

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

PROPOSED AMENDMENT

19 CSR 30-40.750 ST-Segment Elevation Myocardial Infarction (STEMI) Center Designation Application and Review. The department is amending sections (1), (2) and (3) and renumbering throughout; adding a new section (3); and adding the form included after the rule.

PURPOSE: This amendment adds an option and establishes requirements for hospitals which are certified as STEMI centers by the Joint Commission, the American Heart Association or the American College of Cardiology to become designated as level I, II or III STEMI centers without being reviewed by DHSS (the department). This amendment also adds an application for these hospitals which are certified as STEMI centers by the Joint Commission, the American Heart Association or the American College of Cardiology to complete in order to become designated as level I, II or III STEMI centers by the department. This amendment also adds focus reviews to be conducted after an initial review. Additionally, this amendment prohibits hospitals from holding themselves out as STEMI centers designated by the department until STEMI initial reviews have been completed by the department for those hospitals applying to be reviewed and designated by the department as STEMI centers during the first round of applications. The department will give all hospitals designated as STEMI centers through sections (2) and (3) written approval of the date these hospitals may begin holding themselves out as department designated STEMI centers during the first round of applications.

(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 [*by review*] to be in compliance with the requirements of the rules of this chapter shall be designated by the department as STEMI centers. (2)[(A)] **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, 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 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[.];

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

[(A)] 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;

[(B)] 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

[(C)] 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[.];

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

[(A)] 1. STEMI center designation shall be site specific and non-transferable when a STEMI center changes location.

[(B)] 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[.];

[(4)] (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. 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.

[(A)] **1.** Any individual interested in becoming a qualified contractor to conduct reviews shall—

[1.] **A.** Send the department a curriculum vitae (CV) or [resume] **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;

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

[3.] **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.

[(B)] **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[.];

[(5)] **(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[.];

[(6)] **(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:

[(A)] **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;

[(B)] **2.** Airfare shall be paid for each qualified contractor of the review team, if applicable;

[(C)] **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

[(D)] **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:

[1.] **A.** Airport parking;

[2.] **B.** Checking bag charges;

[3.] **C.** Meals during the review; and

[4.] **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;

[(7)] **(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;

[(8)] **(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;

[(9)] **(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;

[(10)] (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[.];

[(11)] (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

[(12)] (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 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 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 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 center/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.

AUTHORITY: section 192.006, RSMo 2000, and sections 190.185 and 190.241, RSMo Supp. [2012] 2017. 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.*

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500.00) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500.00) in the aggregate.

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