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. Only those hospitals found by review to be in compliance with the requirements of the rules of this chapter shall be designated by the department as STEMI centers.