



(EE) Qualified individual—a physician, registered nurse, advanced practice nurse, and/or physician assistant licensed in the state of Missouri who demonstrates administrative ability and shows evidence of educational and clinical experience in the care of cerebrovascular patients;

(FF) Regional outcome data—data used to assess the regional process for pre-hospital, hospital, and regional patient outcomes;

(GG) Repatriation—the process used to return a stroke patient to his or her home community from a level I or level II stroke center after his or her acute treatment for stroke has been completed. This allows the patient to be closer to home for continued hospitalization or rehabilitation and follow-up care as indicated by the patient's condition;

(HH) Reperfusion—the process of restoring normal blood flow to an organ or tissue that has had its blood supply cut off, such as after an ischemic stroke or myocardial infarction;

(II) Requirement (R)—a symbol used to indicate that a standard is a requirement for stroke center designation at a particular level;

(JJ) Review—the inspection of a hospital to determine compliance with the rules of this chapter;

(KK) Stroke—a sudden brain dysfunction due to a disturbance of cerebral circulation. The resulting impairments include, but are not limited to, paralysis, slurred speech, and/or vision loss. Ischemic strokes are typically caused by the obstruction of a cerebral blood vessel. Hemorrhagic strokes are typically caused by rupture of a cerebral artery;

(LL) Stroke call roster—a schedule that provides twenty-four (24) hours a day, seven (7) days a week neurology service coverage. The call roster identifies the physicians or qualified individuals on the schedule that are available to manage and coordinate emergent, urgent, and routine assessment, diagnosis, and treatment of the stroke patients;

(MM) Stroke care—emergency transport, triage and acute intervention, and other acute care services for strokes that potentially require immediate medical or surgical intervention or treatment, and may include education, primary prevention, acute intervention, acute and sub-acute management, prevention of complications, secondary stroke prevention, and rehabilitative services;

(NN) Stroke center—a hospital that is currently designated as such by the department to care for patients with a stroke.

1. A level I stroke center is a receiving center staffed and equipped to provide total care for every aspect of stroke care, including care for those patients with complications, that also functions as a resource center for the

hospitals within that region, and conducts research.

2. A level II stroke center is a receiving center staffed and equipped to provide care for a large number of stroke patients within the region.

3. A level III stroke center is a referral center staffed and equipped to initiate lytic therapy and initiate timely transfer to a higher level of care. The level III stroke center also provides prompt assessment, indicated resuscitation, and appropriate emergency intervention for stroke patients. A level III stroke center may admit and monitor patients as in-patients if there are designated stroke beds and an established relationship exists with a level I or level II stroke center through which the level I or level II stroke center provides medical direction and oversight for those stroke patients kept at the level III stroke center under that relationship.

4. A level IV stroke center is a referral center in an area considered rural or where there are insufficient hospital resources to serve the patient population requiring stroke care. A level IV stroke center provides prompt assessment, indicated resuscitation, appropriate emergency intervention, and arranges and expedites transfer to a higher level stroke center as needed;

(OO) Stroke medical director—a physician designated by the hospital who is responsible for the stroke service and performance improvement and patient safety programs related to stroke care;

(PP) Stroke program—an organizational component of the hospital specializing in the care of stroke patients;

(QQ) Stroke program manager/coordinator—a qualified individual designated by the hospital with responsibility for monitoring and evaluating the care of stroke patients and the coordination of performance improvement and patient safety programs for the stroke center in conjunction with the stroke medical director;

(RR) Stroke team—a component of the hospital stroke program consisting of the core stroke team and the clinical stroke team;

(SS) Stroke unit—the functional division or facility of the hospital that provides care for stroke patients admitted to the stroke center;

(TT) Symptom onset-to-treatment time—the time from symptom onset to initiation of therapy to restore blood flow in an obstructed blood vessel;

(UU) Telemedicine—the use of medical information exchanged from one (1) site to another via electronic communications to improve patient's health status. A neurology specialist will assist the physician in the center in rendering a diagnosis. This may involve

a patient "seeing" a specialist over a live, remote consult or the transmission of diagnostic images and/or video along with patient data to the specialist;

(VV) Thrombolytics—drugs, including recombinant tissue plasminogen activator, used to dissolve clots blocking flow in a blood vessel. These thrombolytic drugs are used in the treatment of acute ischemic stroke and acute myocardial infarction; and

(WW) Transfer agreement—a document which sets forth the rights and responsibilities of two (2) hospitals regarding the inter-hospital transfer of patients.

AUTHORITY: section 192.006, RSMo 2000, and sections 190.185 and 190.241, RSMo Supp. 2012. 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.*

19 CSR 30-40.720 Stroke Center Designation Application and Review

PURPOSE: This rule establishes the requirements for participation in Missouri's stroke center program.

(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. 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) 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) The different types of site reviews to be conducted on hospitals/stroke centers seeking stroke center designation include:

(A) 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) 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) A focus review shall occur on a designated stroke center in which a 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) Stroke center designation shall be valid for a period of four (4) years from the date the stroke center/hospital is designated.

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

(B) 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) 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) Any individual interested in becoming a qualified contractor to conduct reviews shall—

1. 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. Provide the department evidence of his or her previous site survey experience (state and/or national designation survey process); and

3. 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) 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) 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) 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) 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) Airfare shall be paid for each qualified contractor of the review team, if applicable;



(C) 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) 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. Airport parking;
2. Checking bag charges;
3. Meals during the review; and

4. 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) 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) 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) 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) 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) 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.



MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES
SECTION OF HEALTH STANDARDS AND LICENSURE
APPLICATION FOR STROKE CENTER REVIEW AND DESIGNATION

SECTION A			
In accordance with the requirements of the Chapter 190 RSMo and the applicable regulations, this application is hereby submitted for review and designation as a stroke center. Please complete all information applicable to the requested designation level.			Designation Level Requested <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV
Joint Commission Certification <input type="checkbox"/> Primary Stroke Center <input type="checkbox"/> Comprehensive Stroke Center			
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	
Stroke Medical Director		Stroke Program Manager	
Medical Director of Emergency Medicine		Medical Director of Intensive Care Unit	
RESOURCE INFORMATION			
Stroke Caseload	Stroke Team Activations	CT Scan Capability <input type="checkbox"/> FULL <input type="checkbox"/> PARTIAL <input type="checkbox"/> NONE	MRI Capability <input type="checkbox"/> FULL <input type="checkbox"/> PARTIAL <input type="checkbox"/> NONE
Neurosurgical Capability or Transfer Plan	ICU or NICU Beds	Stroke Unit Beds	Stroke Rehab <input type="checkbox"/> INPATIENT <input type="checkbox"/> OUTPATIENT
Neurologists	Neurosurgeons	Neuro-Interventionalists	Emergency Department (ED) Physicians
Anesthesiologists/ CRNAs & AAs	Angiography Suites	Avg number of patients who received neuro-intervention (not required for initial review)	Avg number of patients who received thrombolytics in the past 24 months (not required for initial review)
CERTIFICATION			
We, the undersigned, hereby certify that the information provided in this application for stroke center review and designation is true and accurate; and give assurance of the intent and ability of the hospital to comply with regulations promulgated under the Chapter 190, RSMo.			
We further certify that the hospital will comply with all recommendations for improvement contained in the stroke center site review reports prepared by the Missouri Department of Health and Senior Services.			
Date of application _____			
Signed _____ Chairman/President of Board of Trustees, Owner, or one Partner of Partnership		Signed _____ Hospital Chief Executive Officer	
Signed _____ Stroke Medical Director		Signed _____ Director of Emergency Medicine	



MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES
SECTION OF HEALTH STANDARDS AND LICENSURE
APPLICATION FOR STROKE CENTER REVIEW AND DESIGNATION

SECTION B

Please attach the following documentation to the application form. **Name of Hospital:**

- Hospital organizational chart depicting the relationship of the stroke services to other services and defining the organizational structure of the stroke service.
- Job descriptions and CV for the stroke medical director and stroke coordinator/program manager.
- A narrative description of the administrative commitment for the stroke center, including how stroke center designation relates to the overall mission of the hospital.
- A current board resolution supporting the stroke center.
- A narrative description of the catchment area for the stroke center.
- A narrative description of the prehospital system including the hospital's participation in medical control, quality assurance, and education of the emergency medicine personnel.
- Hospital diversion policy.
- List of the stroke medical director and stroke program coordinator or program manager (core stroke team) indicating the neuro-cerebrovascular related continuing education for each over the past three (3) years. (Do not send continuing education information about the clinical stroke team. This should be available at the time of the review.)
- Multidisciplinary team policy.
- List of all neurologists, neurosurgeons, neuro-interventionalists and emergency department physicians and indicate stroke-related CME for each over the past three (3) years.
- List of physicians and plan for supervised relationship between Level III and higher level stroke center where stroke patients are admitted for care in a Level III center if applicable (this list and plan are only required for Level III centers with a supervised relationship with a Level I or Level II center).
- Narrative description of the system for notifying/activating stroke team.
- One-call stroke team activation protocol.
- Copies of all transfer agreements pertaining to stroke.
- Policy for consultation for physical medicine and rehabilitation, physical therapy, occupational therapy and speech therapy.
- Protocols on post-discharge and post-transfer follow-up for stroke patients.
- A narrative description of the stroke quality improvement (QI) processes utilized by the hospital (Do not send copies of QI minutes or documents. These should be available at the time of review.)
- Examples of stroke-related educational, outreach, and research projects undertaken by the hospital.
- Summary of source of stroke information for Table 1 on next page. Table 1 is only required to be filled out by a stroke center which is applying for renewal of its designation prior to a validation review. Table 1 is not required to be filled out by a hospital requesting an initial review and designation.
- Verification of Primary or Comprehensive Joint Commission certified center (e.g. certificate).



MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES
SECTION OF HEALTH STANDARDS AND LICENSURE
APPLICATION FOR STROKE CENTER REVIEW AND DESIGNATION

Table 1. Ischemic Stroke Numbers for Past Two (2) Years

Table 1 is only required to be filled out by a stroke center which is applying for renewal of its designation prior to a validation review.

A	B	C	D	E
Indicate year ¹ Provide two years of data	Stroke cases ²	Stroke cases eligible for NI ⁴	Stroke cases eligible for Lytics ⁶	Stroke deaths ⁸
	Transfers ³	Received NI ⁵	Received lytics ⁷	
For example: 2011	53 22	14 8	25 12	2
Total				
Average/Year				

¹ Include data for the last two (2) years of hospital data. Indicate time frame in months if it is other than January to December.

² Include all stroke patients, independent of hospital admission or hospital transfer status. To include walk-ins, transfers, EMS transports, admitted patients, and patients that die. Include all stroke patients that have ICD-9-principal diagnosis code of 433.01, 433.10, 433.11, 433.21, 433.31, 433.81, 433.91, 434.00, 434.01, 434.11, 434.91, 436.00, 430.00 and 431.00

³ Provide number of all stroke patients transferred to this hospital from another hospital.

⁴ Provide number of stroke patients eligible for neuro-intervention (NI).

⁵ Provide number of stroke patients that received neuro-intervention (NI).

⁶ Provide number of stroke patients that are eligible for thrombolytics.

⁷ Provide number of stroke patients that received thrombolytics.

⁸ Include all deaths, ED and inpatient, independent of hospital admission or hospital transfer status.