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 (2) and (3) and renumbering throughout sections (2) and (3).

PURPOSE: This amendment adds virtual review requirements, clarifies honorarium and payment requirements for virtual reviews, updates language to be consistent with House Bill 2331 which made changes to sections 190.241 and 190.245, RSMo, effective August 28, 2022, adds Comprehensive Heart Attack Center by the Joint Commission as a type of certification or verification that hospitals may have in order for the department to designate hospitals as level II STEMI centers, adds a requirement that hospitals must provide the department with required medical records and quality improvement documentation or be revoked, allows hospitals to continue to be designated as long as the hospital has submitted an application and the department has not yet been able to conduct a review before expiration, 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 adding Comprehensive Heart Attack Center, 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.

(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. **Expiration of the designation shall occur unless the STEMI center applies for validation review within this three – (3-) year period and the department is unable to conduct a review before the designation expires.**
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;
(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;

(I) **Hospitals/STEMI centers being reviewed 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 pre-review 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 pre-review 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 process to ensure that the hospital meets the requirements for STEMI center designation;

(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 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;
(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;
C. Chest pain with PCI and resuscitation center by the American College of Cardiology; [*or*]
D. Primary Heart Attack Center by the Joint Commission; **or**
E. Comprehensive Heart Attack Center by the Joint Commission;
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. Acute Heart Attack Ready Center by the Joint Commission;
D. Primary Acute Myocardial Infarction (AMI) center by the Joint Commission; or
E. 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 **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**, sharing** [*and*] 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;*

(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.

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 November 21, 2022, effective December 7, 2022, expires June 4, 2023.*

**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.*

***Pursuant to Executive Order 21-07, 19 CSR 30-40.750, subsections (2)(A) and (2)(B) and section (3) was suspended from April 2, 2020 through May 1, 2021. Pursuant to Executive Order 21-09, 19 CSR 30-40.750, paragraph (2)(D)2. and subsections (2)(F) and (2)(G) was suspended from April 2, 2020 through December 31, 2021.*

PUBLIC COST: *This proposed amendment will cost state agencies or political subdivisions two thousand five hundred dollars ($2,500) during a three (3) year designation period.*

PRIVATE COST: *This proposed amendment will cost private entities eight thousand seven hundred fifty dollars ($8,750) during a three (3) year designation period.*

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Nicole Gamm at Nicole.Gamm@health.mo.gov or Missouri Department of Health and Senior Services, P.O. Box 570, Jefferson City, Missouri 65101-0570. 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.*