
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 30-40.420 Trauma Center Designation Requirements.

The department is amending sections (2) and (3) and renumbering throughout, and amending the application for trauma center designation form.

PURPOSE: This amendment decreases validation reviews to every three (3) years, adds virtual review requirements, updates language to be consistent with House Bill 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 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, and removes the data submission requirement. This amendment also makes changes to the application for trauma center designation form included herein in section (3)(A) 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 (HB) 2331 during the 2022 legislative session. HB 2331 made changes to sections 190.241 and 190.245, RSMo. These changes became effective on August 28, 2022. HB 2331 requires trauma centers to be reviewed by the department every three (3) years. House Bill 2331 also allows the department to conduct virtual reviews rather than only on-site reviews of these stroke centers. HB 2331 added a requirement for hospitals to provide the department with quality improvement documentation necessary for the department to conduct a trauma review or the hospital's trauma center designation will be revoked. Finally, HB 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 HB 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 trauma 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 June 4, 2023.

(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;

(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

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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 prereview 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 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.

(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 center 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 prehospital, 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:

[(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)](C) 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.;*

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~~[(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 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.

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MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES
SECTION OF HEALTH STANDARDS AND LICENSURE
APPLICATION FOR TRAUMA VERIFIED HOSPITAL DESIGNATION

In accordance with the requirements of Chapter 190, RSMo, and the applicable regulations, this application is hereby submitted for designation as a trauma center. Please complete all information.		Organization's Trauma Identification Number
CURRENT TRAUMA VERIFICATION ORGANIZATION AND LEVEL		
<p style="text-align: center;">ADULT AND PEDIATRIC (TREATS ADULTS AND CHILDREN)</p> <input type="checkbox"/> Level I Trauma Center by the American College of Surgeons <input type="checkbox"/> Level II Trauma Center by the American College of Surgeons <input type="checkbox"/> Level III Trauma Center by the American College of Surgeons <input type="checkbox"/> Level IV Trauma Center by the American College of Surgeons	<p style="text-align: center;">PEDIATRIC (TREATS CHILDREN ONLY)</p> <input type="checkbox"/> Level I Pediatric Trauma Center by the American College of Surgeons <input type="checkbox"/> Level II Pediatric Trauma Center by the American College of Surgeons	<p style="text-align: center;">ADULT (TREATS ADULTS ONLY)</p> <input type="checkbox"/> Level I Trauma Center by the American College of Surgeons <input type="checkbox"/> Level II Trauma Center by the American College of Surgeons
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	
Trauma Medical Director (Name, email, and contact phone number)	Trauma Program Manager (Name, email, and contact phone number)	
The following should be submitted to the department as indicated:		
<input type="checkbox"/> Proof of trauma verification with the American College of Surgeons with the expiration date of the verification.		
CERTIFICATION		
<p>We, the undersigned, hereby certify that:</p> <p>A. Within thirty (30) days of any changes or receipt of a verification, we will submit to the department proof of trauma verification with the American College of Surgeons.</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 our trauma center.</p> <p>C. Within thirty (30) days of the date that our hospital is no longer verified by the American College of Surgeons, whether because we voluntarily surrendered our verification or because our verification has been suspended or revoked by the American College of Surgeons or has 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 trauma center by the department shall continue only if our hospital remains verified as a trauma center by the American College of Surgeons.</p>		
Date of application _____		
Signed _____ Chairman/President of Board of Trustees, Owner, or one Partner of Partnership	Signed _____ Hospital Chief Executive Officer	
Signed _____ Trauma Medical Director	Signed _____ Director of Emergency Medicine	

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*AUTHORITY: section[s 190.176 and] 190.185, RSMo 2016, and sections **190.176 and** 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 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 30-40.420 Trauma Center Designation Requirements.

Rule Number and Title:	19 CSR 30-40.420 Trauma Center Designation Requirements
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/trauma 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/trauma centers reviewed during the time that the emergency amendment is effective X \$250.00 = \$1,000 for the hospitals/trauma centers reviewed during the time that the emergency amendment is effective.

IV. ASSUMPTIONS

There are currently twenty-two (22) Level I-III trauma centers designated with the department. The department anticipates that four (4) private hospitals/trauma centers will be reviewed during the time the emergency amendment is effective.

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 30-40.720 will cost hospitals/trauma 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).