

**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 30-40.420 Trauma Center Designation Requirements. The department is amending sections (2) and (3) and renumbering throughout sections (2) and (3).

PURPOSE: This amendment decreases validation reviews to every three (3) years, adds virtual review requirements, adds honorarium and payment requirements for virtual reviews and on-site reviews, adds qualified contractor requirements, updates language to be consistent with the House Bill 2331 amendment of sections 190.241 and 190.245, RSMo that became effective August 28, 2022, 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, changes the requirements for hospitals participating in the local and regional emergency medical services systems, 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, removes the data submission requirement for hospitals verified by American College of Surgeons, and removes American College of Surgeons Level IV trauma centers as an alternate designation since the American College of Surgeons has recently eliminated the Level IV trauma center verification. This amendment also makes changes to the application for trauma center designation form included herein in section (3)(A) by removing the American College of Surgeons Level IV trauma centers as an alternate designation and changing the certification section to reflect the new requirements for notification of changes and participation in the local and regional emergency medical services systems and removing the data submission requirement.

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

(F) The review of hospitals for trauma center designation 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. **The department may conduct an onsite review, a virtual review or a combination thereof on the hospitals/trauma centers. For announced reviews that are scheduled with the hospitals/trauma centers, the department will make the hospitals/trauma 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/trauma centers to make the hospitals/trauma 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 cost of any and all site reviews shall be paid by each applicant hospital or renewing trauma center unless adequate funding is available to the department to pay for reviews;

The cost of any and all site reviews shall be paid by each applicant hospital or renewing trauma center unless adequate funding is available to the department to pay for reviews. **Hospitals/trauma centers shall be responsible for paying expenses related to the cost of the qualified contractors to review their respective hospitals/trauma centers 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/trauma 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 levels I and II trauma center reviews shall be paid one thousand four hundred fifty dollars (\$1,450) per reviewer. Qualified contractors of the review team for levels III and IV trauma center reviews shall be paid 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 beginning of the review 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/trauma 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;

(G) For the purpose of reviewing trauma centers and hospitals applying for trauma center designation, the department shall use review teams consisting of two (2) surgeons and one (1) emergency physician who are experts in trauma care and one (1) trauma nurse coordinator/trauma program manager experienced in trauma center review. The team shall be disinterested politically and financially in the hospitals to be reviewed. Out-of-state review teams shall conduct levels I and II reviews. In-state reviewers may conduct level III reviews. In the event that out-of-state reviewers are unavailable, level II reviews may be conducted by in-state reviewers from EMS regions other than the region being reviewed with approval of the director of the Department of Health and Senior Services or his/her designee. When utilizing in-state review teams, the level II trauma center shall have the right to refuse one (1) review team.

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

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

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

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

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

(J) Validation reviews shall occur every [*five (5)*] **three (3)** years;

(K) Hospitals/Trauma centers being reviewed through a virtual survey shall do the following:

1. Provide a videoconferencing platform to be used for the hospital/trauma 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 trauma 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 trauma program manager, the trauma program medical director, the trauma 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 trauma program medical director, the trauma 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;

(L) 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 trauma designation;

[(K)] (M) Upon completion of a review, the reviewers shall submit a report of their findings to the department. The report shall state whether the specific standards for trauma center designation have or have not been met; if not met, in what way they were not met. The report shall include the patient chart audits and a narrative summary to include pre-hospital, hospital, trauma service, emergency department, operating room, recovery room, clinical lab, intensive care unit, blood bank, rehabilitation, performance improvement and patient safety programs, education, outreach, research, chart review, and interviews. The department has final authority to determine compliance with the rules of this chapter;

[(L)] (N) Within thirty (30) days after receiving a review report, the department shall return a copy of the report in whole to the chief executive officer of the hospital reviewed. Included with the report shall be notification indicating that the hospital has met the criteria for trauma center designation or has failed to meet the criteria for the designation level for which it applied and options the hospital may pursue;

[(M)] (O) If a verification review is required, the hospital shall be allowed a period of six (6) months to correct deficiencies. A plan of correction form shall be provided to the department and shall be completed by the hospital and returned to the department within thirty (30) days after notification of review findings;

[(N)] (P) Once a review is completed, a final report shall be prepared by the department. The final report shall be public record and shall disclose the standards by which the reviews were conducted and whether the standards were met. The reports filed by the reviewers shall be held confidential and shall be disclosed only to the hospital's chief executive officer or an authorized representative;

[(O)] (Q) The department shall have the authority to put on probation, suspend, revoke, or deny trauma center designation if *[there is reasonable cause to believe]* **the department has determined** that there has been a substantial failure to comply with the requirements of the rules in this chapter. Once designated as a trauma center, a hospital may voluntarily surrender the designation at any time without giving cause, by contacting the department. In these cases, the application and review process shall be completed again before the designation may be reinstated;

[(P)] (R) Trauma center designation shall be valid for a period of *[five (5)]* **three (3)** years from the date the trauma center is designated. Expiration of the designation shall occur unless the trauma center applies for validation review within this *[five-(5-)]* **three (3)** year period. Trauma center designation shall be site specific and not transferable when a trauma center changes location; and

[(Q)] (S) The department shall investigate complaints against trauma centers. Failure of the hospital to cooperate in providing documentation and interviews with appropriate staff may result in revocation of trauma center designation. Any hospital, which takes adverse action toward an employee for cooperating with the department regarding a complaint, is subject to revocation of trauma center designation.

(T) Failure of a hospital/trauma center to provide all medical records and quality improvement documentation necessary for the department to conduct a trauma review in order to determine if the requirements of 19 CSR 30-40.430 have been met shall result in the revocation of the hospital/trauma center's designation as a trauma center.

(3) Hospitals seeking trauma center designation by the department based on their current verification as a trauma center by the American College of Surgeons shall meet the following requirements:

(B) Both sections A and B of the application for trauma verified hospital designation form, included herein, shall be complete before the department designates a hospital/trauma center. The department shall notify the hospital/trauma center of any apparent omissions or errors in the completion of the application for trauma verified 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 trauma center if such hospital has been verified as a level I trauma center (adult and pediatric) by the American College of Surgeons;

2. The department shall designate a hospital as a level II trauma center if such hospital has been verified as a level II trauma center (adult and pediatric) by the American College of Surgeons;

3. The department shall designate a hospital as a level III trauma center if such hospital has been verified as a level III trauma center (adult and pediatric) by the American College of Surgeons;

[4. The department shall designate a hospital as a level IV trauma center if such hospital has been verified as a level IV trauma center (adult and pediatric) by the American College of Surgeons;]

5. The department shall designate a hospital as a level I pediatric trauma center if such hospital has been verified as a level I pediatric trauma center (only treats children) by the American College of Surgeons;

6. The department shall designate a hospital as a level II pediatric trauma center if such hospital has been verified as a level II pediatric trauma center (only treats children) by the American College of Surgeons;

7. The department shall designate a hospital as a level I trauma center if such hospital has been verified as a level I trauma center (only treats adults) by the American College of Surgeons; and

8. The department shall designate a hospital as a level II trauma center if such hospital has been verified as a level II trauma center (only treats adults) by the American College of Surgeons;

(C) *[Annually from the date of designation by the department submit to the department proof of verification as a trauma center by the American College of Surgeons and the names and contact information of the medical director of the trauma center and the program manager of the trauma center;*

(D)] Within thirty (30) days of any changes **or receipt of a verification, the hospital shall** submit to the department proof of verification as a trauma center by the American College of Surgeons and the names and contact information of the medical director of the trauma center and the program manager of the trauma center. **Verification as a trauma center by the American College of Surgeons shall accompany the application for trauma verified hospital designation form. A hospital shall report to the department in writing within thirty (30) days of the date the hospital no longer is verified as a trauma center by the American College of Surgeons for which the hospital used to receive its corresponding designation with the department as a trauma center, whether because the hospital voluntarily surrendered this verification, or because the hospital's verification was suspended or revoked by the American College of Surgeons or expired;**

[(E) Submit to the department a copy of the verifying organization's final trauma center verification survey results within thirty (30) days of receiving such results;

(F) Submit to the department a completed application for trauma verified hospital designation form every three (3) years;

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

*(H) (D) 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;***

[(I) Submit data to meet the data submission requirements in 19 CSR 30-40.430;

(J)] (E) The designation of a hospital as a trauma center pursuant to section (3) shall continue if such hospital retains verification as a trauma center by the American College of Surgeons; and

*[(K)] (F) The department may remove a hospital's designation as a trauma center if requested by the hospital or **if** the department determines that the verification by the American College of Surgeons has been suspended or revoked. The department may also remove a hospital's designation as a trauma center if the department determines the hospital's verification with the American College of Surgeons has expired. Any decision made by the department to withdraw the designation of a trauma center that is based on the revocation or suspension of a verification by the American College of Surgeons shall not be subject to judicial review.*

AUTHORITY: sections 190.176 and 190.185, RSMo 2016, and section 190.241, RSMo Supp. [2017] 2022. Emergency rule filed Aug. 28, 1998, effective Sept. 7, 1998, expired March 5, 1999. Original rule filed Sept. 1, 1998, effective Feb. 28, 1999. Amended: Filed May 19, 2008, effective Jan. 30, 2009. 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 November 21, 2022, effective December 7, 2022, expires June 4, 2023.*

**Original authority: 190.176, RSMo 1998, amended 2008, 2011; 190.185, RSMo 1973, amended 1989, 1993, 1995, 1998, 2002; and 190.241, RSMo 1987, amended 1998, 2008, 2016, 2017.*

***Pursuant to Executive Order 21-07, 19 CSR 30-40.420, subsection (2)(A) and section (3) was suspended from April 2, 2020 through May 1, 2021. Pursuant to Executive Order 21-09, 19 CSR 30-40.420, subsections (2)(G) and (2)(J) and section 190.241.3, RSMo was suspended from April 2, 2020 through December 31, 2021.*

PUBLIC COST: This proposed amendment will cost state agencies or political subdivisions eighty-two thousand one hundred fifty dollars (\$82,150) during the three (3) year designation period.

PRIVATE COST: This proposed amendment will cost private entities twenty-six thousand two hundred dollars (\$26,200) during the 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.*