

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
September 16, 2009 (Final Draft)

19 CSR 30-40.420 Trauma Center Designation Requirements. The department is amending section (3) and the form attached to the end of this rule.

PURPOSE: This amendment adds level IV to the designation requirements.

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 Department.. Hospitals desiring trauma center designation shall apply to the Department. Only those hospitals found by review to be in compliance with the requirements of the rules in this chapter shall be designated by the Department as trauma centers.

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

(A) 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 Department office or may be obtained by mailing a written request to Missouri Department of Health and Senior Services, Department, PO Box 570, Jefferson City, MO 65102-0570.

Trauma Center Designation Requirements
September 16, 2009

(B) The 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) 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) 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) 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 Department to pay for reviews.

(A) 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 **and level IV 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) 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 Department and verified by Department personnel.

(C) 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) 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 Department personnel in these reviews and, if they successfully pass reverification and meet all requirements herein, submit that review for Department reverification.**

(E) Upon completion of a review, the reviewers shall submit a report of their findings to the Department **within thirty (30) days of completion of the review**. 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 Department from the ACS verification

Trauma Center Designation Requirements
September 16, 2009

committee. The report shall include the patient chart audits and a narrative summary to include pre-hospital, hospital, trauma service, emergency department, clinical lab, **operating room**, recovery room, intensive care unit, blood bank, rehabilitation, performance improvement and patient safety programs, education, outreach, research, chart review and interviews. **The report shall also state whether the specific standards for trauma center designation have or have not been met. If the specific standards for trauma center designation have not been met, then the report shall state in what ways the specific standards were not met.** The Department has final authority to determine compliance with the rules of this chapter.

(F) 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.

(G) 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 by the hospital and returned to the Department within thirty (30) days after notification of review findings.

(H) 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.

(4) The 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 Department. In these cases, the application and review process shall be completed again before the designation may be reinstated.

(A) 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) 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.

AUTHORITY: section 190.185, RSMo Supp. 2008 and section 190.241, RSMo [Supp. 1998] 2000. 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 ??????*

Trauma Center Designation Requirements
September 16, 2009

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

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

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed with Teresa Generous, 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.*