
EMERGENCY RULE

Title 19 – DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30 – Division of Regulation and Licensure Chapter 40 – Comprehensive Emergency Medical Services Systems Regulations

EMERGENCY AMENDMENT

19 CSR 30-40.750 ST-Segment Elevation Myocardial Infarction (STEMI) Center Designation Application and Review. The department is amending sections (2) and (3), and amending the Application for STEMI center designation form.

PURPOSE: This amendment adds virtual review requirements, clarifies honorarium and payment requirements for virtual reviews, updates language to be consistent with HB 2331 amendment, adds a requirement that hospitals must provide the department with required medical records and quality improvement documentation or be revoked, changes the requirements for hospitals participating in local and regional emergency medical services system, removes the data submission requirement for hospitals verified or certified by department approved national certifying bodies, and updates what the hospitals have to submit to the department to confirm verification or certification with national certifying bodies and when to submit changes of this verification or certification. This amendment also makes changes to the application for STEMI center designation form included herein in section (3)(A) by changing the certification section to reflect the new requirements for notification of changes and participation in local and regional emergency medical services systems and removing the data submission requirement.

EMERGENCY STATEMENT: This emergency amendment makes several updates to this rule that were prompted by the passage of House Bill 2331 that passed during the 2022 legislative session. House Bill 2331 made changes to sections 190.241 and 190.245, RSMo which became effective on August 28, 2022. House Bill 2331 allows the department to conduct virtual reviews rather than only on-site reviews of these STEMI centers. House Bill 2331 added a requirement for hospitals to provide the department with quality improvement documentation necessary for the department to conduct a STEMI review or the hospital's STEMI center designation will be revoked. Finally, House Bill 2331 made changes about how hospitals which are verified or certified by national certifying bodies designated by the department need to report changes of their verification or certification to the department and how these hospitals participate in local and regional emergency medical services systems. This emergency amendment is necessary in order to make this rule consistent with the changes made in House Bill 2331 that became effective on August 28, 2022. This emergency amendment is in the interest of both the hospitals and the department to ensure that hospitals which are applying for designation with the department because they are certified or verified by a department approved national designating body do not have to provide the department with any additional information than what is now required by the changes made to section 190.241, RSMo by HB 2331. Finally, the emergency amendment is necessary for the department to conduct virtual reviews instead of only on-site reviews. Due to complications caused by COVID-19, the department is having a difficult time in getting qualified contractors to review the STEMI centers and hospitals are still being challenged with COVID-19 in their hospitals. National certifying bodies began using virtual reviews during the COVID-19 pandemic and these virtual reviews have proven to be a solution to conducting reviews while COVID-19 is still an issue for out-of-state- qualified contractors

traveling to these reviews and for hospitals having to handle a review team in their hospitals. As a result, the department finds a compelling governmental interest, which requires this emergency action. The scope of this emergency amendment is limited to the circumstances creating the emergency and complies with the protections extended in the Missouri and United States Constitutions. The department believes this emergency amendment is fair to all interested persons and parties under the circumstances. This emergency amendment was filed November 21, 2022, becomes effective December 7, 2022, and expires on June 4, 2023.

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

(D) **The department may conduct an onsite review, a virtual review or a combination thereof on the hospitals/STEMI centers. For announced reviews that are scheduled with the hospitals/STEMI centers, the department will make the hospitals/STEMI centers aware at least thirty (30) days prior to the scheduled review whether the department intends that the review will be conducted onsite and/or virtually. Due to unforeseen circumstances, the department may need to change whether the review is conducted onsite and/or virtually less than thirty (30) days before the announced review. The department will contact the hospitals/STEMI centers to make the hospitals/STEMI centers aware of any changes about how the review will be conducted, either onsite and/or virtually, prior to the date of the announced review.** 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. **This review may occur onsite and/or virtually;**

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. **This review may occur onsite and/or virtually;** 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. **This review may occur onsite and/or virtually;**

(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

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again before the designation may be reinstated;

(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 **whether the review occurs on-site or virtually**. 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]* **one thousand four hundred fifty dollars (\$1,450)** 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]* **one thousand dollars (\$1,000)** per reviewer. This honorarium shall be paid to each qualified contractor of the review team at the time the site survey begins **if on-site or prior to the review begins if the review is conducted virtually**;

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, **unless the review is conducted virtually**. 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. **If the reviewer solely participated virtually in the review and did not travel by vehicle to the review, then no mileage shall be paid.** 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;

If the reviewer solely participated virtually in the review and did not travel by vehicle to the review, then no mileage shall be paid. 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) Hospitals/STEMI centers being reviewed by the department through a virtual survey shall do the following:

1. Provide a videoconferencing platform to be used for the hospital/STEMI center virtual review;

2. Provide a live tour of the hospital;

3. Ensure the videoconferencing platform used during the review is compliant with state and federal laws for protected health information;

4. Assign an onsite visit coordinator for the review. The onsite visit coordinator role cannot be fulfilled by the STEMI program manager. This onsite visit coordinator will be responsible for the logistical aspects of the virtual review. Responsibilities include, at least, the following:

- A. Scheduling the videoconferencing meetings;
- B. Sending out calendar invitations;
- C. Providing Electronic Medical Record (EMR) access to designated individuals;
- D. Ensuring all required participants are on the videoconferencing line

for the various parts of the review; and

E. Sending separate calendar invitations for each section of the virtual review to hospital staff, qualified contractors and the department;

5. Assign one staff navigator per qualified contractor to

help remotely navigate the EMR, the patient performance improvement patient safety (PIPS) documentation, and supporting documentation. The staff navigator role cannot be fulfilled by the STEMI program manager, the STEMI program medical director, the STEMI program registrar or the onsite visit coordinator for the review. The individuals designated as the staff navigators shall be familiar with navigating through the EMR;

6. Provide the department with requested patient care report information for the review no later than thirty (30) days prior to the virtual review;

7. Provide the department with requested medical records, PIPS documentation, registry report and all supporting documentation at least seven (7) days prior to the virtual visit through a method that is compliant with state and federal laws for protected health information;

8. Schedule a prereview call with the qualified contractors, the department, the STEMI program medical director, the STEMI program manager, the staff navigators and the onsite visit coordinator approximately one (1) week prior to the virtual review;

9. Test the functionality of the videoconferencing platform for the live tour of the hospital prior to the prereview call; and

10. Provide a list of attendees for the review meeting and their roles to the review team and the department prior to the virtual review;

(J) The department may conduct an on-site review of the hospital prior to the virtual review to ensure that the hospital meets the requirements for STEMI center designation;

[(I)](K) 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)](L) 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)](M) 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

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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)](N) 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)](O) 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;

(P) Failure of a hospital/STEMI center to provide all medical records and quality improvement documentation necessary for the department to conduct a STEMI review in order to determine if the requirements of 19 CSR 30-40.760 have been met shall result in the revocation of the hospital/STEMI center's designation as a STEMI center;

[(N)](Q) 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)](R) The department may deny, place on probation, suspend, or revoke such designation in any case in which it has **[reasonable cause to believe] determined** 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] determined** 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 **or verification** 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 **or verified** 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;

(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 **or receipt of a certificate or verification, the hospital shall** 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. **A certificate or verification as a STEMI center by the Joint Commission, the American Heart Association, or the American College of Cardiology shall accompany the application for STEMI certified hospital designation form. A hospital shall report to the department in writing within thirty (30) days of the date the hospital no longer is certified or verified as a STEMI center by the Joint Commission, the American Heart Association or the American College of Cardiology for which the hospital used to receive its corresponding designation by the department as a STEMI center, whether because the hospital voluntarily surrendered this certificate or verification, or because the hospital's certificate or verification was suspended or revoked by the Joint Commission, the American Heart Association or the American College of Cardiology or expired;***

[(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)](E) *Participate in local and regional emergency medical services systems [by reviewing and sharing outcome data and] for purposes of providing training [and], sharing clinical educational resources, and collaborating on improving patient outcomes;*

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

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~~[(L)]~~(F) 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)]~~(G) 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 or verification 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 or verification 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 or verification by the Joint Commission, the American Heart Association, or the American College of Cardiology shall not be subject to judicial review.

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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			
<p style="text-align: center; margin: 0;">LEVEL I</p> <input type="checkbox"/> Joint Commission, Comprehensive Cardiac Center	<p style="text-align: center; margin: 0;">LEVEL II</p> <input type="checkbox"/> American Heart Association, Mission Lifeline Percutaneous Coronary Intervention (PCI)/ STEMI Receiving Center <input type="checkbox"/> American College of Cardiology, Chest Pain with PCI Center <input type="checkbox"/> American College of Cardiology, Chest Pain with PCI and Resuscitation Center <input type="checkbox"/> Joint Commission, Primary Heart Attack Center	<p style="text-align: center; margin: 0;">LEVEL III</p> <input type="checkbox"/> American Heart Association, Mission Lifeline Non/PCI STEMI Referral Center <input type="checkbox"/> Joint Commission, Chest Pain Center <input type="checkbox"/> Joint Commission, Primary Acute Myocardial Infarction (AMI) Center <input type="checkbox"/> American College of Cardiology, Chest Pain Center <input type="checkbox"/> Joint Commission, Acute Heart Attack Ready 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:			
<input type="checkbox"/> Proof of STEMI certification with the Joint Commission, American Heart Association or American College of Cardiology with the expiration date of the certification.			
CERTIFICATION			
<p>We, the undersigned, hereby certify that:</p> <p>A. Within thirty (30) days of any changes or receipt of a certificate or verification, we will submit to the department proof of STEMI certification with the Joint Commission, American Heart Association or American College of Cardiology.</p> <p>B. Within thirty (30) days, we will submit to the department any changes in the names and/or contact information of our medical director and the program manager of the STEMI center.</p> <p>C. Within thirty (30) days that our hospital is no longer certified or verified with the Joint Commission, the American Heart Association or the American College of Cardiology, whether because we voluntarily surrendered our certification or verification or because our certification or verification has been suspended or revoked by the Joint Commission, the American Heart Association or American College of Cardiology or expired, we will report this change in writing to the department.</p> <p>D. We will participate in local and regional emergency medical services systems for purposes of providing training, sharing clinical educational resources, and collaborating on improving patient outcomes.</p> <p>E. 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, the American Heart Association or the American College of Cardiology.</p>			
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	

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*AUTHORITY: sections 190.185 and 192.006, RSMo 2016, and section 190.241, RSMo Supp. [2019] 2022. 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. Emergency amendment filed Aug. 28, 2019, effective Sept. 12, 2019, expired March 9, 2020. Amended: Filed Aug. 28, 2019, effective March 30, 2020. Emergency amendment filed Nov. 21, 2022, effective Dec. 7, 2022, expires June 4, 2023. An emergency amendment and a proposed amendment covering this same material will be published in the Jan. 3, 2023, issue of the **Missouri Register**.*

PUBLIC COST: This emergency amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the time the emergency is effective.

PRIVATE COST: This emergency amendment will cost private entities one thousand dollars (\$1,000) in the time the emergency is effective.

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FISCAL NOTE PRIVATE COST

- I. Department Title: Department of Health and Senior Services
Division Title: Division of Regulation and Licensure
Chapter Title: 19 CSR 30-40.750 ST-Segment Elevation Myocardial Infarction (STEMI)
Center Designation Application and Review.**

Rule Number and Title:	19 CSR 30-40.750 ST-Segment Elevation Myocardial Infarction (STEMI) Center Designation Application and Review
Type of Rulemaking:	Emergency Amendment

II. SUMMARY OF FISCAL IMPACT

Affected Agency or Political Subdivision	Estimated Cost of Compliance in the Aggregate
Four (4) hospitals/STEMI centers	\$1,000 in the time the emergency is effective
TOTAL COSTS =	\$1,000 in the time the emergency is effective

III. WORKSHEET

Four (4) private hospitals/STEMI centers reviewed during the time that the emergency amendment is effective X \$250.00 = \$1,000 for the hospitals/STEMI centers reviewed during the time that the emergency amendment is effective.

IV. ASSUMPTIONS

There are currently forty-five (45) Level I-IV STEMI centers designated with the department. The department anticipates that four (4) private hospitals/STEMI centers will be reviewed during the time the emergency amendment is in effect.

All hospitals have internet capability, programs for the use of virtual meetings and the use of a secure means to send documents which contain information subject to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The department estimates that costs associated with the additional virtual survey requirements in 19 CSR 30-40.750 will cost hospitals/STEMI centers approximately \$250 based on the use of the computer programs to send this information and to utilize for virtual meetings and during the review (including the live tour).