

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 (1), (2), and (3) and renumbering throughout; adding a new sections (3); and adding the form included after the rule.

PURPOSE: This amendment adds an option and establishes requirements for hospitals which are verified as trauma centers by the American College of Surgeons to become designated as level I, II III or IV trauma centers without being reviewed by DHSS (the department). This amendment also adds an application for these hospitals which are verified as trauma centers by the American College of Surgeons to complete in order to become designated as level I, II III or IV trauma centers, by the department. This amendment also changes the EMS Bureau to the department.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome and expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) Participation in Missouri's trauma center program is voluntary and no hospital shall be required to participate. No hospital shall in any way indicate to the public that it is a trauma center unless that hospital has been designated as such by the [*Emergency Medical Services (EMS) Bureau*] **Department of Health and Senior Services (the department)**. Hospitals desiring trauma center designation shall apply to the [*EMS Bureau*] **department either through the option outlined in section (2) or section (3)**. Only those hospitals found [*by review*] to be in compliance with the requirements of the rules in this chapter shall be designated by the [*EMS Bureau*] **department** as trauma centers.

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

(A) The application required for trauma center designation shall be made upon forms prepared or prescribed by the [*EMS Bureau*] **department** and shall contain information the [*EMS Bureau*] **department** deems necessary to make a fair determination of eligibility for review and designation in accordance with the rules of this chapter.

[(A)] (B) An application shall include the following information: designation level requested; name, address, and telephone number of hospital; name of chief executive officer, chairman/president of board of trustees, surgeon in charge of trauma care, trauma nurse coordinator/program manager, director of emergency medicine, and director of trauma intensive care; number of emergency department trauma caseload, trauma team activations, computerized tomography scan capability, magnetic resonance imaging capability, operating rooms, intensive care unit/critical care unit beds, burn beds, rehabilitation beds, trauma surgeons, neurosurgeons, orthopedists, emergency department physicians, anesthesiologists, certified registered nurse anesthetists, pediatricians, and pediatric surgeons; date of application; and signatures of the chairman/president of board of trustees, hospital chief executive officer, surgeon in charge of trauma, and director of emergency medicine. The trauma center review and designation application form, included herein, is available at the [EMS Bureau] **Health Standards and Licensure (HSL)** office or may be obtained by mailing a written request to Missouri Department of Health and Senior Services, [EMS Bureau] **HSL**, PO Box 570, Jefferson City, MO 65102-0570.

[(B)] (C) The [EMS Bureau] **department** shall notify the hospital of any apparent omissions or errors in the completion of the application and shall contact the hospital to arrange a date for the review.

[(C)] (D) Failure of a hospital to cooperate in arranging for a mutually suitable date for review shall constitute forfeiture of application when a hospital's initial review is pending or suspension of designation when a hospital's verification or validation review is pending.

[(D)] (E) Hospitals designated as trauma centers under the previous designation system shall maintain their designation until a review is conducted using the rules of this chapter.

[(3)] (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 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 [EMS Bureau] **department** to pay for reviews.

[(A)] (G) For the purpose of reviewing trauma centers and hospitals applying for trauma center designation, the [EMS Bureau] **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.

[(B)] (H) Any substantial deficiencies cited in the initial review or the validation review regarding patient care issues, especially those related to delivery of timely surgical intervention, shall require a focused review to be conducted. When deficiencies involve documentation or policy or equipment, the hospital's plan of correction shall be submitted to the [EMS Bureau] **department** and verified by [EMS Bureau] **department** personnel.

[(C)] (I) The verification review shall be conducted in the same manner and detail as initial and validation reviews. A review of the physical plant will not be necessary unless a deficiency was cited in the physical plant in the preceding initial or validation review. If deficiencies relate only to a limited number of areas of hospital operations, a focused review shall be conducted. The review team for a focused review shall be comprised of review team members with the required expertise to evaluate corrections in the specified deficiency area.

[(D)] (J) Validation reviews shall occur every five (5) years. *[Level I and II trauma centers undergoing American College of Surgeons reverification review at shorter intervals may incorporate EMS Bureau personnel in these reviews and, if they successfully pass reverification and meet all requirements herein, submit that review for EMS Bureau reverification.]*

[(E)] (K) Upon completion of a review, the reviewers shall submit a report of their findings to the [EMS Bureau] **department**. *[If this is also an American College of Surgeons (ACS) verification or reverification, the hospital shall request a copy of the report be sent directly to the EMS Bureau from the ACS verification committee.]* 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 [EMS Bureau] **department** has final authority to determine compliance with the rules of this chapter.

[(F)] (L) Within thirty (30) days after receiving a review report, the [EMS Bureau] **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.

[(G)] (M) 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 [EMS Bureau] **department** and shall be completed by the hospital and returned to the [EMS Bureau] **department** within thirty (30) days after notification of review findings.

[(H)] (N) Once a review is completed, a final report shall be prepared by the [EMS Bureau] **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.

[(4)] **(O)** The [EMS Bureau] **department** shall have the authority to put on probation, suspend, revoke, or deny trauma center designation if there is reasonable cause to believe 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 [EMS Bureau] **department**. In these cases, the application and review process shall be completed again before the designation may be reinstated.

[(A)] **(P)** Trauma center designation shall be valid for a period of five (5) 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)-year period. Trauma center designation shall be site specific and not transferable when a trauma center changes location.

[(B)] **(Q)** The [EMS Bureau] **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 [EMS Bureau] **department** regarding a complaint, is subject to revocation of trauma center designation.

(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:

(A) An application for trauma center designation by the department for hospitals that have been verified as a trauma center by the American College of Surgeons 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 trauma verified 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 trauma 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 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 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 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 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 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 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 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 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;

8. The department shall designate a hospital 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 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;

(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) Participate in local and regional emergency medical services systems by reviewing and sharing outcome data and providing training and clinical educational resources;

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

(J) 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) 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.

(4) Hospitals that choose to apply to the department under sections (2) and (3) above and maintain a trauma designation with both the Department and the American College of Surgeons may request either of the following two (2) options:

(A) Hospitals may choose to apply to the department under section (2) above and meet the requirements in section (2) above and 19 CSR 30-40.410 and 19 CSR 30-40.430. Hospitals may request a separate review by only the Department pursuant to section (2). Hospitals may choose to apply to the department under Section (3) above and meet the requirements set by the American College of Surgeons. Hospitals may request a separate review by only the American College of Surgeons; or

(B) Hospitals may choose to apply to the department under section (2) above and meet the requirements in section (2) above and 19 CSR 30-40.410 and 19 CSR 30-40.430. Hospitals may choose to apply to the department under Section (3) above and meet the requirements set by the American College of Surgeons. Hospitals may request a joint review by both the American College of Surgeons and the department. In a joint review, department personnel shall be incorporated into these reviews upon the consent of the American College of Surgeons. During these joint reviews, the trauma review team chosen by the American College of Surgeons shall also include at least one (1) emergency department physician and at least one (1) trauma program manager (nurse). All costs for the review and review team shall be paid by the hospitals. If a hospital successfully passes the joint review by the department and the American College of Surgeons, then the hospital will be designated by the department as a trauma center under both sections (2) and (3) above.

AUTHORITY: Sections 190.176, 190.185, and 190.241, RSMo Supp. [2007] 2017 [and section 190.241, HB 1790, 94th General Assembly, Second Regular Session, 2008].
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.*

**Original authority: 190.185, RSMo 1973, amended 1989, 1993, 1995, 2002 and 190.241, RSMo 1987, amended 1998, 2008.*

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

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

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