

**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 (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, clarifies honorarium and payment requirements for virtual reviews, 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 primary stroke center with thrombectomy capability as a type of certification or verification that hospitals may have in order for the department to designate hospitals as level II stroke centers, 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 and the department has not yet been able to conduct a review, changes the requirements for hospitals participating in local and regional emergency medical services systems, removes the data submission requirement for hospitals certified or verified by department approved national bodies and 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. This amendment also makes changes to the application for stroke center designation form included herein in section (3)(A) by adding primary stroke center with thrombectomy capability, 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 stroke center by the department shall meet the following requirements:

(D) The department may conduct an onsite review, a virtual review or a combination thereof on the hospitals/stroke centers. For announced reviews that are scheduled with the hospitals/stroke centers, the department will make the hospitals/stroke 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/stroke centers to make the hospitals/stroke 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 different types of [site] reviews to be conducted on hospitals/stroke centers seeking stroke center designation by the department include:

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. **This review may occur onsite and/or virtually;**

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)] **three (3)** 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. **This review may occur onsite and/or virtually;** and

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. **This review may occur onsite and/or virtually;**

(E) Stroke center designation shall be valid for a period of [four (4)] **three (3)** years from the date the stroke center/hospital is designated. **Expiration of the designation shall occur unless the stroke center applies for validation review within this three – (3-) year period and the department is unable to conduct a review before the designation expires.**

1. Stroke center designation shall be site specific and non-transferable when a stroke center changes location.

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;

(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:

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 stroke center reviews shall be paid [*six hundred dollars (\$600) for the day of travel reviewer and eight hundred fifty dollars (\$850) for the day of the review*] **one thousand four hundred fifty dollars (\$1,450)** per reviewer. Qualified contractors of the review team for levels 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*] **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 review beginning 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/stroke 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;

(I) **Hospitals/stroke centers being reviewed through a virtual survey shall do the following:**

1. **Provide a videoconferencing platform to be used for the hospital/stroke center virtual review;**

2. **Provide a live tour of the hospital;**

3. **Ensure the video and audio conferencing service 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 stroke 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 stroke program manager, the stroke program medical director, the stroke 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 through a method that is compliant with state and federal laws for protected health information 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 stroke program medical director, the stroke 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 video and audio conferencing service 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;

(J) 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 stroke designation;

(K) 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;

[(J)] (L) 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;

[(K)] (M) 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;

[(L)] (N) 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;

(O) Failure of a hospital/stroke center to provide all medical records and quality improvement documentation necessary for the department to conduct a stroke review in order to determine if the requirements of 19 CSR 30-40.730 have been met shall result in the revocation of the hospital/stroke center's designation as a stroke center;

[(M)] (P) 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; and

[(N)] (Q) The department may deny, place on probation, suspend, or revoke such designation in any case in which it has [*reasonable cause to believe*] **determined** 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*] **determined** 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 **or verification** 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 **or verified** 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 **with thrombectomy capability or 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 **or receipt of a certificate or verification, the hospital shall** submit[,] to the department proof of certification or verification 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. **A certificate or verification as a stroke center by the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program shall accompany the application for stroke certified hospital designation form. A hospital shall report to the department in writing within thirty (30) days of the date the hospital no longer is certified or verified as a stroke center by the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program for which the hospital used to receive its corresponding designation with the department as a stroke center, whether because the hospital voluntarily surrendered this certificate or verification, or because the hospital's certificate or verification was suspended or revoked by the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program or expired;**

[(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)] (D) Any hospital designated as a level III stroke center that is certified **or verified** 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)] (E) 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;***

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

(K)] (F) 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)] (G) 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 **or verification** 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 **or revocation** by the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program shall not be subject to judicial review.

AUTHORITY: sections 190.185 and 192.006, RSMo 2016, and section 190.241, RSMo Supp. [2019] 2022. Original rule filed Nov. 15, 2012, effective June 30, 2013. Emergency amendment filed Aug. 7, 2017, effective Aug. 17, 2017, expired Feb. 22, 2018. Amended: Filed Aug. 7, 2017, effective March 30, 2018. ** Emergency amendment filed November 21, 2022, effective December 7, 2022, expires June 4, 2023.*

**Original authority: 190.185, RSMo 1973, amended 1989, 1993, 1995, 1998, 2002; 190.241, RSMo 1987, amended 1998, 2008, 2016, 2017; and 192.006, RSMo 1993, amended 1995.*

***Pursuant to Executive Order 21-07, 19 CSR 30-40.720, subsections (2)(A) and (2)(B) and section (3) was suspended from April 2, 2020 through May 1, 2021. Pursuant to Executive Order 21-09, 19 CSR 30-40.720, paragraph (2)(D)2. and subsections (2)(F) and (2)(G) was suspended from April 2, 2020 through December 31, 2021.*

PUBLIC COST: This proposed amendment will cost state agencies or political subdivisions ninety-seven thousand six hundred dollars (\$97,600) during the three (3) year designation period.

PRIVATE COST: This proposed amendment will cost private entities twenty-seven thousand two hundred fifty dollars (\$27,250) 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.*