659.79 for annually thereafter.

## C. Medical Equipment.

 Electronic communication devices for STEMI/ cardiac catheterization lab team members - 2 electronic communication devices (cell phone and beeper) X \$300 for the annual cost of each electronic communication device X 2 STEMI/cardiac catheterization lab team members carrying this device ( one member on call and one back-up member) X one level I STEMI center X 3 years = \$3,600 for the first 3 year period and 2 electronic communication devices (cell phone and beeper) X \$300 for the annual cost of each electronic communication device X 2 STEMI call roster members ( one member on call and one back-up member) carrying this device X one level I STEMI center X 1 year = \$1,200 annually thereafter.

- 2) Resuscitation equipment for the emergency department-
  - a) Laryngoscopes at least 2 X \$300 each = \$600 X one level I STEMI center = \$600 X 3 years = \$1,800 for the first 3 year period and at least 2 X \$300 each = \$600 X one level I STEMI center X 1 year = \$600 annually thereafter.
  - b) Endotracheal tubes of all sizes \$250 for a pack of 10 X 50 packs = \$12,500 X one level I STEMI center X 3 years = \$37,500 for the first 3 year period and \$250 for a pack of 10 X 50 packs = \$12,500 X one level I STEMI center X 1 year = \$12,500 annually thereafter.
  - c) Bag-mask resuscitator \$250 for a pack of 10 X 50 packs = \$12,500 X one level I STEMI center X 3 years = \$37,500 for the first 3 year period and \$250 for a pack of 10 X 50 packs = \$12,500 X one level I STEMI center X 1 year = \$12,500 annually thereafter.
  - d) Sources of oxygen (air outlet \$70 X 7 = \$490 for the first year for one level I STEMI center + \$150 per year X 2 years for upkeep and maintenance of air outlets for one level I STEMI center = \$300 for a total of \$790 for air outlets for the first 3 year period) + (nasal cannula \$.40 X 500 patients = \$200 X 3 years for one level I STEMI center = \$600 for the first 3 year period) + (masks \$2.40 X 500 patients = \$1,200 X 3 years for one level I STEMI center = \$3,600 for the first 3 year period) + (ambu bags \$10.50 X 100 = \$1050 X 3 years for one level I STEMI center = \$3,150 for the first 3 year period) + (oxygen tank \$70 X 300 = \$21,000 X 3 years for one level I STEMI center = \$63,000 for the first 3 year period) + (regulator for oxygen tank \$30 X 25 = \$750 X 3 years for one level I STEMI center = \$2,250 for the first 3 year period) + (oxygen tubing \$.40 for 7 feet X 500 patients = \$200 X 3 years for one level I STEMI center = \$600 for the first 3 year period) for a total of \$73,990 for the first 3 year period and (air outlet upkeep and maintenance \$150 X one level I STEMI center X 1 year = \$150) + (regulator for air outlet \$35 X 15 X one level I STEMI center X 1 year = \$525) + (nasal cannula \$.40 X 500 patients X one level I STEMI center X 1 year = \$200) + (masks \$2.40 X 500 X one level I STEMI center X 1 year = \$1,200) + (ambu bags \$10.50 X 100 X one level I STEMI center X 1 year = \$1,050) + (oxygen tank \$70 X 300 X one level I STEMI center X 1 year = \$21,000) + (regulator for oxygen tank \$30 X 25 X one level I STEMI center X 1 year = \$750) + (oxygen tubing \$.40 for 7 feet X 500 patients X one level I STEMI center X 1 year = \$200) for a total of \$25,075 annually thereafter.
  - e) Mechanical ventilator \$7000 X one level I STEMI center = \$7000 for the first year and \$1,500 for the annual upkeep and maintenance in the future of one level I STEMI center X 2 years (years 2 through 3) = \$3,000 for 2 years for a total of \$10,000 for the first 3 year period and \$1,500 for the upkeep and maintenance

for one level I STEMI center X 1 year = \$1,500 annually thereafter.

- f) Suction devices suction device canisters and tubing for wall suction \$50 X 500 patients = \$25,000 X one level I STEMI center = \$25,000 X 3 years = \$75,000 for the first 3 year period and \$50 X 500 patients X one level I STEMI center X 1 year = \$25,000 annually thereafter.
- g) Electrocardiograph, cardiac monitor and defibrillator \$37,895 for the cost of the first year and \$1,500 for the annual upkeep and maintenance of one level I STEMI center X 2 years (years 2 through 3) = \$3,000 for a total of \$40,895 for the first 3 year period and \$1,500 for upkeep and maintenance X one level I STEMI center X 1 year = \$1,500 annually thereafter.
- h) Central line insertion equipment \$600 X 300 patients = \$180,000 X one level I STEMI center = \$180,000 X 3 years = \$540,000 for the first 3 year period and \$600 X 300 patients = \$180,000 X one level I STEMI center X 1 year = \$180,000 annually thereafter.
- i) All standard intravenous fluids, all standard administration devices and all standard intravenous catheters (\$4.00 each for standard intravenous fluids X 500 patients = \$2,000) + (\$4.00 each for standard administration devices X 500 patients = \$2,000) + (\$4.00 each for standard intravenous catheters X 500 = \$2,000) = \$6,000 X one level I STEMI center = \$6,000 X 3 years = \$18,000 for the first 3 year period and \$6,000 X one level I STEMI center X 1 year = \$6,000 annually thereafter.
- j) Intraosseous devices -needles \$25 each X 300 patients = \$7,500 X one level I STEMI center = \$7,500 X 3 years = \$22,500 for the first 3 year period and \$25 each X 300 patients = \$7,500 X one level I STEMI center X 1 year = \$7,500 annually thereafter.
- k) Drugs necessary for STEMI emergency care e.g. saline, epinephrine, atropine, lidocaine, magnesium sulfate \$100 X 500 patients = \$50,000 X one level I STEMI center = \$50,000 X 3 years = \$150,000 for the first 3 year period and \$100 X 500 = \$50,000 X one level I STEMI center X 1 year = \$50,000 annually thereafter.
- Supplies necessary for emergency care (IV start packs, IV tubing, syringes, gauze alcohol preps, light bulbs, exam gloves, batteries) \$50 X 500 patients = \$25,000 X one level I STEMI center X 3 years = \$75,000 for the first 3 year period and \$25,000 X one level I STEMI center X 1 year = \$25,000 annually thereafter.
- m) Two-way communication link with emergency medical service vehicles / equipment necessary to communicate with emergency medical services regarding pre-hospital ECG STEMI findings \$1,200 apiece X one level I STEMI center = \$1,200 for the first year + \$200 for upkeep and maintenance for one level I STEMI center X 2 years (years 2 through 3) = \$400 for a total of \$1,600 for the first 3 year period and \$200 for upkeep and maintenance for one level I STEMI center X 1 year = \$200 annually thereafter.
- n) End-tidal carbon dioxide monitor \$3,900 X one level I STEMI center = \$3,900 for the first year and \$1,500 for the annual upkeep

and maintenance for one level I STEMI center X 2 years (years 2 through 3) = \$3,000 for a total of \$6,900 for the first 3 year period and \$1,500 for the annual upkeep and maintenance for one level I STEMI center X one level I STEMI center X 1 year = \$1,500 annually thereafter.

- o) Temperature control devices for patient and resuscitation fluids \$270 pack of 10 (Bair Hugger Therapy) X 30 = \$8,100 X one level I STEMI center X 3 years = \$24,300 for the first 3 year period and \$270 pack of 10 (Bair Hugger Therapy) X 30 = \$8,100 X one level I STEMI center X 1 year = \$8,100 annually thereafter.
- p) External pacemaker \$10 per set for pacer electrodes average cost (this will be used with the cardiac defibrillator already accounted for in g above) X 30 = \$300 X one level I STEMI center X 3 years = \$900 for the first 3 year period and \$10 per set X 30 = \$300 X one level I STEMI center X 1 year = \$300 annually thereafter.
- q) Transvenous pacemaker \$200 average cost of pacer wires and equipment X 30 = \$6,000 X one level I STEMI center X 3 years = \$18,000 + generator cost \$7,000 X 5 generators = \$35,000 for thefirst year + \$1,000 X 2 years (years 2 through 3) for maintenanceand upkeep of generators for a total of \$37,000 for the generatorsand a total of \$55,000 for the first 3 year period and\$200 average cost X 30 = \$6,000 + \$1,000 for the maintenance andupkeep of the generator = \$7,000 X one level I STEMI center X 1year = \$7,000 annually thereafter.

Total cost for resuscitation equipment for one level I STEMI center for the emergency room department for the first 3 year period -\$1,800 (letter a above) + \$37,500 (letter b above) + \$37,500 (letter c above) + \$73,990 (letter d above) + \$10,000 (letter e above) + \$75,000 (letter f above) + \$40,895 (letter g above) + \$540,000 (letter h above) + \$18,000 (letter i above) + \$22,500 (letter j above) + \$150,000 (letter k above) + \$75,000 (letter l above) + \$1,600 (letter m above) + \$6,900 (letter n above) + \$24,300 (letter o above) + \$900 (letter p above) + \$55,000 (letter q above) = \$1,170,885 for the first 3 year period.

Total cost for resuscitation equipment for one level I STEMI center for the emergency room department for annually thereafter - \$600 (letter a above) + \$12,500 (letter b above) + \$12,500 (letter c above) + \$25,075 (letter d above) + \$1,500 (letter e above) + \$25,000 (letter f above) + \$1,500 (letter g above) + \$180,000 (letter h above) + \$6,000 (letter i above) + \$7,500 (letter j above) + \$50,000 (letter k above) + \$25,000 (letter l above) + \$200 (letter m above) + \$1,500 (letter n above) + \$8,100 (letter o above) + \$300 (letter p above) + \$7,000 (letter q above) = \$364,275 for annually thereafter.

- 3) Resuscitation equipment for the intensive care unit
  - a) Airway control and ventilation equipment including laryngoscopes, endotracheal tubes, bag-mask resuscitator, and a mechanical ventilator - (laryngoscopes at least 2 X \$300 each =

\$600 X 3 years X one level I STEMI center = \$1,800 for the first 3

year period) + (endotracheal tubes of all sizes \$250 for a pack of 10 X 50 packs = \$12,500 X 3 years X one level I STEMI center = \$37,500 for the first 3 year period) + (bag-mask resuscitator \$250 for a pack of 10 X 50 packs X 3 years X one level I STEMI center = \$37,500 for the first 3 year period) + (mechanical ventilator \$7000 X one level I STEMI center X 1 year (the first year) + \$1,500 for the upkeep and maintenance of ventilator X 2 years (years 2 through 3) X one level I STEMI center = \$3,000 for a total of \$10,000 for the first 3 year period) = for a total of \$86,800 for the first 3 year period and (laryngoscopes at least 2 X \$300 each = \$600 X one level I STEMI center X 1 year = \$600) + (endotracheal tubes of all sizes \$250 for a pack of 10 X 50 packs = \$12,500 X one level I STEMI center X 1 year = \$12,500) + (bag-mask resuscitator \$250 for a pack of 10 X 50 packs = \$12,500 X one level I STEMI center X 1 year = \$12,500) + (mechanical ventilator \$1,500 for upkeep and maintenance X one level I STEMI center X 1 year = \$1500) = \$1,500 for a total of \$27,100 annually thereafter. b) Oxygen source with concentration controls - (air outlet \$70 X 7 = \$490 X one level I STEMI center X 1 year (the first year) = \$490 + \$150 for upkeep and maintenance of air outlets X 2 years (years 2 through 3) = \$300 for a total of \$790 for the first 3 year period) + (regulator \$35 X 25 = \$875 X 3 years X one level I STEMI center = \$2,625 for the first 3 year period) + (nasal cannula \$.40 X 500 = \$200 X 3 years X one level I STEMI center = \$600 for the first 3 year period) + (masks \$2.40 X 500 patients = \$1,200 X 3 years X one level I STEMI center = \$3,600 for the first 3 year period) + (ambu bags \$10.50 X 100 = \$1,050 X 3 years X one level I STEMI center = \$3,150 for the first 3 year period) + (oxygen tank \$70 X 300 = \$21,000 X 3 years X one level I STEMI center = \$63,000 for the first 3 year period) + (regulator for oxygen tank \$30 X 25 = \$750 X 3 years X one level I STEMI center = \$2,250 for the first 3 year period) + (oxygen tubing \$.40 for 7 feet X 500 patients = \$200 X 3 years X one level I STEMI center = \$600 for the first 3 year period) for a total of \$76,615 for the first 3 year period and (air outlet upkeep and maintenance = \$150 X one level I STEMI center X 1 year = \$150 + (regulator \$35 X 25 = \$875 X one level I STEMI center X 1 year = \$875) + (nasal cannula \$.40 X 500 = \$200 X one level I STEMI center X 1 year = \$200) + (masks \$2.40 X 500 patients = \$1,200 X one level I STEMI center X 1 year = \$1,200) + (ambu bags \$10.50 X 100 = \$1,050 X one level I STEMI center X 1 year = \$1,050) + (oxygen tank \$70 X 300 = \$21,000 X one level I STEMI center X 1 year = \$21,000) + (regulator for oxygen tank \$30 X 25 = \$750 X one level I STEMI center X 1 year = \$750) + (oxygen tubing \$.40 for 7 feet X 500 patients = \$200 X one level I STEMI center X 1 year = \$200) for a total of \$25,425 annually thereafter.

c) Cardiac emergency cart, including medications - \$1600 cart + medications and suction devices \$1000 = \$2,600 X one level I STEMI center X 1 year (the first year) = \$2,600 + \$1,000 medications X 2 years (years 2 through 3) = \$2,000 for a total of \$4,600 for the first 3 year period and \$1,000 medications and suction devices X one level 1 STEMI center X 1 year = \$1,000 annually thereafter.

- d) Telemetry, electrocardiograph capability, cardiac monitor and defibrillator - (telemetry \$800 X 500 patients = \$400,000 X 3 years X one level I STEMI center = \$1,200,000) + (electrocardiograph, cardiac monitor and defibrillator = \$37,895 X 1 year (first year) X one level I STEMI center = \$37,895 + \$1,500 X 2 years (years 2 through 3) X one level I STEMI center = \$3,000 for a total of \$40,895) for a total of \$1,240,895 for the first 3 year period and (telemetry \$800 X 500 patients = \$400,000 X one level I STEMI center X 1 year = \$400,000) + (\$1,500 for upkeep and maintenance of electrocardiograph, cardiac monitor and defibrillator X one level I STEMI center X 1 year = \$1,500) for a total of \$401,500 for one level I STEMI center annually thereafter.
- e) Electronic pressure monitoring and pulse oximetry (electronic pressure monitoring devices \$100 X 25 = \$2,500 X 3 years X one level I STEMI center = \$7,500) + (pulse oximetry devices \$100 X 25 = \$2,500 X 3 years X one level I STEMI center = \$7,500) for a total of \$15,000 for the first 3 year period and electronic pressure monitoring devices \$100 X 25 X one level I STEMI center X 1 year = \$2,500 + pulse oximetry devices \$100 X 25 X one level I STEMI center X 1 year = \$2,500 for a total of \$5,000 annually thereafter.
- f) End-tidal carbon dioxide monitor \$3,900 X one level I STEMI center X 1 year (first year) = \$3,900 for the first year + \$1,500 for annual upkeep and maintenance X one level I STEMI center X 2 years (years 2 through 3) = \$3,000 for a total of \$6,900 for the first 3 year period and \$1,500 X one level I STEMI center X 1 year = \$1,500 annually thereafter.
- g) Patient weight devices \$1000 X one level I STEMI center X 1 year (the first year) + \$250 annual upkeep and maintenance X one level I STEMI center X 2 years (years 2 through 3) = \$500 for a total of \$1,500 for the first 3 year period and \$250 X one level I STEMI center X 1 year = \$250 annually thereafter.
- h) Drugs, intravenous fluids and supplies (drugs are already accounted for in letter c above) (all standard intravenous fluids \$4.00 each X 500 patients = \$2,000 X 3 years X one level I STEMI center= \$6,000) + (all standard administration devices \$4.00 each X 500 patients = \$2,000 X 3 years X one level I STEMI center = \$6,000) + (all standard intravenous catheters \$4.00 each X 500 patients = \$2,000 X 3 years X one level I STEMI center = \$6,000) + (all standard intravenous catheters \$4.00 each X 500 patients = \$2,000 X 3 years X one level I STEMI center = \$6,000) for a total of \$18,000 for the first 3 year period and (all standard intravenous fluids \$4.00 each X 500 patients X one level I STEMI center X 1 year = \$2,000) + (all standard administration devices \$4.00 each X 500 patients X one level I STEMI center X 1 year = \$2,000) + (all standard intravenous catheters \$4.00 each X 500 patients X one level I STEMI center X 1 year = \$2,000) + (all standard intravenous catheters \$4.00 each X 500 patients X one level I STEMI center X 1 year = \$2,000) + (all standard intravenous catheters \$4.00 each X 500 patients X one level I STEMI center X 1 year = \$2,000) + (all standard intravenous catheters \$4.00 each X 500 patients X one level I STEMI center X 1 year = \$2,000) for a total of \$6,000 annually thereafter.