Public Education, and Training Programs for Stroke Center Designation.

(A) The stroke 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; resolve problems; and improve patient care. (I-R, II-R, III-R, IV-R)

1. The stroke 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. Door-to-needle time; (I-R, II-R, III-R)

B. Number of patients presenting within the treatment window; and (I-R, II-R, III-R)

C. Number of eligible patients treated with thrombolytics. (I-R, II-R, III-R)

2. The stroke center shall at least quarterly conduct a regular morbidity and mortality review meeting which shall be documented in the meeting minutes and/or the meeting attendance documents. (I-R, II-R, III-R, IV-R)

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

4. The stroke center shall conduct monthly reviews of pre-hospital stroke care including inter-facility transfers. **(**I-R, II-R, III-R, IV-R)

5. The stroke center shall participate in the emergency medical services regional system of stroke care in its respective emergency medical services region as defined in 19 CSR 30-40.302. (I-R, II-R, III-R, IV-R)

6. The stroke center shall document review of its cases of stroke patients who received U.S. Food and Drug Administration-approved thrombolytics and who remained at the referring hospital greater than ninety (90) minutes prior to transfer. (I-R, II-R, III-R)

7. The stroke center shall document its review of cases of stroke patients who did not receive U.S. Food and Drug Administration-approved thrombolytics and who remained greater than sixty (60) minutes at the referring hospital prior to transfer. (II-R, III-R, IV-R)

8. The stroke center shall review and monitor the core competencies of the physicians, practitioners, and nurses and document these core competencies have been met. (I-R, II-R, III-R, IV-R)

(B) The stroke center shall establish a patient and public education program to promote stroke prevention and stroke symptoms awareness. (I-R, II-R, III-R, IV-R)

(C) It is recommended that level I, II, and III stroke centers establish a professional education outreach program in catchment areas to provide training and other supports to improve care of stroke patients. (I-R, II-R, III-R)

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

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

2. A mechanism to assure that all nurses providing care to stroke patients complete a minimum of required continuing education as set forth in section (4) of this rule to become credentialed in stroke care; and (I-R, II-R, III-R, IV-R)

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

(E) The stroke center shall provide and monitor timely feedback to the emergency medical service providers and referring hospital, if involved. This feedback shall include, at least, diagnosis, treatment, and disposition of the patients. 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, III-R, IV-R)

(F) Stroke 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 Stroke Research for Stroke Center Designation.

(A) Level I stroke centers shall support an ongoing stroke research program as evidenced by any of the following:

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

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

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

4. Receipt of grants for study of stroke care; (I-R)

5. Participation in multi-center studies; and (I-R)

6. Epidemiological studies and individual case studies. (I-R)

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

AUTHORITY: section 192.006, RSMo 2000, and sections 190.185 and 190.241, RSMo Supp. 2012. Original rule filed Nov. 15, 2012, effective June 30, 2013.*

**Original authority: 192.006, RSMo 1993, amended 1995; 190.185, RSMo 1973, amended 1989, 1993, 1995, 1998, 2002; and 190.241, RSMo 1987, amended 1998, 2008.*

19 CSR 30-40.740 Definitions and Abbreviations Relating to ST-Segment Elevation Myocardial Infarction (STEMI) Centers

PURPOSE: This rule defines terminology related to STEMI centers.

(1) For the purposes of 19 CSR 30-40.750 and 19 CSR 30-40.760 the following terms shall mean:

(A) Acute—an injury or illness that happens or appears quickly and can be serious or life-threatening;

(B) Anesthesiologist assistant (AA)—a person who—

1. Has graduated from an anesthesiologist assistant program accredited by the American Medical Association's Committee on Allied Health Education and Accreditation or by its successor agency;

2. Has passed the certifying examination administered by the National Commission on Certification of Anesthesiologist Assistants;

3. Has active certification by the National Commission on Certification of Anesthesiologist Assistants;

4. Is currently licensed as an anesthesiologist assistant in the state of Missouri; and

5. Provides health care services delegated by a licensed anesthesiologist;

(C) Board-admissible/board-eligible—a physician who has applied to a specialty board of the American Board of Medical Specialties, the American Osteopathic Association Board of Osteopathic Specialists, or the Royal College of Physicians and Surgeons of Canada and has received a ruling that he or she has fulfilled the requirements to take the examinations. Board certification is generally obtained within five (5) years of the first appointment;

(D) Board-certified—a physician who has fulfilled all requirements, has satisfactorily completed the written and oral examinations, and has been awarded a board diploma in a specialty field by the American Board of Medical Specialties, the American Osteopathic Association Board of Osteopathic

Specialists, or the Royal College of Physicians and Surgeons of Canada;

(E) Cardiac catheterization laboratory—the setting within the hospital where percutaneous coronary interventions are done. Specialized staff, equipment, and protocol must be in place;

(F) Cardiac catheterization team—physicians and clinical staff who perform percutaneous coronary interventions and who are part of the clinical STEMI team;

(G) Cardiogenic shock—a life threatening condition in which the heart muscle does not pump enough blood to meet the body's needs;

(H) Cardiologist—a licensed physician with appropriate specialty training;

(I) Cardiology Service—an organizational component of the hospital specializing in the care of patients who have had STEMIs or some other cardiovascular condition or disorder;

(J) Catchment area—the surrounding area served by the institution (the STEMI center);

(K) Certified registered nurse anesthetist (CRNA)—a registered nurse who—

1. Has graduated from a school of nurse anesthesia accredited by the Council on Accreditation of Educational Programs of Nurse Anesthesia or its predecessor;

2. Has been certified as a nurse anesthetist by the Council on Certification of Nurse Anesthetists; and

3. Has been licensed in Missouri pursuant to Chapter 335, RSMo;

(L) Clinical staff—an individual that has specific training and experience in the treatment and management of STEMI patients. Examples include physicians, registered nurses, advanced practice nurses, physician assistants, pharmacists, and technologists;

(M) Clinical team—a team of health care professionals involved in the care of the STEMI patient and may include, but not be limited to, cardiologists, interventional cardiologists, cardiovascular surgeons, anesthesiologists, emergency medicine, and other STEMI center clinical staff. The clinical team is part of the hospital's STEMI team;

(N) Contiguous leads—the electrical cables that attach the electrodes on the patient to the electrocardiograph recorder and which are next to one another. They view the same general area of the heart;

(O) Continuing education—education approved or recognized by a national and/or state professional organization and/or STEMI medical director;

(P) Continuing medical education (CME)—the highest level of continuing education for physicians that is approved by a national and/or state professional organization and/or STEMI medical director;

(Q) Core team—a subunit of the hospital STEMI team which consists of a physician experienced in diagnosing and treating STEMI (usually the STEMI medical director) and at least one (1) other health care professional or qualified individual competent in STEMI care as determined by the hospital (usually the STEMI program manager/coordinator);

(R) Credentialed or credentialing—a hospital-specific system of documenting and recognizing the qualifications of medical staff and nurses and authorizing the performance of certain procedures and establishing clinical privileges in the hospital setting;

(S) Department—the Missouri Department of Health and Senior Services;

(T) Door-to-balloon-time—the time from arrival at the hospital door to percutaneous coronary intervention balloon inflation for the purpose of restoring blood flow in an obstructed coronary artery in the cardiac catheterization lab. This term is commonly abbreviated as D2B;

(U) Door-to-device-time—the time from patient arrival at the hospital to the time the device is in the affected cardiac blood vessel;

(V) Door-to-needle-time—the time from arrival at the hospital door to initiation of lytic therapy to restore blood flow in an obstructed blood vessel;

(W) Electrocardiogram (ECG/EKG)—a recorded tracing of the electrical activity of the heart. The heart rate, heartbeat regularity, size and chamber position, presence of any prior heart attack, current injury, and the effects of drugs or devices (i.e., pacemaker can be determined). An abnormal ECG pattern is seen during a heart attack because damaged areas of the heart muscle do not conduct electricity properly;

(X) Emergency medical service regions—the six (6) regions in the state of Missouri which are defined in 19 CSR 30-40.302;

(Y) First medical contact—a patient's initial contact with a health-care provider either pre-hospital, which could be contact with emergency medical service personnel or another medical provider, or in the hospital;

(Z) First medical contact to balloon or device time—the time from a patient's first medical contact with a health-care provider to the time when the balloon is inflated or the device is in the affected cardiac blood vessel;

(AA) First medical contact to hospital door time—the time from a patient's first medical contact with a health-care provider to the time when the patient arrives at the hospital door;

(BB) Hospital—an establishment as defined by section 197.020.2, RSMo, or a hospital operated by the state;

(CC) Immediately available (IA)—being present at bedside at the time of the patient's arrival at the hospital when prior notification is possible and no more than twenty (20) minutes from the hospital under normal driving and weather conditions;

(DD) In-house (IH)—being on the hospital premises twenty-four (24) hours a day;

(EE) Intermediate care unit—the functional division or facility of the hospital that provides care for STEMI patients admitted to the STEMI center;

(FF) Interventional cardiologist—a licensed cardiologist with the appropriate specialty training;

(GG) Lytic therapy (fibrinolysis/thrombolysis)—drug therapy used to dissolve clots blocking flow in a blood vessel. It refers to drugs used for that purpose, including recombinant tissue plasminogen activator. This type of therapy can be used in the treatment of acute ischemic stroke and acute myocardial infarction;

(HH) Mentoring relationship—a relationship in which a high volume percutaneous coronary interventions operator, often described as performing one hundred fifty (150) or more procedures per year, serves as a mentor for an operator who performs less than eleven (11) primary percutaneous coronary interventions per year;

(II) Missouri STEMI registry—a statewide data collection system comprised of key data elements as identified by the Department of Health and Senior Services used to compile and trend statistics of STEMI patients both pre-hospital and hospital, using a coordinated electronic reporting method provided by the Missouri Department of Health and Senior Services;

(JJ) Multidisciplinary team—a team of appropriate representatives of hospital units involved in the care of the STEMI patient. This team supports the care of the STEMI patient with the STEMI team;

(KK) Patient—an individual who is sick, injured, wounded, diseased, or otherwise incapacitated or helpless, or dead, excluding deceased individuals being transported from or between private or public institutions, homes, or cemeteries, and individuals declared dead prior to the time an ambulance is called for assistance;

(LL) Peer review system—is the process the STEMI center establishes for physicians to review STEMI cases on patients that are admitted to the STEMI center, transferred out of the STEMI center, or die as a result of

the STEMI (independent of hospital admission or hospital transfer status);

(MM) Percutaneous coronary intervention (PCI)—is a procedure used to open or widen narrowed or blocked blood vessels to restore blood flow supplying the heart. A primary percutaneous coronary intervention is one that is generally done on an emergency basis for a ST-elevation myocardial infarction (STEMI). Treatment occurs while the blood clot is still forming—usually within twenty-four (24) hours of onset, but ideally within two (2) hours of symptoms onset. An elective percutaneous coronary intervention is one that is done on a non-urgent basis to reduce signs and symptoms of angina;

(NN) Percutaneous coronary intervention window—the time frame in which percutaneous coronary intervention is most advantageous and recommended;

(OO) Phase I cardiac rehabilitation—an inpatient program that provides an individualized exercise and education plan for patients with cardiac illnesses;

(PP) Physician—a person licensed as a physician pursuant to Chapter 334, RSMo;

(QQ) Promptly available (PA)—arrival at the hospital at the patient's bedside within thirty (30) minutes after notification of a patient's arrival at the hospital;

(RR) Protocol—a predetermined, written medical care guideline, which may include standing orders;

(SS) Qualified individual—a physician, registered nurse, advanced practice registered nurse, and/or physician assistant that demonstrates administrative ability and shows evidence of educational preparation and clinical experience in the care of STEMI patients and is licensed by the state of Missouri;

(TT) Regional outcome data—data used to assess the regional process for pre-hospital, hospital, and regional patient outcomes;

(UU) Repatriation—the process used to return a STEMI patient to his or her home community from a level I or level II STEMI designated hospital after his or her acute treatment for STEMI has been completed. This allows the patient to be closer to home for continued hospitalization or rehabilitation and follow-up care as indicated by the patient's condition;

(VV) Reperfusion—the process of restoring normal blood flow to an organ or tissue that has had its blood supply cut off, such as after an ischemic stroke or myocardial infarction;

(WW) Requirement (R)—a symbol to indicate that a standard is a requirement for STEMI center designation at a particular level;

(XX) Review—is the inspection of a hospital to determine compliance with the rules of this chapter;

(YY) ST-elevation myocardial infarction (STEMI)—a myocardial infarction for which the electrocardiogram shows ST-segment elevation, usually in association with an acutely blocked coronary artery. A STEMI is one type of heart attack that is a potentially lethal condition for which specific therapies, administered rapidly, reduce mortality and disability. The more time that passes before blood flow is restored, the more damage that is done to the heart muscle;

(ZZ) STEMI call roster—a schedule 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;

(AAA) STEMI care—education, prevention, emergency transport, triage, acute care, and rehabilitative services for STEMI that requires immediate medical or surgical intervention or treatment;

(BBB) STEMI center—a hospital that is currently designated as such by the department to care for patients with ST-segment elevation myocardial infarctions.

1. A level I STEMI center is a receiving center staffed and equipped to provide total care for every aspect of STEMI care, including care for those patients with complications. It functions as a resource center for the hospitals within that region and conducts research.

2. A level II STEMI center is a receiving center staffed and equipped to provide care for a large number of STEMI patients within the region.

3. A level III STEMI center is primarily a referral center that provides prompt assessment, indicated resuscitation, and appropriate emergency intervention for STEMI patients to stabilize and arrange timely transfer to a Level I or II STEMI center, as needed.

4. A level IV STEMI center is a referral center in an area considered rural or where there are insufficient hospital resources to serve the patient population requiring STEMI care. The level IV STEMI center provides prompt assessment, indicated resuscitation, appropriate emergency intervention, and arranges and expedites transfer to a higher level STEMI center as needed;

(CCC) STEMI identification—a diagnosis is made on a basis of symptoms, clinical examination, and electrocardiogram changes, specifically ST-segment elevation;

(DDD) STEMI medical director—a physician designated by the hospital who is responsible for the STEMI service and performance improvement and patient safety programs related to STEMI care;

(EEE) STEMI program—an organizational component of the hospital specializing in the care of STEMI patients;

(FFF) STEMI program manager—a qualified individual designated by the hospital with responsibility for monitoring and evaluating the care of STEMI patients and the coordination of performance improvement and patient safety programs for the STEMI center in conjunction with the physician in charge of STEMI care;

(GGG) STEMI team—a component of the hospital STEMI program which consists of the core team and the clinical team;

(HHH) Symptom onset-to-treatment time—the time from symptom onset to initiation of therapy to restore blood flow in an obstructed blood vessel;

(III) Thrombolytics—drugs, including recombinant tissue plasminogen activator, used to dissolve clots blocking flow in a blood vessel. These thrombolytic drugs are used in the treatment of acute ischemic stroke and acute myocardial infarction; and

(JJJ) Transfer agreement—a document which sets forth the rights and responsibilities of two (2) hospitals regarding the inter-hospital transfer of patients.

AUTHORITY: section 192.006, RSMo 2000, and sections 190.185 and 190.241, RSMo Supp. 2012. Original rule filed Nov. 15, 2012, effective June 30, 2013.*

**Original authority: 192.006, RSMo 1993, amended 1995; 190.185, RSMo 1973, amended 1989, 1993, 1995, 1998, 2002; and 190.241, RSMo 1987, amended 1998, 2008.*

19 CSR 30-40.750 ST-Segment Elevation Myocardial Infarction (STEMI) Center Designation Application and Review

PURPOSE: This rule establishes the requirements for participation in Missouri's STEMI center program.

(1) Participation in Missouri's STEMI center program is voluntary and no hospital shall be required to participate. No hospital shall hold itself out to the public as a state-designated STEMI center unless it is designated as such by the Department of Health and Senior Services (department). Hospitals desiring STEMI center designation shall apply to the department either through the option outlined in section (2) or section (3). Only those hospitals found to be in compliance with the requirements of the rules of this chapter shall be designated by the department as STEMI

centers.

(2) Hospitals requesting to be reviewed and designated as a STEMI center by the department shall meet the following requirements:

(A) An application for STEMI center designation shall be made upon forms prepared or prescribed by the department and shall contain information the department deems necessary to make a fair determination of eligibility for review and designation in accordance with the rules of this chapter. The STEMI center review and designation application form, included herein, is available at the Health Standards and Licensure (HSL) office, online at the department's website at www.health.mo.gov, or may be obtained by mailing a written request to the Missouri Department of Health and Senior Services, HSL, PO Box 570, Jefferson City, MO 65102-0570. The application for STEMI cen- ter designation shall be submitted to the department no less than sixty (60) days and no more than one hundred twenty (120) days prior to the desired date of the initial designation or expiration of the current designation;

(B) Both sections A and B of the STEMI center review and designation application form, included herein, shall be complete before the department will arrange a date for the review. The department shall notify the hospital/STEMI center of any apparent omissions or errors in the completion of the STEMI center review and designation application form. When the STEMI center review and designation application form is complete, the department shall contact the hospital/STEMI center to arrange a date for the review;

(C) The hospital/STEMI center shall cooperate with the department in arranging for a mutually suitable date for any announced reviews;

(D) The different types of site reviews to be conducted on hospitals/STEMI centers seeking STEMI center designation by the department include:

1. An initial review shall occur on a hospital applying to be initially designated as a STEMI center. An initial review shall include interviews with designated hospital staff, a review of the physical plant and equipment, and a review of records and documents as deemed necessary to assure compliance with the requirements of the rules of this chapter;

2. A validation review shall occur on a designated STEMI center applying for renewal of its designation as a STEMI center. Validation reviews shall occur no less than every three (3) years. A validation review shall include interviews with designated STEMI center staff, a review of the physical plant and equipment, and a review of records and documents as deemed necessary to assure compliance with the requirements of the rules of this chapter; and

3. A focus review shall occur on a designated STEMI center in which an initial or validation review was conducted and substantial deficiency(ies) were cited. A review of the physical plant will not be necessary unless a deficiency(ies) was cited in the physical plant in the preceding validation review. The focus review team shall be comprised of a representative from the department and may include a qualified contractor(s) with the required expertise to evaluate corrections in areas where deficiencies were cited;

(E) STEMI center designation shall be valid for a period of three (3) years from the date the STEMI center/hospital is designated.

1. STEMI center designation shall be site specific and non-transferable when a STEMI center changes location.

2. Once designated as a STEMI center, a STEMI center may voluntarily surrender the designation at any time without giving cause, by contacting the department in writing. In these cases, the application and review process shall be completed again before the designation may be reinstated;

(F) For the purpose of reviewing previously designated STEMI centers and hospitals applying for STEMI center designation, the department shall use review teams consisting of qualified contractors. These review teams shall consist of one (1) STEMI coordinator or STEMI program manager who has experience in STEMI care and one (1) emergency medicine physician experienced in STEMI care. The review team shall also consist of at least one (1) and no more than two (2) cardiologist(s)/interventional cardiologist(s) who are experts in STEMI care. One (1) representative from the department will also be a participant of the review team. This representative shall coordinate the review with the hospital/STEMI center and the other review team members.

1. Any individual interested in becoming a qualified contractor to conduct reviews shall—

A. Send the department a curriculum vitae (CV) or résumé that includes his or her experience and expertise in STEMI care and whether an individual is in good standing with his or her licensing boards. A qualified contractor shall be in good standing with his or her respective licensing boards;

B. Provide the department evidence of his or her previous site survey experience (state and/or national designation survey process); and

C. Submit a list to the department that details any ownership he or she may have in a Missouri hospital(s), whether he or she has been terminated from any Missouri hospital(s), any lawsuits he or she has currently or had in the past with any Missouri hospital(s), and any Missouri hospital(s) for which his or her hospital privileges have been revoked.

2. Qualified contractors for the department shall enter into a written agreement with the department indicating, that among other things, they agree to abide by Chapter 190, RSMo, and the rules in this chapter, during the review process;

(G) Out-of-state review team members shall conduct levels I and II hospital/STEMI center reviews. Review team members are considered out-of-state review team members if they work outside of the state of Missouri. In-state review team members may conduct levels III and IV hospital/STEMI center reviews. Review team members are considered in-state review team members if they work in the state of Missouri. In the event that out-of-state reviewers are unavailable, levels I and II STEMI center reviews may be conducted by in-state reviewers from Emergency Medical Services (EMS) regions as set forth in 19 CSR 30-40.302 other than the region being reviewed with the approval of the director of the department or his/her designee. When utilizing in-state review teams, levels I and II hospital/STEMI centers shall have the right to refuse one (1) in-state review team or certain members from one (1) in-state review team;

(H) Hospitals/STEMI centers shall be responsible for paying expenses related to the costs of the qualified contractors to review their respective hospitals/STEMI center during initial, validation, and focus reviews. The department shall be responsible for paying the expenses of its representative. Costs of the review to be paid by the hospital/STEMI center include:

1. An honorarium shall be paid to each qualified contractor of the review team. Qualified contractors of the review team for level I and II STEMI center reviews shall be paid six hundred dollars ($600) for the day of travel per reviewer and eight hundred fifty dollars ($850) for the day of the review per reviewer. Qualified contractors of the review team for level III and IV STEMI center reviews shall be paid five hundred dollars ($500) for the day of travel per reviewer and five hundred dollars ($500) for the day of the review per reviewer. This honorarium shall be paid to each qualified contractor of the review team at the time the site survey begins;

2. Airfare shall be paid for each qualified contractor of the review team, if applicable;

3. Lodging shall be paid for each qualified contractor of the review team. The hospital/STEMI center shall secure the appropriate number of hotel rooms for the qualified contractors and pay the hotel directly; and

4. Incidental expenses, if applicable, for each qualified contractor of the review team shall not exceed two hundred fifty dollars ($250) and may include the following:

A. Airport parking;

B. Checking bag charges;

C. Meals during the review; and

D. Mileage to and from the review if no airfare was charged by the reviewer. Mileage shall be paid at the federal mileage rate for business miles as set by the Internal Revenue Service (IRS). Federal mileage rates can be found at the website www.irs.gov;

(I) Upon completion of a review, the qualified contractors from the review team shall submit a report of their findings to the department. This report shall state whether the specific standards for STEMI center designation have or have not been met and if not met, in what way they were not met. This report shall detail the hospital/STEMI center's strengths, weaknesses, deficiencies, and recommendations for areas of improvement. This report shall also include findings from patient chart audits and a narrative summary of the following areas: prehospital, hospital, STEMI service, emergency department, operating room, angiography suites, recovery room, clinical lab, intensive care unit, rehabilitation, performance improvement and patient safety programs, education, outreach, research, chart review, and interviews. The department shall have the final authority to determine compliance with the rules of this chapter;

(J) The department shall return a copy of the report to the chief executive officer, the STEMI medical director, and the STEMI program manager/coordinator of the hospital/STEMI center reviewed. Included within the report shall be notification indicating whether the hospital/STEMI center has met the criteria for STEMI center designation or has failed to meet the criteria for STEMI center designation as requested. Also, if a focus review of the STEMI center is required, the time frame for this focus review will be shared with the chief executive officer, the STEMI medical director, and the STEMI program manager/coordinator of the STEMI center reviewed;

(K) When the hospital/STEMI center is found to have deficiencies, the hospital/STEMI center shall submit a plan of correction to the department. The plan of correction shall include identified deficiencies, actions to be taken to correct deficiencies, time frame in which the deficiencies are expected to be resolved, and the person responsible for the actions to resolve the deficiencies. A plan of correction form shall be completed by the hospital and returned to the department within thirty (30) days after notification of review findings and designation. If a focus review is required, the STEMI center shall be allowed a minimum period of six (6) months to correct deficiencies;

(L) No hospital shall hold itself out as a STEMI center designated by the department until given written approval by the department. The department shall give written approval to the hospitals to begin holding themselves out as designated STEMI centers by the department after all initial STEMI reviews have been completed for those hospitals which applied for STEMI review and designation with the department during the first round of applications and the time for plans of corrections have expired;

(M) A STEMI center shall make the department aware in writing within thirty (30) days if there are any changes in the STEMI center's name, address, contact information, chief executive officer, STEMI medical director, or STEMI program manager/coordinator;

(N) Any person aggrieved by an action of the department affecting the STEMI center designation pursuant to Chapter 190, RSMo, including the revocation, the suspension, or the granting of, refusal to grant, or failure to renew a designation, may seek a determination by the Administrative Hearing Commission under Chapter 621, RSMo. It shall not be a condition to such determination that the person aggrieved seek reconsideration, a rehearing, or exhaust any other procedure within the department; and

(O) The department may deny, place on probation, suspend, or revoke such designation in any case in which it has reasonable cause to believe that there has been a substantial failure to comply with the provisions of Chapter 190, RSMo, or any rules or regulations promulgated pursuant to this chapter. If the department has reasonable cause to believe that a hospital is not in compliance with such provisions or regulations, it may conduct additional announced or unannounced site reviews of the hospital to verify compliance. If a STEMI center fails two (2) consecutive on-site reviews because of substantial noncompliance with standards prescribed by sections 190.001 to 190.245, RSMo, or rules adopted by the department pursuant to sections 190.001 to 190.245, RSMo, its center designation shall be revoked.

(3) Hospitals seeking STEMI center designation by the department based on their current certification as a STEMI center by the Joint Commission, American Heart Association, or American College of Cardiology shall meet the following requirements:

(A) An application for STEMI center designation by the department for hospitals that have been certified as a STEMI/chest pain center by the Joint Commission, American Heart Association, or American College of Cardiology shall be made upon forms prepared or prescribed by the department and shall contain information the department deems necessary to make a determination of eligibility for review and designation in accordance with the rules of this chapter. The application for STEMI certified hospital designation form, included herein, is available at the Health Standards and Licensure (HSL) office, or online at the department's website at www.health.mo.gov, or may be obtained by mailing a written request to the Missouri Department of Health and Senior Services, HSL, PO Box 570, Jefferson City, MO 65102-0570. The application for STEMI center designation shall be submitted to the department no less than sixty (60) days and no more than one hundred twenty (120) days prior to the desired date of the initial designation or expiration of the current designation;

(B) Both sections A and B of the application for STEMI certified hospital designation form, included herein, shall be complete before the department designates a hospital/STEMI center. The department shall notify the hospital/STEMI center of any apparent omissions or errors in the completion of the application for STEMI certified hospital designation form. Upon receipt of a completed and approved application, the department shall designate such hospital as follows:

1. The department shall designate a hospital as a level I STEMI center if such hospital has been certified as a comprehensive cardiac center by the Joint Commission;

2. The department shall designate a hospital as a level II STEMI center if such hospital has been certified as any of the following:

A. Mission lifeline Percutaneous Coronary Intervention (PCI)/STEMI receiving center by the American Heart Association;

B. Chest pain center with PCI center by the American College of Cardiology; or

C. Chest pain with PCI and resuscitation center by the American College of Cardiology;

3. The department shall designate a hospital as a level III STEMI center if such hospital has been certified as any of the following:

A. Mission lifeline non/PCI STEMI referral center by the American Heart Association;

B. Chest pain center by the Joint Commission;

C. Primary Acute Myocardial Infarction (AMI) center by the Joint Commission; or

D. Chest pain center by the American College of Cardiology;

(C) No hospital shall hold itself out as a STEMI center designated by the department until given written approval by the department. The department shall give written

approval to the hospitals to begin holding themselves out as designated STEMI centers by the department after all initial STEMI reviews have been completed for those hospitals which applied for STEMI review and designation with the department during the first round of applications and the time for plans of corrections have expired. This does not prohibit the hospitals from holding themselves out as certified STEMI/chest pain centers by the Joint Commission, the American Heart Association, or the American College of Cardiology;

(D) Annually from the date of designation by the department submit to the department proof of certification as a STEMI/chest pain center by the Joint Commission, the American Heart Association, or the American College of Cardiology and the names and contact information of the medical director of the STEMI/chest pain center and the program manager of the STEMI chest pain center;

(E) Within thirty (30) days of any changes submit to the department proof of certification as a STEMI/chest pain center by the Joint Commission, the American Heart Association, or the American College of Cardiology and the names and contact information of the medical director of the STEMI/chest pain center and the program manager of the STEMI/chest pain center;

(F) Submit to the department a copy of the certifying organization's final STEMI/chest pain center certification survey results within thirty (30) days of receiving such results;

(G) Submit to the department a completed application for STEMI certified hospital designation form every three (3) years;

(H) Participate in the emergency medical services regional system of STEMI care in its respective emergency medical services region as defined in 19 CSR 30-40.302;

(I) Any hospital designated as a level III STEMI center that is certified by the Joint Commission, the American Heart Association, or the American College of Cardiology shall have a formal agreement with a level I or level II STEMI center designated by the department for physician consultative services for evaluation of STEMI patients;

(J) Participate in local and regional emergency medical services systems by reviewing and sharing outcome data and providing training and clinical educational resources;

(K) Submit data to meet the data submission requirements in section 190.241, RSMo, and 19 CSR 30-40.760;

(L) The designation of a hospital as a STEMI center pursuant to section (3) shall continue if such hospital retains certification as a STEMI center by the Joint Commission, the American Heart Association, or the American College of Cardiology; and

(M) The department may remove a hospital's designation as a STEMI center if requested by the hospital or the department determines that the Joint Commission, the American Heart Association, or American College of Cardiology certification has been suspended or revoked. The department may also remove a hospital's designation as a STEMI center if the department determines the hospital's certification with the Joint Commission, the American Heart Association, or American College of Cardiology has expired. Any decision made by the department to withdraw the designation of a STEMI center that is based on the revocation or suspension of a certification by the Joint Commission, the American Heart Association, or the American College of Cardiology shall not be subject to judicial review.

MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES
SECTION OF HEALTH SERVICES AND LICENSURE

APPLICATION FOR STEMI CENTER REVIEW AND DESIGNATION

SECTION A

In accordance with the requirements of the Chapter 190 RSMo and the applicable regulations, this application is hereby submitted for review and designation as a STEMI center. Please complete all information applicable to the requested designation level.

Designation Level Requested ☐ I ☐ II ☐ III ☐ IV

HOSPITAL INFORMATION

Name Of Hospital (Name To Appear On Designation Certificate)	Telephone Number	
Address (Street And Number)	City	Zip

PROFESSIONAL INFORMATION

Chief Executive Officer	Chairman/President of Board of Trustees
STEMI Medical Director	STEMI Program Manager
Medical Director of Emergency Medicine	Medical Director of Intensive Care/Cardiac Care Unit

RESOURCE INFORMATION

STEMI Caseload	STEMI Team Activations	Cardiac Cath Lab Team Activations for STEMI	CT Capability ☐ FULL ☐ PARTIAL ☐ NONE
MRI Capability ☐ FULL ☐ PARTIAL ☐ NONE	Cardiothoracic Surgery Capability or Plan	ICU/CCU Beds	Cath Lab Suites
Cardiac Rehab ☐ Phase I ☐ Plan for Rehab	Cardiologists	Interventional Cardiologists	Cardiothoracic Surgeons
ED Physicians	Anesthesiologists/CRNAs & AAs	Avg Elective PCI/Primary PCIs over the last 3 years (not required for initial review)	Average STEMI cases lytics eligible/STEMI cases that receive lytics in the past 3 years (not required for initial review)

CERTIFICATION

We, the undersigned, hereby certify that the information provided in this application for STEMI center review and designation is true and accurate; and give assurance of the intent and ability of the hospital to comply with regulations promulgated under Chapter 190 RSMo.

We further certify that the hospital will comply with all recommendations for improvement contained in the STEMI center site review reports prepared by the Missouri Department of Health and Senior Services.

Date of application_____

Signed_____
Chairman/President of Board of Trustees, Owner, or one Partner of Partnership

Signed_____
Hospital Chief Executive Officer

Signed_____
STEMI Medical Director

Signed_____
Director of Emergency Medicine

MO 580

EMS

MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES
SECTION OF HEALTH STANDARDS AND LICENSURE
APPLICATION FOR STEMI CENTER REVIEW AND DESIGNATION

SECTION B

Please attach the following documentation to the application form.

Name of Hospital:

- ☐ Hospital organizational chart depicting the relationship of the STEMI services to other services and defining the organizational structure of the STEMI service.
- ☐ Job descriptions and CV for the STEMI medical director and STEMI coordinator/program manager.
- ☐ A narrative description of the administrative commitment for the STEMI center, including how STEMI center designation relates to the overall mission of the hospital.
- ☐ A current board resolution supporting the STEMI center.
- ☐ A narrative description of the catchment area for the STEMI center.
- ☐ A narrative description of the prehospital system including the hospital's participation in medical control, quality assurance, and education of the emergency medicine personnel.
- ☐ Hospital diversion policy.
- ☐ List of the STEMI medical director and STEMI program coordinator or program manager (core STEMI team) indicating the cardiac related continuing education for each over the past three (3) years. (Do not send continuing education information about the clinical STEMI team. This should be available at the time of the review.)
- ☐ Multidisciplinary team policy.
- ☐ List of all cardiologists, cardiothoracic surgeons, interventional cardiologists and emergency department physicians indicating cardiac-related CME for each over the past three (3) years.
- ☐ List of mentors, if applicable, their relationship to the hospital and the mentor plan.
- ☐ Narrative description of the system for notifying/activating STEMI team
- ☐ Cardiac catheterization lab team activation protocol.
- ☐ One-call cardiac catheterization lab activation by EMS protocol and/or by ED protocol.
- ☐ Copies of all transfer agreements pertaining to STEMI.
- ☐ Policy for cardiac rehabilitation.
- ☐ Protocols on post-discharge and post-transfer follow-up for STEMI patients.
- ☐ A narrative description of the STEMI quality improvement (QI) processes utilized by the hospital (Do not send copies of QI minutes or documents. These should be available at the time of review.)
- ☐ Examples of STEMI-related educational, outreach, and research projects undertaken by the hospital.

MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES
SECTION OF HEALTH STANDARDS AND LICENSURE

APPLICATION FOR ST-ELEVATION MYOCARDIAL INFARCTION (STEMI) CERTIFIED HOSPITAL DESIGNATION

SECTION A

In accordance with the requirements of Chapter 190, RSMo, and the applicable regulations, this application is hereby submitted for designation as a STEMI center. Please complete all information.	Organization's STEMI Identification Number

Current STEMI Certification Organization and Level

LEVEL I	LEVEL II	LEVEL III
☐ Joint Commission, Comprehensive Cardiac Center	☐ American Heart Association, Mission Lifeline Percutaneous Coronary Intervention (PCI)/ STEMI Receiving Center	☐ American Heart Association, Mission Lifeline Non/PCI STEMI Referral Center
	☐ American College of Cardiology, Chest Pain with PCI Center	☐ Joint Commission, Chest Pain Center
	☐ American College of Cardiology, Chest Pain with PCI and Resuscitation Center	☐ Joint Commission, Primary Acute Myocardial Infarction (AMI) Center
		☐ American College of Cardiology, Chest Pain Center

HOSPITAL INFORMATION

Name of Hospital (Name to Appear on Designation Certificate)		Telephone Number
Address (Street and Number)	City	Zip Code

PROFESSIONAL INFORMATION

Chief Executive Officer	Chairman/President of Board of Trustees
STEMI Medical Director (Name, email, and contact phone number)	STEMI Program Manager (Name, email, and contact phone number)

Section B

The following should be submitted to the department as indicated:

☐ Proof of STEMI certification with the Joint Commission, American Heart Association or American College of Cardiology with the expiration date of the certification.

☐ Copy of the final STEMI survey results from the Joint Commission, American Heart Association or American College of Cardiology.

If applying for Level III STEMI Center designation, the following should be submitted to the Department:

☐ Formal agreement with Level I or Level II STEMI center for physician consultative services for evaluation of STEMI patients.

CERTIFICATION

We, the undersigned, hereby certify that:

A. We will annually and within thirty (30) days of any changes submit to the department proof of STEMI certification with the Joint Commission, American Heart Association or American College of Cardiology.

B. We will annually and within thirty (30) days of any changes submit to the department names and contact information of our medical director and the program manager of the STEMI center.

C. We will submit to the department a copy of our final STEMI certification survey results from the Joint Commission, American Heart Association or American College of Cardiology within thirty (30) days of receiving such results.

D. We will participate in the emergency medical services regional system of STEMI care in our respective emergency medical services region as defined in 19 CSR 30-40.302.

E. We will participate in local and regional emergency medical services sytems by reviewing and sharing outcome data and providing training and clinical educational resources.

F. We will submit data to meet the data submission requirements outlined in section 190.241, RSMo, and 19 CSR 30-40.760.

G. We understand that our designation as a STEMI center by the department shall continue only if our hospital remains certified as a STEMI center by the Joint Commission, American Heart Association or American College of Cardiology.

Date of application _____

Signed _____
Chairman/President of Board of Trustees, Owner, or one Partner of Partnership

Signed _____
Hospital Chief Executive Officer

Signed _____
STEMI Medical Director

Signed _____
Director of Emergency Medicine

AUTHORITY: sections 190.185 and 192.006, RSMo 2016, and section 190.241, RSMo Supp. 2017. Original rule filed Nov. 15, 2012, effective June 30, 2013. Emergency amendment filed Feb. 2, 2018, effective Feb. 12, 2018, expired Aug. 10, 2018. Amended: Filed Feb. 2, 2018, effective Aug. 30, 2018.*

**Original authority: 190.185, RSMo 1973, amended 1989, 1993, 1995, 1998, 2002; 190.241, RSMo 1987, amended 1998, 2008, 2016, 2017; and 192.006, RSMo 1993, amended 1995.*

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, III-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, III-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 healthcare professionals 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 thirty-six (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 take-off 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, III-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-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 CRNAs 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 board-admissible physician in emergency medicine by the American Board of Medical Specialties, the American Osteopathic Association Board of Osteopathic Specialists, 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 board-admissible 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)

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

unit A. The STEMI center intensive care 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)

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/IH, III-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's 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 post-anesthesia 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 cardiothoracic 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 board-certified 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 intervention-related 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 pre-hospital 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, III-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, effective June 30, 2013.*

**Original authority: 190.185, RSMo 1973, amended 1989, 1993, 1995, 1998, 2002 and 190.241, RSMo 1987, amended 1998, 2008.*

19 CSR 30-40.770 Community-based or Regional Plan for Emergency Medical Services for Trauma, ST-Segment Elevation Myocardial Infarction (STEMI), or Stroke

PURPOSE: This rule establishes the procedures for the submission of a community-based or regional plan for the transportation of patients to stroke, STEMI, or trauma centers.

(1) A community or region developing its own transportation plan for stroke, STEMI, and trauma patients may submit a plan at any time and shall ensure that it complies with section 190.200.3, RSMo. Such a plan shall also—

(A) Identify the geographic boundaries of the area covered by the plan;

(B) Designate, and provide contact information for, an individual, plan's designee who will serve as the plan's point of contact throughout the plan's approval and administration process; and

(C) Identify individuals involved in the drafting, planning, and/or consultation of the plan, who shall collectively be known as the "planning committee."

(2) Upon completion of a community-based or regional plan, the plan shall be submitted to the chair of the regional emergency medical services advisory committee defined by section 190.102, RSMo, and the regional emergency medical services medical director defined by section 190.103, RSMo, for the geographic area covered by the plan. Upon receipt of a plan submitted pursuant to the provisions of section 190.200, RSMo, the chair and medical director shall forward the plan to the emergency medical services medical director's advisory committee (the committee) as defined by section 190.103, RSMo, for consideration. Within forty-five (45) days of receipt of a community-based or regional plan, the committee shall meet and complete its review of the plan. Upon a finding of good cause, the chair of the committee may grant the committee a reasonable extension of time for review of the plan.

(3) In reviewing a community-based or regional plan, the committee shall determine whether the plan meets the requirements of section 190.200.3, RSMo, and this rule.

(4) At the conclusion of its review, the committee shall vote on the question of whether

to recommend or not recommend the plan for approval. If a majority of the committee votes to recommend the plan for approval, said recommendation shall constitute *prima facie* evidence that the plan meets the requirements of section 190.200.3, RSMo, and should be approved. The committee shall attach such conditions (such as regular analysis and reporting of medical outcomes to the committee) to its recommendation for approval as it deems appropriate to ensure that the plan continues to meet the requirements of Chapter 190, RSMo. If a majority of the committee votes to not recommend the plan, that decision, with an explanation of the reason(s) for the decision, shall be provided in writing to the plan's designee. A community or region receiving a non-recommendation by the committee may modify its plan according to the committee's reason(s) for non-recommendation and resubmit the plan within thirty (30) days directly to the committee.

(5) Following recommendation of a community-based or regional plan, the committee shall forward the plan to the Director of the Department of Health and Senior Services (director) for approval. The director shall have thirty (30) days to review the plan for its compliance with section 190.200.3, RSMo. At the conclusion of the review, the director shall approve or disapprove the plan. If the director disapproves the plan, the reason(s) for disapproval shall be provided in writing to the plan's designee along with the right to appeal the director's decision. The director's decision shall be the final agency action. A community or region whose plan is not approved by the director may modify its plan according to the director's reason(s) for disapproval and resubmit the plan within thirty (30) days directly to the committee and follow the approval process as outlined herein.

(6) Once a plan is approved by the director, the planning committee shall—

(A) Notify all agencies impacted by the plan of the manner in which emergency medical care is modified within the region based on the plan;

(B) Monitor per the plan the related medical and system outcomes and regional resources and capacity;

(C) Revise the plan when indicated based on medical and system outcomes, emerging clinical research or guidelines, or when revision is indicated based on changes in capacity or other related issues and submit through the approval process as outlined herein; and

(D) Notify the committee and department at least thirty (30) days before ceasing to use the plan.

AUTHORITY: section 192.006, RSMo 2000, and sections 190.185 and 190.241, RSMo Supp. 2012. Original rule filed Nov. 15, 2012, effective June 30, 2013.*

**Original authority: 192.006, RSMo 1993, amended 1995; 190.185, RSMo 1973, amended 1989, 1993, 1995, 1998, 2002; and 190.241, RSMo 1987, amended 1998, 2008.*

19 CSR 30-40.780 Definitions and Abbreviations Relating to the Transport Protocol for Stroke and the Transport Protocol for ST-Segment Elevation Myocardial Infarction (STEMI) Patients

PURPOSE: This rule defines terminology related to the state transport protocol for stroke and the state transport protocol for STEMI.

(1) The following definitions and abbreviations shall be used in the interpretation of the rule in 19 CSR 30-40.790:

(A) Field is the specific area or location, outside of the hospital, where an injury, accident, or medical emergency occurs requiring immediate assistance of medical personnel for the purpose of treating or transporting the sick or injured to another location for treatment;

(B) Local and regional process is the process that has been established and agreed upon specifically pertaining to a local city, town, or small district, or a combination of localities forming a regional area. This is not the community-based or regional plan;

(C) Lytics are thrombolytic drugs, including recombinant tissue plasminogen activator, used to dissolve clots blocking flow in a blood vessel. These lytic/thrombolytic drugs are used in the treatment of acute ischemic stroke and acute myocardial infarction;

(D) Lytic/therapeutic window is the period of time during which lytics can be administered following the onset of symptoms in order to reduce brain or heart injury;

(E) Lytic therapy (fibrinolysis/thrombolysis) is drug therapy used to dissolve clots blocking flow in a blood vessel. It refers to drugs used for that purpose, including recombinant tissue plasminogen activator. This type of therapy can be used in the treatment of acute ischemic stroke and acute myocardial infarction;

(F) Lytic/thrombolytic ineligible patients are those patients identified as ineligible for lytic/thrombolytic therapy due to specific contraindications. An appropriate course of treatment will be utilized when lytic/thrombolytic therapy is contraindicated;

(G) Out of the lytic/therapeutic or potential therapeutic window is the period of time following the accepted time (lytic/therapeutic window and potential therapeutic window) frames for specific therapies for a patient suffering an ischemic stroke;

(H) Outside of the percutaneous coronary intervention (PCI) window is the period of time following the accepted time frame in which PCI is most advantageous and recommended;

(I) Percutaneous coronary intervention (PCI) is a procedure used to open or widen narrowed or blocked blood vessels to restore blood flow supplying the heart;

(J) Percutaneous coronary intervention (PCI) window is a time frame in which PCI is most advantageous and recommended;

(K) Potential therapeutic window is the period of time after the accepted window for lytic therapy has expired in which interventional therapy may be beneficial in restoring blood flow during an ischemic stroke; and

(L) Recombinant tissue plasminogen activator (t-PA also known as rt-PA) is a thrombolytic (clot-dissolving) agent, the goal of which is to destroy the thrombus (clot) within the blood vessel by stimulating fibrinolysis (clot breakdown) to allow restoration of blood flow.

AUTHORITY: sections 190.185 and 190.241, RSMo Supp. 2012. Original rule filed Nov. 15, 2012, effective June 30, 2013.*

**Original authority: 190.185, RSMo 1973, amended 1989, 1993, 1995, 1998, 2002 and 190.241, RSMo 1987, amended 1998, 2008.*

19 CSR 30-40.790 Transport Protocol for Stroke and ST-Segment Elevation Myocardial Infarction (STEMI) Patients

PURPOSE: This rule establishes protocols for transporting suspected STEMI patients by severity and time of onset to the STEMI center where resources exist to provide appropriate care and suspected stroke patients by severity and time of onset to the stroke center where resources exist to provide appropriate care.

(1) All ground and air ambulances shall use the following state transport protocol for suspected stroke patients except in those circumstances listed in sections (3), (4), and (5) of this rule:

(A) Step 1—Assess for life threatening conditions (serious airway or respiratory compromise or immediate life threatening conditions that cannot be managed in the field).

1. If there are life threatening conditions, transport the patient to the nearest appropriate facility for stabilization prior to transport to a stroke center. Consider air/ground/facility options for timely and medically appropriate care (particularly in non-urban areas).

2. If there are no life threatening conditions, go to step 2 below in subsection (1)(B); and

(B) Step 2—Assess the duration of onset of symptoms (time last known well).

1. Group 1—If the patient is within the lytic/therapeutic window then transport to a level I, II, or III stroke center according to local and regional process. Consider the time for transport, the patient's condition, air/ground/hospital options for timely and medically appropriate care (particularly in non-urban areas), and the treatment windows. Continue to reassess the patient. If the patient's condition changes, then start back with subsection (1)(A) and follow the state stroke protocol outlined in section (1) starting from subsection (1)(A) and on according to the patient's condition. Consider out-of-state transport based on local and regional process for bi-state regions.

2. Group 2—If the patient is within the potential therapeutic window then transport to a level I stroke center or transport to a level I, II, or III stroke center according to local and regional process. Consider the time for transport, the patient's condition, air/ground/hospital options for timely and medically appropriate care (particularly in non-urban areas), and the treatment windows. Continue to reassess the patient. If the patient's condition changes then start back with subsection (1)(A) and follow the state stroke protocol outlined in section (1) starting from subsection (1)(A) and on according to the patient's condition. Consider out-of-state transport based on local and regional process for bi-state regions.

3. Group 3—If the patient is out of the lytic/therapeutic and potential therapeutic windows, then transport to a level I, II, III, or IV stroke center according to local and regional process. Consider the time for transport, the patient's condition, air/ground/hospital options for timely and medically appropriate care (particularly in non-urban areas), and the treatment windows. Continue to reassess the patient. If the patient's condition changes, then start back with subsection (1)(A) and follow the state stroke protocol outlined in section (1) starting from subsection (1)(A) and on according to the patient's condition. Consider out-of-state transport based on local and regional process for bi-state regions.

(2) All ground and air ambulances shall use the following state transport protocol for suspected STEMI patients except in those circumstances listed in sections (3), (4), and (5) of this rule:

(A) Step 1—Assess for life threatening conditions (serious airway or respiratory compromise or immediate life threatening conditions that cannot be managed in the field).

1. If there are life threatening conditions, then transport the patient to the nearest appropriate facility for stabilization prior to transport to a STEMI center. Consider air/ground/facility options for timely and medically appropriate care (particularly in non-urban areas).

2. If there are no life threatening conditions, then go on to step 2 below in subsection (2)(B) and assess vital signs and perform an electrocardiogram (ECG) if the ground or air ambulance has that capability. An electrocardiogram and electrocardiogram equipment are recommended;

(B) Step 2—Determine if the patient's vital signs and the electrocardiogram identifies the following:

1. ST-elevation in two (2) contiguous leads or new or presumed new left bundle branch block; and

2. The patient has two (2) of the following three (3) signs of cardiogenic shock:

A. Hypotension where systolic blood pressure is less than ninety millimeters of mercury (90 mmHG);

B. Respiratory distress where respirations are less than ten (10) or greater than twenty-nine (29) per minute; or

C. Tachycardia where the heart rate is greater than one hundred beats per minute (100 BPM);

3. If the patient has an electrocardiogram with ST-elevation in two (2) contiguous leads or new or presumed new left bundle branch block and two (2) of the three (3) signs of cardiogenic shock then transport to a level I STEMI center according to local and regional process. Consider the time for transport, the patient's condition, and the air/ground/hospital options for timely and medically appropriate care (particularly in non-urban areas);

4. If initial transport from the scene to a level I STEMI center is prolonged, then consider transporting to the nearest appropriate facility for stabilization prior to transport to a level I STEMI center;

5. Continue to reassess the patient. If the patient's condition changes, then start back at subsection (2)(A) above and follow the state STEMI protocol outlined in section (2) starting from subsection (2)(A) and on according to the patient's condition;

6. Consider out-of-state transport based on local and regional process for the bi-state region;

7. Communicate electrocardiogram findings to the hospital;

8. If the patient has a positive electrocardiogram but is negative for signs of cardiogenic shock, then go to step 3 in subsection (2)(C) below; and

(C) Step 3—Calculate the estimated time from STEMI identification with the patient to expected percutaneous coronary intervention (PCI) with the patient in order to determine whether the patient is within the percutaneous cornary intervention window. Communicate electrocardiogram findings to the hospital. If no ST-elevation or new or presumed new left bundle branch block then consider a fifteen-(15-) lead electrocardiogram, if available.

1. Group 1—If the patient is within the PCI window or the patient has had chest pain longer than twelve (12) hours or the patient is lytic/thrombolytic ineligible then transport to a level I or level II STEMI center according to local and regional process. Consider the time for transport, the air/ground/hospital options for timely and medically appropriate care (particularly in non-urban areas), the patient's condition, and all treatment windows. Consider the ischemic time and the potential role for lytics (within the lytic window) at an intervening STEMI center in route to the percutaneous coronary intervention center if approaching longer times within the percutaneous coronary intervention window. Continue to reassess the patient. If the patient's condition changes, then start back at subsection (2)(A) and follow the state STEMI protocol outlined in section (2) starting from subsection (2)(A) and on according to the patient's condition. Consider out-of-state transport based on local and regional process for bi-state regions.

2. Group 2—If the patient is outside the percutaneous coronary intervention window and within the lytic/therapeutic window, or outside both windows and the patient has no other known complications, then transport to the STEMI center (level I, II, III, or IV) according to local and regional process. Consider the time for transport, air/ground/hospital options for timely and medically appropriate care (particularly in non-urban areas), the patient's condition, and all the treatment windows. Consider the lytic window and the potential for STEMI center lytic administration when determining the destination(s). Continue to reassess the patient. If the patient's condition changes, then start back at subsection (2)(A) above and follow

the state STEMI protocol outlined in section (2) starting from subsection (2)(A) and on according to the patient's condition. Consider out-of-state transport based on local and regional process for bi-state regions.

(3) When initial transport from the scene of illness or injury to a STEMI or stroke center would be prolonged, the STEMI or stroke patient may be transported to the nearest appropriate facility for stabilization prior to transport to a STEMI or stroke center.

(4) Nothing in this rule shall restrict an individual patient's right to refuse transport to a recommended destination. All ground and air ambulances shall have a written process in place to address patient competency and refusal of transport to the recommended destination.

(5) Ground and air ambulances are not required to use the state transport protocols in this rule when the ambulance is using a community-based or regional plan that has been approved by the department pursuant to section 190.200.3, RSMo, that waives the requirements of this rule. Copies of flow charts of an algorithm depicting the stroke and STEMI state transport protocols are available at the Health Standards and Licensure (HSL) office, online at the department's website www.health.mo.gov, or may be obtained by mailing a written request to the Missouri Department of Health and Senior Services, HSL, PO Box 570, Jefferson City, MO 65102-0570 or by calling (573) 751-6400.

AUTHORITY: sections 190.185 and 190.241, RSMo Supp. 2012. Original rule filed Nov. 15, 2012, effective June 30, 2013.*

**Original authority: 190.185, RSMo 1973, amended 1989, 1993, 1995, 1998, 2002 and 190.241, RSMo 1987, amended 1998, 2008.*

19 CSR 30-40.800 EMT-Community Paramedic, Community Paramedic Program, and Medical Director for EMT-Community Paramedic Program

PURPOSE: This rule establishes the requirements for certification and recertification as an EMT-Community Paramedic, the scope of practice and authority to practice for an EMT-Community Paramedic, requirements for a medical director of an ambulance service which utilizes EMT-Community Paramedics and implements a community paramedic program, and requirements for a community paramedic program.

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) Application Requirements for Emergency Medical Technician Community Paramedic (EMT-CP) Certification.

(A) Each applicant for certification as an EMT-CP shall be currently licensed with the Emergency Medical Services (EMS) Bureau as an EMT-Paramedic in the state of Missouri. If the application is approved, the applicant's length of certification as an EMT-CP will begin on the issuance date of the certification as an EMT-CP by the department and end on the applicant's Missouri EMT-Paramedic license expiration date.

(B) Each applicant for certification as an EMT-CP shall submit an application approved by the EMS Bureau which is included herein. This application shall be submitted to the EMS Bureau either via mail to the Department of Health and Senior Services, Emergency Medical Services (EMS) Bureau, PO Box 570, Jefferson City, MO 65102-0570 or online at www.health.mo.gov.

1. Each applicant shall attach to the application a certified copy of his/her community paramedic certification program transcript.

2. Each applicant shall provide the necessary information on his/her application so the EMS Bureau can perform criminal history checks to determine the recency and relatedness of any criminal convictions prior to the certification of the applicant.

3. Each applicant shall truthfully and accurately provide all information and certification required on the EMS Bureau application for community paramedic certification. Incomplete or inaccurate information on an application shall be cause to deny a certification or take action upon a certification.

4. If, after submitting an application, the applicant identifies an error or if any contact information changes after the applicant is certified as an EMT-CP, then the applicant shall submit the correction in writing to the EMS Bureau at the Department of Health and Senior Services, EMS Bureau, PO Box 570, Jefferson City, MO 65102-0570.

(2) EMT-Community Paramedic (EMT-CP) Certification Requirements.

(A) The applicant for EMT-CP certification shall have successfully completed a community paramedic certification program from a college, university, or educational institution that meets the following requirements:

1. Is accredited by the Committee on Accreditation of Educational Programs for the Emergency Medical Services Professions (CoAEMSP) or prior to January 1, 2016, conducted a pilot program meeting or exceeding the requirements in paragraphs (2)(A)2. and (2)(A)3. below;

2. Provides a minimum of sixty (60) hours of didactic training and practical and lab skills covering at a minimum the following subjects:

A. The Community Paramedic's Role in the Health Care System which includes training on mental health illnesses and Alzheimer's disease;

B. The Social Determinants of Health Model;

C. The Role of the Community Paramedic in the Community;

D. Developing Cultural Competency; and

E. Personal Safety and Wellness of the Community Paramedic; and

3. Includes at least forty (40) hours of clinical experience in a clinical setting.

(3) EMT-Community Paramedic (EMT-CP) Recertification Requirements.

(A) An applicant for recertification as an EMT-CP shall be currently licensed with the EMS Bureau as an EMT-Paramedic in the state of Missouri.

(B) The applicant for recertification as an EMT-CP shall certify to the EMS Bureau that the applicant has successfully completed four (4) hours of continuing education annually which relate to the community paramedic topics outlined in subparagraphs (2)(A)2.A.–E. above. These annual four (4) hours will be in addition to the one-hundred forty-four (144) hours of continuing education required for relicensure as an EMT-Paramedic pursuant to 19 CSR 30-40.342(3)(B)2.A.

(C) The applicant for recertification as an EMT-CP shall list the following information about his/her continuing education on the applicant's application:

1. Name or type of course;

2. The division or module;

3. The number of hours of the course;

4. The training entity accreditation number, EMS Bureau approval number, or other accrediting agency which taught the course; and

5. The date the applicant completed the