

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 30-40.720 Stroke Center Designation Application and Review. The department is amending sections (1), (2) and (3) and renumbering throughout; adding a new section (3); and adding the form included after the rule.

PURPOSE: This amendment adds an option for hospitals which are certified as stroke centers by the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program to become designated as level I, II or III stroke centers without being reviewed by the department. This amendment also adds an application for these hospitals which are certified as stroke centers by the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program to complete in order to become designated as level I, II or III stroke centers by the department. This amendment establishes requirements for the hospitals to meet that are certified as stroke centers by the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program and choose to be designated as level I, II or III stroke centers by the department. This amendment also adds focus reviews to be conducted after an initial review.

(1) Participation in Missouri's stroke center program is voluntary and no hospital shall be required to participate. No hospital shall hold itself out to the public as a state-designated stroke center unless it is designated as such by the Department of Health and Senior Services (department). Hospitals desiring stroke center designation shall apply to the 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 of this chapter shall be designated by the department as stroke centers.

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

(A) An application for stroke 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. The stroke center review and designation application 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 stroke 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 stroke center review and designation application form, included herein, shall be complete before the department will arrange a date for the review. The department shall notify the hospital/stroke center of any apparent omissions or errors in the completion of the stroke center review and designation application form. When the stroke center review and designation application form is complete, the department shall contact the hospital/stroke center to arrange a date for the review.

(C) The hospital/stroke center shall cooperate with the department in arranging for a mutually suitable date for any announced reviews.

[(D)] *The hospital/stroke center may request any announced initial and validation reviews by the department be coordinated with the hospital's/stroke center's Joint Commission Stroke Center Survey, if applicable. The department may grant such a request to the extent practical.*

[(2)] (D) The different types of site reviews to be conducted on hospitals/stroke centers seeking stroke center designation **by the department** include:

[(A)] 1. An initial review shall occur on a hospital applying to be initially designated as a stroke 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;

[(B)] 2. A validation review shall occur on a designated stroke center applying for renewal of its designation as a stroke center. Validation reviews shall occur no less than every four (4) years. A validation review shall include interviews with designated stroke 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; and

[(C)] 3. A focus review shall occur on a designated stroke 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.

[(3)] (E) Stroke center designation shall be valid for a period of four (4) years from the date the stroke center/hospital is designated.

[(A)] 1. Stroke center designation shall be site specific and non-transferable when a stroke center changes location.

[(B)] 2. Once designated as a stroke center, a stroke 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.

[(4)] (F) For the purpose of reviewing previously designated stroke centers and hospitals applying for stroke center designation, the department shall use review teams consisting of qualified contractors. These review teams shall consist of one (1) stroke coordinator or stroke program manager who has experience in stroke care and one (1) emergency medicine physician also experienced in stroke care. The review team shall also consist of at least one (1) and no more than two (2) neurologist(s)/neuro-interventionalist(s) who are experts in stroke care. One (1) representative from the department will also be a participant of the review team. This representative shall coordinate the review with the hospital/stroke center and the other review team members. *[For a hospital applying to the department as a level I stroke center for an initial review and which provides the department with verification of certification by the Joint Commission as a Comprehensive Stroke Center, the review team shall consist of at least one (1) representative from the department and may also include one (1) qualified contractor. For a hospital applying to the department as a level II stroke center for an initial review and which provides the department with verification of certification by the Joint Commission as a Primary Stroke Center, the review team shall consist of at least one (1) representative from the department and may also include one (1) qualified contractor.]*

[(A)] **1.** Any individual interested in becoming a qualified contractor to conduct reviews shall—

[1.] **A.** Send the department a curriculum vitae (CV) or resume that includes his or her experience and expertise in stroke 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;

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

[3.] **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.

[(B)] **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.

[(5)] **(G)** Out-of-state review team members shall conduct levels I and II hospital/stroke center reviews. Review team members are considered out-of-state review team members if they work outside of the state of Missouri. In-state review team members may conduct levels III and IV hospital/stroke center reviews. Review team members are considered in-state review team members if they work in the state of Missouri. In the event that out-of-state reviewers are unavailable, levels I and II stroke center reviews may be conducted by in-state reviewers from Emergency Medical Services (EMS) regions as set forth in 19 CSR 30-40.302 other than the region being reviewed with the approval of the director of the department or his/her designee. When utilizing in-state review teams, levels I and II hospital/stroke centers shall have the right to refuse one (1) in-state review team or certain members from one (1) in-state review team.

[(6)] **(H)** Hospitals/stroke centers shall be responsible for paying expenses related to the cost of the qualified contractors to review their respective hospitals/stroke 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/stroke center include:

[(A)] **1.** An honorarium shall be paid to each qualified contractor of the review team. Qualified contractors of the review team for level I and II stroke 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 per reviewer. Qualified contractors of the review team for level III and IV stroke 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 per reviewer. This honorarium shall be paid to each qualified contractor of the review team at the time the site survey begins;

[(B)] **2.** Airfare shall be paid for each qualified contractor of the review team, if applicable;

[(C)] **3.** Lodging shall be paid for each qualified contractor of the review team. The hospital/stroke center shall secure the appropriate number of hotel rooms for the qualified contractors and pay the hotel directly; and

[(D)] **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:

[1.] **A.** Airport parking;

[2.] **B.** Checking bag charges;

[3.] **C.** Meals during the review; and

[4.] **D.** Mileage to and from the review if no airfare was charged by the reviewer. 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.

[(7)] **(I)** 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 stroke 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/stroke 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, stroke 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.

[(8)] **(J)** The department shall return a copy of the report to the chief executive officer, the stroke medical director, and the stroke program manager/coordinator of the hospital/stroke center reviewed. Included within the report shall be notification indicating whether the hospital/stroke center has met the criteria for stroke center designation or has failed to meet the criteria for the stroke center designation requested. Also, if a focus review of the stroke center is required, the time frame for this focus review will be shared with the chief executive officer, the stroke medical director, and the stroke program manager/coordinator of the stroke center reviewed.

(9) When the hospital/stroke center is found to have deficiencies, the hospital/stroke 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, then the stroke center shall be allowed a minimum period of six (6) months to correct deficiencies.

[(10)] **(K)** A stroke center shall make the department aware in writing within thirty (30) days if there are any changes in the stroke center's name, address, contact information, chief executive officer, stroke medical director, or stroke program manager/coordinator.

[(11)] **(L)** Any person aggrieved by an action of the Department of Health and Senior Services affecting the stroke 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 thereon 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.

[(12)] **(M)** The department may deny, place on probation, suspend, or revoke such designation in any case in which it has reasonable cause to believe 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 of Health and Senior Services has reasonable cause to believe 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 stroke 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 stroke center designation by the department based on their current certification as a stroke center by the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program shall meet the following requirements:

(A) An application for stroke center designation by the department for hospitals that have been certified as a stroke center by the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program 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 stroke 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 stroke 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 stroke certified hospital designation form, included herein, shall be complete before the department designates a hospital/stroke center. The department shall notify the hospital/stroke center of any apparent omissions or errors in the completion of the application for stroke 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 a level I stroke center if such hospital has been certified as a comprehensive stroke center by the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program;

2. The department shall designate a hospital a level II stroke center if such hospital has been certified as a primary stroke center by either the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program; or

3. The department shall designate a hospital a level III stroke center if such hospital has been certified as an acute stroke-ready center by the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program;

(C) Annually from the date of designation by the department submit to the department proof of certification as a stroke center by the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program and the names and contact information of the medical director of the stroke center and the program manager of the stroke center;

(D) Within thirty (30) days of any changes submit to the department proof of certification as a stroke center by the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program and the names and contact information of the medical director of the stroke center and the program manager of the stroke center;

(E) Submit to the department a copy of the certifying organization's final stroke certification survey results within thirty (30) days of receiving such results;

(F) Submit to the department a completed application for stroke certified hospital designation form every four (4) years;

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

(H) Any hospital designated as a level III stroke center that is certified by the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program as an acute stroke-ready center shall have a formal agreement with a level I or level II stroke center designated by the department for physician consultative services for evaluation of stroke patients for thrombolytic therapy and the care of the patient post-thrombolytic therapy;

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

(J) Submit data to meet the data submission requirements outlined in 19 CSR 30-40.730(1)(Q);

(K) The designation of a hospital as a stroke center pursuant to section (3) shall continue if such hospital retains certification as a stroke center by the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program; and

(L) The department may remove a hospital's designation as a stroke center if requested by the hospital or the department determines that the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program certification has been suspended or revoked. Any decision made by the department to withdraw the designation of a stroke center that is based on the revocation or suspension of a certification by the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program shall not be subject to judicial review.

AUTHORITY: section 192.006, RSMo 2000, and sections 190.185 and 190.241, RSMo Supp. [2012] 2016. Original rule filed Nov. 15, 2012, effective June 30, 2013.*

**Original authority: 192.006, RSMo 1993, amended 1995; 190.185, RSMo 1973, amended 1989, 1993, 1995, 1998, 2002; and 190.241, RSMo 1987, amended 1998, 2008.*

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

PRIVATE COST: This proposed amendment will not cost private entities more than (\$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.*