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Part I

SALUS POPULI SUPREMA LEX ESTO

*“The welfare of the people shall be the supreme law.”*



ROBIN CARNAHAN  
SECRETARY OF STATE

MISSOURI  
REGISTER

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Documents will be accepted for filing on all regular workdays from 8:00 a.m. until 5:00 p.m. We encourage early filings to facilitate the timely publication of the *Missouri Register*. Orders of Rulemaking appearing in the *Missouri Register* will be published in the *Code of State Regulations* and become effective as listed in the chart above. Advance notice of large volume filings will facilitate their timely publication. We reserve the right to change the schedule due to special circumstances. Please check the latest publication to verify that no changes have been made in this schedule. To review the entire year's schedule, please check out the website at <http://www.sos.mo.gov/adrules/pubsched.asp>

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## HOW TO CITE RULES AND RSMo

**RULES**—Cite material in the *Missouri Register* by volume and page number, for example, Vol. 28, *Missouri Register*, page 27. The approved short form of citation is 28 MoReg 27.

The rules are codified in the *Code of State Regulations* in this system—

Title	Code of State Regulations	Division	Chapter	Rule
1	CSR	10-	1.	010
Department		Agency, Division	General area regulated	Specific area regulated

They are properly cited by using the full citation, i.e., 1 CSR 10-1.010.

Each department of state government is assigned a title. Each agency or division within the department is assigned a division number. The agency then groups its rules into general subject matter areas called chapters and specific areas called rules. Within a rule, the first breakdown is called a section and is designated as (1). Subsection is (A) with further breakdown into paragraph 1., subparagraph A., part (I), subpart (a), item I. and subitem a.

**RSMo**—The most recent version of the statute containing the section number and the date.

**U**nder this heading will appear the text of proposed rules and changes. The notice of proposed rulemaking is required to contain an explanation of any new rule or any change in an existing rule and the reasons therefor. This is set out in the Purpose section with each rule. Also required is a citation to the legal authority to make rules. This appears following the text of the rule, after the word "Authority."

**E**ntirely new rules are printed without any special symbology under the heading of proposed rule. If an existing rule is to be amended or rescinded, it will have a heading of proposed amendment or proposed rescission. Rules which are proposed to be amended will have new matter printed in boldface type and matter to be deleted placed in brackets.

**A**n important function of the *Missouri Register* is to solicit and encourage public participation in the rulemaking process. The law provides that for every proposed rule, amendment, or rescission there must be a notice that anyone may comment on the proposed action. This comment may take different forms.

**I**f an agency is required by statute to hold a public hearing before making any new rules, then a Notice of Public Hearing will appear following the text of the rule. Hearing dates must be at least thirty (30) days after publication of the notice in the *Missouri Register*. If no hearing is planned or required, the agency must give a Notice to Submit Comments. This allows anyone to file statements in support of or in opposition to the proposed action with the agency within a specified time, no less than thirty (30) days after publication of the notice in the *Missouri Register*.

**A**n agency may hold a public hearing on a rule even though not required by law to hold one. If an agency allows comments to be received following the hearing date, the close of comments date will be used as the beginning day in the ninety- (90-) day-count necessary for the filing of the order of rulemaking.

**I**f an agency decides to hold a public hearing after planning not to, it must withdraw the earlier notice and file a new notice of proposed rulemaking and schedule a hearing for a date not less than thirty (30) days from the date of publication of the new notice.

Proposed Amendment Text Reminder:

**Boldface text indicates new matter.**

*[Bracketed text indicates matter being deleted.]*

**Title 19—DEPARTMENT OF HEALTH AND  
SENIOR SERVICES  
Division 30—Division of Regulation and Licensure  
Chapter 40—Comprehensive Emergency Medical  
Services Systems Regulations**

**PROPOSED RULE**

**19 CSR 30-40.710 Definitions and Abbreviations Relating to Stroke Centers**

*PURPOSE: This rule defines terminology related to stroke centers.*

(1) As used in 19 CSR 30-40.720 and 19 CSR 30-40.730, the following terms shall mean:

(A) Acute—an injury or illness that happens or appears quickly and can be serious or life threatening;

(B) Anesthesiologist assistant (AA)—a person who—

1. Has graduated from an anesthesiologist assistant program accredited by the Medical Association's Committee on Allied Health Education and Accreditation or by its successor agency;

2. Has passed the certifying examination administered by the National Commission on Certification of Anesthesiologist Assistants;

3. Has active certification by the National Commission on Certification of Anesthesiologist Assistants;

4. Is currently licensed as an anesthesiologist assistant in the state of Missouri; and

5. Provides health care services delegated by a licensed anesthesiologist;

(C) Board-admissible/board-eligible—a physician who is eligible to apply or has applied to a specialty board of the American Board of Medical Specialties, the Bureau of Osteopathic Specialties and Boards of Certification, or the Royal College of Physicians and Surgeons of Canada and has received a ruling that he or she has fulfilled the requirements to take the examinations. Board certification is generally obtained within five (5) years of the first appointment;

(D) Board-certified—a physician who has fulfilled all requirements, has satisfactorily completed the written and oral examinations, and has been awarded a board diploma in a specialty field by the American Board of Medical Specialties, the Bureau of Osteopathic Specialties and Boards of Certification, or the Royal College of Physicians and Surgeons of Canada;

(E) Catchment area—the surrounding area served by the institution (the stroke center);

(F) Certified registered nurse anesthetist (CRNA)—a registered nurse who has graduated from a school of nurse anesthesia accredited by the Council on Accreditation of Education Programs of Nurse Anesthesia or its predecessor and who has been certified as a nurse anesthetist by the Council on Certification of Nurse Anesthetists;

(G) Clinical staff—an individual that has specific training and experience in the treatment and management of stroke patients. Examples include: physicians, registered nurses, advanced practice nurses, physician assistants, pharmacists, and technologists;

(H) Clinical team—a team of health care professionals involved in the care of the stroke patient and may include, but not be limited to, neurologists, neuro-interventionalists, neurosurgeons, anesthesiologists, emergency medicine, and other stroke center clinical staff. The clinical team is part of the hospital program's stroke team;

(I) Continuing education—education approved or recognized by a national and/or state professional organization and/or stroke medical director;

(J) Continuing medical education (CME)—the highest level of continuing education for physicians that is approved or recognized by a national and/or state professional organization and/or stroke medical director;

(K) Core team—a subunit of the hospital stroke team consisting of a physician experienced in diagnosing and treating cerebrovascular disease (usually the stroke medical director) and at least one (1) other health care professional or qualified individual competent in stroke care as determined by the hospital (usually the stroke program manager/coordinator);

(L) Credentialed or credentialing—a hospital-specific system of documenting and recognizing the qualifications of medical staff and nurses and authorizing the performance of certain procedures and establishing clinical privileges in the hospital setting;

(M) Department—the Missouri Department of Health and Senior Services;

(N) Door-to-needle time—the time from arrival at the hospital door to initiation of lytic therapy to restore blood flow in an obstructed blood vessel;

(O) Emergency medical service regions—the six (6) regions in the state of Missouri that are defined in 19 CSR 30-40.302;

(P) Hospital—an establishment as defined by section 197.020.2.,

RSMo, or a hospital operated by the state;

(Q) Immediately available (IA)—being present at the bedside at the time of the patient's arrival at the hospital when prior notification is possible and no more than twenty (20) minutes from the hospital under normal driving and weather conditions;

(R) In-house (IH)—being on the hospital premises twenty-four (24) hours a day;

(S) Lytic therapy (also known as fibrinolysis/thrombolysis)—a drug therapy used to dissolve clots blocking flow in a blood vessel. It refers to drugs used for that purpose, including recombinant tissue plasminogen activator. This type of therapy can be used in the treatment of acute ischemic stroke and acute myocardial infarction;

(T) Missouri stroke registry—a statewide data collection system comprised of key data elements as defined in 19 CSR 30-40.730 that are used to compile and trend statistics of stroke patients in both pre-hospital and hospital settings, using a coordinated electronic reporting method provided by the department;

(U) Multidisciplinary team—a team of appropriate representatives of hospital units involved in the care of the stroke patient. This team supports the care of the stroke patient with the stroke team;

(V) Neuro-interventional team—a team of physicians, nurses, and other clinical staff, and technical support that perform the neuro-interventions and who are part of the stroke clinical team;

(W) Neurology service—an organizational component of the hospital specializing in the care of patients who have had strokes or some other neurological condition or disorder;

(X) Patient—an individual who is sick, injured, wounded, diseased, or otherwise incapacitated or helpless, or dead, excluding deceased individuals being transported from or between private or public institutions, homes, or cemeteries, and individuals declared dead prior to the time an ambulance is called for assistance;

(Y) Peer review system—the process the stroke center establishes for physicians to review stroke cases on patients who are admitted to the stroke center, transferred out of the stroke center, or die as a result of the stroke (independent of hospital admission or hospital transfer status);

(Z) Physician—a person licensed as a physician pursuant to Chapter 334, RSMo;

(AA) Promptly available (PA)—arrival at the hospital at the patient's bedside within thirty (30) minutes after notification of a patient's arrival at the hospital;

(BB) Protocol—a predetermined, written medical care guideline, which may include standing orders;

(CC) Qualified individual—a physician, registered nurse, advanced practice registered 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;

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

(EE) 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;

(FF) 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;

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

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

(II) 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;

(JJ) 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;

(KK) 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;

(LL) 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;

(MM) 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;

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

(OO) 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;

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

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

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

(SS) 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;

(TT) 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

(UU) 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.*

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

*PRIVATE COST: This proposed rule 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 rule 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.*

**Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES**  
**Division 30—Division of Regulation and Licensure**  
**Chapter 40—Comprehensive Emergency Medical Services Systems Regulations**

**PROPOSED RULE**

**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](http://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.

(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](http://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**

<b>SECTION A</b>			
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	
<b>HOSPITAL INFORMATION</b>			
Name Of Hospital (Name To Appear On Designation Certificate )		Telephone Number	
Address (Street And Number)		City	Zip Code
<b>PROFESSIONAL INFORMATION</b>			
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	
<b>RESOURCE INFORMATION</b>			
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)
<b>CERTIFICATION</b>			
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.

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

<b>Table 1. Ischemic Stroke Numbers for Past Two (2) Years</b>				
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.				
<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
<b>Indicate year<sup>1</sup></b> Provide two years of data	<b>Stroke cases<sup>2</sup></b>	<b>Stroke cases eligible for NI<sup>4</sup></b>	<b>Stroke cases eligible for Lytics<sup>6</sup></b>	<b>Stroke deaths<sup>8</sup></b>
	Transfers <sup>3</sup>	Received NI <sup>5</sup>	Received lytics <sup>7</sup>	
<b>For example:</b>	<b>53</b>	<b>14</b>	<b>25</b>	<b>2</b>
<b>2011</b>	<b>22</b>	<b>8</b>	<b>12</b>	
<b>Total</b>				
<b>Average/Year</b>				

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

<sup>2</sup> 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

<sup>3</sup> Provide number of all stroke patients transferred to this hospital from another hospital.

<sup>4</sup> Provide number of stroke patients eligible for neuro-intervention (NI).

<sup>5</sup> Provide number of stroke patients that received neuro-intervention (NI).

<sup>6</sup> Provide number of stroke patients that are eligible for thrombolytics.

<sup>7</sup> Provide number of stroke patients that received thrombolytics.

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

*AUTHORITY: section 192.006, RSMo 2000, and sections 190.185 and 190.241, RSMo Supp. 2012. Original rule filed Nov. 15, 2012.*

*PUBLIC COST: This proposed rule will cost state agencies or political subdivisions three hundred eighty-seven thousand seven hundred forty dollars (\$387,740) for the initial five- (5-) year period and one hundred nineteen thousand nine hundred forty dollars (\$119,940) annually thereafter.*

*PRIVATE COST: This proposed rule will cost private entities two hundred ten thousand five hundred sixty dollars (\$210,560) for the initial five- (5-) year period and one hundred nineteen thousand seven hundred dollars (\$119,700) annually thereafter.*

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with Teresa Generous, Director, Division of Regulation and Licensure, Missouri Department of Health and Senior Services, 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.*

**FISCAL NOTE  
 PUBLIC COST**

- I. Department Title: Missouri Department of Health and Senior Services  
 Division Title: Division of Regulation and Licensure  
 Chapter Title: Chapter 40-Comprehensive Emergency Medical Services System**

<b>Rule Number and Name:</b>	<b>19 CSR 30-40.720 Stroke Center Designation Requirements.</b>
<b>Type of Rulemaking:</b>	<b>Proposed</b>

**II. SUMMARY OF FISCAL IMPACT**

Affected Agency or Political Subdivision	Estimated Cost of Compliance in the Aggregate
<b>18 public hospitals</b>	<b>\$93,240 for the initial five year period and \$61,040 annually thereafter.</b>
<b>Department of Health and Senior Services' costs</b>	<b>\$294,500 for the initial five year period and \$58,900 annually thereafter.</b>
<b>Total</b>	<b>\$387,740 for the initial five year period and \$119,940 annually thereafter.</b>

**III. WORKSHEET**

**1. Honorariums.**

- A. For level one and two designated stroke centers during the initial five year period- \$600 for the day of travel per reviewer + \$850 for the day of the review per reviewer X four reviewers at the most= \$5,800.  
 \$5,800 X two level one/two initial reviews= \$11,600.  
 \$5,800 X one level one/two validation review= \$5,800.  
 \$5,800 X one level one/two focus review= \$5,800.**

**\$11,600 + \$5,800 + \$5,800 = \$23,200 for the initial five year period for honorariums to be paid for reviews of level one/two designated stroke centers.**

**For level one and two designated stroke centers each year after the initial five year period-\$600 for the day of travel per reviewer + \$850 for the day of the review per reviewer X four reviewers at the most= \$5,800.**

**\$5,800 X one level one/two initial review= \$5,800.  
 \$5,800 X two level one/two validation reviews= \$11,600.  
 \$5,800 X one level one/two focus review=\$5,800.**

**\$5,800 + \$11,600 + \$5,800 = \$23,200 for each year after the initial five year period for honorariums to be paid for reviews of level one/two designated stroke centers.**

**B. For level three and four designated stroke centers during the initial five year period- \$500 for the day of travel per reviewer + \$500 for the day of review per reviewer X four reviewers at the most = \$4,000.**

**\$4000 X four level three/four initial reviews= \$16,000.**

**\$4000 X four level three/four validation review= \$16,000.**

**\$4000 X one level three/four focus review= \$4,000.**

**\$16,000+\$16,000+\$4,000 = \$36,000 for the initial five year period for honorariums to be paid for reviews of level three/four designated stroke centers.**

**For level three and four designated stroke centers during each year after the initial five year period- \$500 for the day of travel per reviewer + \$500 for the day of the review per reviewer X four reviewers at the most = \$4,000.**

**\$4,000 X one level three/four initial review= \$4,000.**

**\$4,000 X two level three/four validation reviews= \$8,000.**

**\$4,000 X one level three/four focus review= \$4,000.**

**\$4,000+\$8,000+\$4,000 = \$16,000 total honorariums for each year after the initial five year period for level three/four designated stroke centers.**

#### **Total Honorariums-**

**\$23,200 (level one/two designated stroke centers for the initial five year period) + \$36,000 (level three/four designated stroke centers for the initial five year period)= \$59,200 total for level one/two/three/four designated stroke centers for the initial five year period.**

**\$23,200 (level one/two designated stroke centers for each year after the initial five year period)+ \$16,000 (level three/four designated stroke centers for each year after the initial five year period)= \$39,200 total for level one/two/three/four designated stroke centers for each year after the initial five year period.**

#### **2. Airfare-**

**For the initial five year period- \$400 per reviewer X four reviewers at the most= \$1,600 X four level one/two reviews during the initial five year period= \$6,400.**

**For each year after the initial five year period- \$400 per reviewer X four reviewers at the most = \$1,600 X four reviews each year after the initial five year period= \$6,400.**

**3. Mileage-**

**For the initial five year period- 500 miles per reviewer X \$0.51 X four reviewers at the most= \$1020 X nine level three/four reviews during the initial five year period= \$9,180.**

**For each year after the initial five year period- 500 miles per reviewer X \$0.51 X four reviewers at the most= \$1,020 X four level three/four reviews during each year after the initial five year period=\$4,080.**

**4. Lodging-**

**For the initial five year period- \$105 per reviewer X four reviewers at the most= \$420 X 13 reviews during the initial five year period= \$5,460.**

**For each year after the initial five year period- \$105 per reviewer X four reviewers at the most=\$420 X eight reviews each year after the initial five year period= \$3,360.**

**5. Incidental expenses for the initial five year period- \$250 per reviewer X four reviewers at the most= \$1,000 X 13 reviews during the initial five year period= \$13,000.**

**For each year after the initial five year period- \$250 per reviewer X four reviewers at the most= \$1,000 X eight reviews each year after the initial five year period= \$8,000.**

**6. Department of Health and Senior Services' costs for staff liaison -**

**For the first five year period -**

**Salary and benefits - \$80,000 X five years = \$400,000 divided by 2 because staff liaison also works with the ST Segment Elevation Myocardial Infarction (STEMI) program for STEMI designated centers = \$200,000**

**Indirect costs - \$20,000 X five years = \$100,000 divided by 2 because staff liaison also works with the STEMI program for STEMI designated centers = \$50,000**

**Network costs - \$2,200 X five years = \$11,000 divided by 2 because staff liaison also works with the STEMI program for STEMI designated centers = \$5,500**

**Mileage - 500 miles X .37 rate X twenty reviews/visits to hospitals average each year X five years = \$18,500**

**Lodging - \$105.00 X twenty reviews/visits to hospitals average each year X five years = \$10,500**

**Incidental expenses such as food - \$100 X twenty reviews/visits to hospitals average each year X five years = \$10,000**

**Total - \$294,500 for the first five year period.**

**For each year after the initial five year period -**

Salary and benefits - \$80,000 X one year = \$80,000 divided by 2 because staff liaison also works with the ST Segment Elevation Myocardial Infarction (STEMI) program for STEMI designated centers = \$40,000

Indirect costs - \$20,000 X one year = \$20,000 divided by 2 because staff liaison also works with the STEMI program for STEMI designated centers = \$10,000

Network costs - \$2,200 X one year = \$2,200 divided by 2 because staff liaison also works with the STEMI program for STEMI designated centers = \$1,100

Mileage - 500 miles X .37 rate X twenty reviews/visits to hospitals average each year X one year = \$3,700

Lodging - \$105.00 X twenty reviews/visits to hospitals average each year X one year = \$2,100

Incidental expenses such as food - \$100 X twenty reviews/visits to hospitals average each year X one year = \$2,000

Total - \$58,900 for each year after the initial five year period.

**Total -**

For the initial five year period- \$59,200 (honorariums) + \$6,400 (airfare) + \$9,180 (mileage) + \$5,460 (lodging) + \$13,000 (incidental expenses) + \$294,500 (DHSS staff member liaison costs) = \$387,740 for the initial five year period.

For each year after the five year period- \$39,200 (honorariums) + \$6,400 (airfare) + \$4,080 (mileage) + \$3,360 (lodging) + \$8,000 (incidental expenses) + \$58,900 (DHSS staff member liaison costs) = \$119,940 annually thereafter.

#### IV. ASSUMPTIONS

There is one unlicensed public hospital in Missouri and 17 licensed public hospitals in Missouri. All of these public hospitals have the potential to apply for designation as a level one, two, three or four stroke center. Stroke center designation is valid for a period of four years from the date the stroke center/hospital is designated.

It is anticipated that there will be at least six public hospitals applying to become designated stroke centers during the first five year period as the interest expressed to the Department about hospitals becoming designated stroke centers has been very positive. It is anticipated that two of the public hospitals applying to become a stroke designated center during the first five year period will be requesting a level one or level two designation and four public hospitals will be requesting to become a level three or level four designated stroke center during the first five year period. Similarly, during the first five years, there will be at least five public hospitals requiring a validation review at the end of the four year designation period in order to become designated as a stroke center again. It is anticipated that one of the public hospitals requesting a validation review will be a level one or level two designated stroke center and four public hospitals requiring a validation review will be level three or level four designated stroke centers. Finally, there will be an average of two focus reviews during the first five years. Focus reviews for the trauma designated centers, a designation process the Department has had in place for greater than ten years, have been required infrequently. It is anticipated one of the focus reviews will be with a level one or level two designated stroke center and



**the other focus review will be conducted on a level three or level four designated stroke center.**

**After the first five years, the Department anticipates one level one or level two public hospital will request an initial review each year after the initial five year period and one level three or level four public hospital will request an initial review each year after the initial five year period. The Department anticipates two level one or level two designated stroke centers will require a validation review each year after the initial five year period and two level three or level four designated stroke centers will require a validation review each year after the initial five year period. Finally, the Department anticipates one level one or level two designated stroke center will require a focus review each year after the initial five year period and one level three or level four designated stroke center will require a focus review each year after the initial five year period.**

**The review teams will have at the most four reviewers.**

**Reviewers of level one and level two trauma designated centers have been receiving approximately \$1450 for honorariums. Reviewers of level three trauma designated centers have been receiving approximately \$1000 for honorariums. The Department used these numbers for the reviewers of stroke designated centers too.**

**Only reviewers for level one and level two stroke designated centers will incur airfare charges because reviewers for level three and level four stroke designated centers are in-state reviewers.**

**The airfare charge of \$400 per reviewer is an estimate found by looking at airfares on airline websites. This airfare charge is for a coach reservation on a roundtrip flight.**

**The mileage rate is figured by the federal business rate from the Internal Revenue Service which is currently \$0.51.**

**The estimate of 500 miles is an average to drive from the outermost points north to south or east to west in Missouri.**

**The mileage estimate is figured only with level three and level four designated stroke center reviews as these will all be in-state reviewers.**

**The lodging costs of \$105.00 per reviewer is based on the current state reimbursement rate for St. Louis hotels.**

**The Department has placed a maximum of \$250.00 for the reimbursement of incidental expenses by reviewers.**

**Costs related to the Department's liaison are expected to increase with inflation.**

**The mileage rate for the Department's liaison is \$.37 which is the current state rate of reimbursement.**

**Incidental expenses for the Department's liaison will mostly be for food/meal reimbursement.**

**FISCAL NOTE  
PRIVATE COST**

- I. Department Title: Missouri Department of Health and Senior Services  
Division Title: Division of Regulation and Licensure  
Chapter Title: Chapter 40-Comprehensive Emergency Medical Services System**

<b>Rule Number and Title:</b>	<b>19 CSR 30-40.720 Stroke Center Designation Requirements.</b>
<b>Type of Rulemaking:</b>	<b>Proposed</b>

**II. SUMMARY OF FISCAL IMPACT**

Estimate of the number of entities by class which would likely be affected by the adoption of the rule:	Classification by types of the business entities which would likely be affected:	Estimate in the aggregate as to the cost of compliance with the rule by the affected entities:
<b>148</b>	<b>Private hospitals</b>	<b>\$210,560 for the initial five year period and \$119,700 annually thereafter.</b>

**III. WORKSHEET**

**1. Honorariums.**

- A. For level one and two designated stroke centers during the initial five year period- \$600 for the day of travel per reviewer + \$850 for the day of the review per reviewer X four reviewers at the most= \$5,800.  
\$5,800 X four level one/two initial reviews= \$23,200.  
\$5,800 X four level one/two validation reviews= \$23,200.  
\$5,800 X two level one/two focus reviews= \$11,600.**

**\$23,200 + \$23,200 + \$11,600 = \$58,000 for the initial five year period for honorariums to be paid for reviews of level one/two designated stroke centers.**

**For level one and two designated stroke centers each year after the initial five year period-\$600 for the day of travel per reviewer + \$850 for the day of the review per reviewer X four reviewers at the most= \$5,800.**

$\$5,800 \times \text{two level one/two initial reviews} = \$11,600.$   
 $\$5,800 \times \text{three level one/two validation reviews} = \$17,400.$   
 $\$5,800 \times \text{two level one/two focus reviews} = \$11,600.$

$\$11,600 + \$17,400 + \$11,600 = \$40,600$  for each year after the initial five year period for honorariums to be paid for reviews of level one/two designated stroke centers.

- B. For level three and four designated stroke centers during the initial five year period- \$500 for the day of travel per reviewer + \$500 for the day of review per reviewer X four reviewers at the most = \$4,000.**

$\$4000 \times \text{eight level three/four initial reviews} = \$32,000.$   
 $\$4000 \times \text{eight level three/four validation reviews} = \$32,000.$   
 $\$4000 \times \text{three level three/four focus reviews} = \$12,000.$

$\$32,000 + \$32,000 + \$12,000 = \$76,000$  for the initial five year period for honorariums to be paid for reviews of level three/four designated stroke centers.

For level three and four designated stroke centers during each year after the initial five year period- \$500 for the day of travel per reviewer + \$500 for the day of the review per reviewer X four reviewers at the most = \$4,000.

$\$4,000 \times \text{two level three/four initial reviews} = \$8,000.$   
 $\$4,000 \times \text{five level three/four validation reviews} = \$20,000.$   
 $\$4,000 \times \text{two level three/four focus reviews} = \$8,000.$

$\$8,000 + \$20,000 + \$8,000 = \$36,000$  total honorariums for each year after the initial five year period for level three/four designated stroke centers.

**Total Honorariums-**

$\$58,000$  (level one/two designated stroke centers for the initial five year period) +  $\$76,000$  (level three/four designated stroke centers for the initial five year period) =  $\$134,000$  total for level one/two/three/four designated stroke centers for the initial five year period.

$\$40,600$  (level one/two designated stroke centers for each year after the initial five year period) +  $\$36,000$  (level three/four designated stroke centers for each year after the initial five year period) =  $\$76,600$  total for level one/two/three/four designated stroke centers for each year after the initial five year period.

**2. Airfare-**

For the initial five year period- \$400 per reviewer X four reviewers at the most= \$1600 X 10 level one/two reviews during the initial five year period = \$16,000.

For each year after the initial five year period- \$400 per reviewer X four reviewers at the most = \$1,600 X seven reviews each year after the initial five year period = \$11,200.

**3. Mileage-**

For the initial five year period- 500 miles per reviewer X \$0.51 X four reviewers at the most= \$1,020 X 19 level three/four reviews during the initial five year period= \$19,380.

For each year after the initial five year period- 500 miles per reviewer X \$0.51 X four reviewers at the most = \$1,020 X nine level three/four reviews during each year after the initial five year period = \$9,180.

**4. Lodging-**

For the initial five year period- \$105 per reviewer X four reviewers at the most = \$420 X 29 reviews during the initial five year period = \$12,180.

For each year after the initial five year period- \$105 per reviewer X four reviewers at the most = \$420 X 16 reviews each year after the initial five year period = \$6,720.

**5. Incidental expenses for the initial five year period- \$250 per reviewer X four reviewers at the most= \$1,000 X 29 reviews during the initial five year period = \$29,000**

For each year after the initial five year period- \$250 per reviewer X four reviewers at the most = \$1,000.00 X 16 reviews each year after the initial five year period= \$16,000.

**Total-**

For the initial five year period- \$134,000 (honorariums) + \$16,000 (airfare) + \$19,380 (mileage) + \$12,180 (lodging) + \$29,000 (incidental expenses) = \$210,560.

For each year after the five year period- \$76,600 (honorariums) + \$11,200 (airfare) + \$9,180 (mileage) + \$6,720 (lodging) + \$16,000 (incidental expenses) = \$119,700.

#### IV. ASSUMPTIONS

**There are 148 private licensed hospitals in Missouri. All of these private hospitals have the potential to apply for designation as a level one, two, three or four stroke center. Stroke center designation is valid for a period of four years from the date the stroke center/hospital is designated.**

**It is anticipated that there will be at least twelve private hospitals on average applying to become a designated stroke center (level one, level two, level three or level four) during the first five year period as the interest expressed to the Department about hospitals becoming designated stroke centers has been very positive. It is anticipated that four of the private hospitals applying to become a stroke designated center each year will be requesting a level one or level two designation and eight private hospitals will be requesting to become a level three or level four designated stroke center during this five year period. Similarly, during the first five years, there will be at least twelve private hospitals requiring a validation review at the end of the four year designation period in order to become designated as a stroke center again. It is anticipated that four of the private hospitals requesting a validation review will be a level one or level two designated stroke center and eight private hospitals requiring a validation review will be a level three or level four designated stroke center. Finally, there will be an average of five focus reviews during the first five years. Focus reviews for the trauma designated centers, a designation process the Department has had in place for greater than ten years, have been required infrequently. It is anticipated two of the focus reviews will be with a level one or level two designated stroke center and three focus reviews will be conducted on a level three or level four designated stroke center.**

**After the first five years, the Department anticipates two level one or level two private hospitals will request an initial review each year after the initial five year period and two level three or level four private hospitals will request an initial review each year after the initial five year period. The Department anticipates three level one or level two designated stroke centers will require a validation review each year after the initial five year period and five level three or level four designated stroke centers will require a validation review after the initial five year period. Finally, the Department anticipates two level one or level two designated stroke centers will require a focus review each year after the initial five year period and two level three or level four designated stroke centers will require a focus review each year after the initial five year period.**

**The review teams will have at the most four reviewers.**

**Reviewers of level one and level two trauma designated centers have been receiving approximately \$1450 for honorariums. Reviewers of level three trauma designated centers have been receiving approximately \$1000 for honorariums. The Department used these numbers for the reviewers of stroke designated centers too.**

**Only reviewers for level one and level two stroke designated centers will incur airfare charges because reviewers for level three and level four stroke designated centers are in-state reviewers.**

**The airfare charge of \$400 per reviewer is an estimate found by looking at airfares on airline websites. This airfare charge is for a coach reservation on a roundtrip flight.**

**The mileage rate is figured by the federal business rate from the Internal Revenue Service which is currently \$0.51.**

**The estimate of 500 miles is an average to drive from the outermost points north to south or east to west in Missouri.**

**The mileage estimate is figured only with level three and level four designated stroke center reviews as these will all be in-state reviewers.**

**The lodging costs of \$105.00 per reviewer is based on the current state reimbursement rate for St. Louis hotels.**

**The Department has placed a maximum of \$250.00 for the reimbursement of incidental expenses by reviewers.**

**Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES**  
**Division 30—Division of Regulation and Licensure**  
**Chapter 40—Comprehensive Emergency Medical Services Systems Regulations**

**PROPOSED RULE**

**19 CSR 30-40.730 Standards for Stroke Center Designation**

*PURPOSE: This rule establishes standards for level I, II, III, and IV stroke center designation.*

*AGENCY NOTE:*

*I-R, II-R, III-R, or IV-R after a standard indicates a requirement for level I, II, III, or IV stroke centers respectively.*

*I-IH, II-IH, III-IH, or IV-IH after a standard indicates an in-house requirement for level I, II, III, or IV-IH stroke centers respectively.*

*I-IA, II-IA, III-IA, or IV-IA indicates an immediately available requirement for level I, II, III, or IV stroke centers respectively.*

*I-PA, II-PA, III-PA, or IV-PA indicates a promptly available requirement for level I, II, III, or IV stroke centers respectively.*

*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) General Standards for Stroke Center Designation.

(A) The stroke center board of directors, administration, medical staff, and nursing staff shall demonstrate a commitment to quality stroke care. Methods of demonstrating the commitment shall include, but not be limited to, a board resolution that the hospital governing body agrees to establish policy and procedures for the maintenance of services essential for a stroke center; assure that all stroke patients will receive medical care at the level of the hospital's designation; commit the institution's financial, human, and physical resources as needed for the stroke program; and establish a priority admission for the stroke patient to the full services of the institution. (I-R, II-R, III-R, IV-R)

(B) Stroke centers shall agree to accept all stroke patients appropriate for the level of care provided at the hospital, regardless of race, sex, creed, or ability to pay. (I-R, II-R, III-R, IV-R)

(C) The stroke center shall demonstrate evidence of a stroke program. The stroke program shall be available twenty-four (24) hours a day, seven (7) days a week to evaluate and treat stroke patients. (I-R, II-R, III-R, IV-R)

1. The stroke center shall maintain a stroke team that at a minimum shall consist of—

A. A core team which provides administrative oversight and includes:

(I) A physician experienced in diagnosing and treating cerebrovascular disease (usually the stroke medical director); and (I-R, II-R, III-R, IV-R)

(II) At least one (1) other health care professional or qualified individual credentialed in stroke patient care (usually the stroke program manager/coordinator); (I-R, II-R, III-R, IV-R)

B. A stroke call roster 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 stroke patients. A level I stroke center call roster shall include, but not be limited to, the emergency department physician, neuro-interventionalist, neuro-

logist, and others as appropriate. A level II stroke center call roster shall include, but not be limited to, the emergency department physician, a physician with experience and expertise in diagnosing and treating patients with cerebrovascular disease, and others as appropriate. The level III stroke center call roster shall include, but not be limited to, the emergency department physician and others as appropriate. A level IV stroke center call roster shall include, but not be limited to, the emergency department physician and other qualified individuals as appropriate. (I-R, II-R, III-R, IV-R)

(I) This coverage shall be available from notification of stroke patients according to the response requirements as set out below—

(a) Level I and II stroke centers shall have this coverage available within fifteen (15) minutes of notification of a stroke patient; and (I-R, II-R)

(b) Level III and IV stroke centers shall have a regional networking agreement with a level I or level II stroke center for telephone consult or telemedicine consultation available within fifteen (15) minutes of notification of a stroke patient; and (III-R, IV-R)

C. A clinical team appropriate to the center level designation that may include, but not be limited to, members of the stroke call roster, neurologists, physicians with expertise caring for stroke patients, neuro-interventionalists, neurosurgeons, anesthesiologists, intensivists, emergency department physicians, and other stroke center clinical staff as applicable. (I-R, II-R, III-R, IV-R)

2. The stroke center shall have a peer review system to review stroke cases respective of the stroke center's designation. (I-R, II-R, III-R, IV-R)

3. The stroke team members shall have appropriate experience to maintain skills and proficiencies to care for stroke patients. The stroke center shall maintain evidence that it meets the following requirements by documenting the following:

A. A list of all stroke team members; (I-R, II-R, III-R, IV-R)

B. Position qualifications and completion of continuing education requirements by stroke team members as set forth in sections (1), (2), and (4) of this rule; (I-R, II-R, III-R, IV-R)

C. Management of sufficient numbers of stroke patients by the stroke team members in order to maintain their stroke skills; (I-R, II-R, III-R, IV-R)

D. Participation by the core team and members of the stroke call roster in at least half of the regular, ongoing stroke program peer review system meetings as shown in meeting attendance documents. The stroke medical director shall disseminate the information and findings from the peer review system meetings to the stroke call roster members and the core team and document such dissemination; (I-R, II-R, III-R, IV-R)

E. Participation by stroke team members in at least half of the regular, ongoing stroke program performance improvement and patient safety meetings and documentation of such attendance in the meeting minutes and/or meeting attendance documents. The stroke medical director shall disseminate the information and findings from the performance improvement and patient safety meetings to the stroke team members and document such dissemination. If a stroke team member is unable to attend a stroke program performance improvement and patient safety meeting, then the stroke team member shall send an appropriate representative in his/her place; (I-R, II-R, III-R, IV-R)

F. Maintenance of skill levels in the management of stroke patients by the stroke team members as required by the stroke center and the stroke medical director and documentation of such continued experience; (I-R, II-R, III-R, IV-R)

G. Review of regional outcome data on quality of patient care by the stroke team members as part of the stroke center's performance improvement and patient safety process; and (I-R, II-R, III-R, IV-R)

H. Evidence of a written agreement between a level III stroke center and a level I or II stroke center when a level III stroke center

has a supervised relationship with a physician affiliated with a level I or II stroke center. A level III stroke center which provides lytic therapy to stroke patients may have an established plan for admitting and caring for stroke patients under a supervised relationship with a physician affiliated with a level I or II stroke center. This supervised relationship shall consist of a formally established and pre-planned relationship between the centers in which a physician from a level I or level II center supervises a physician in a level III center in the evaluation of a stroke patient for lytic therapy and the care of the patient post-lytic therapy in certain circumstances where that level III center does not transfer the patient to a higher level stroke center. In this setting, management decisions, including, but not limited to, administration of lytic therapy, transfer or non-transfer of patient, and post-lytic therapy shall be made jointly between the supervising and supervised physicians. Care protocols and pathways for patients that fall into this category shall be established by both parties at the outset of the establishment of the relationship. This supervised relationship shall be established by written agreement and detail the supervision of patient care. This written agreement may also include, but not be limited to, observation of patient care, review of level III stroke center's patient encounters, review of level III center's outcomes, evaluation of the level III center's process pertaining to stroke patients, and lytic therapy and guidance on methods to improve process, performance, and outcomes.

4. The stroke center shall maintain a multidisciplinary team, in addition to the stroke team, to support the care of stroke patients. (I-R, II-R, III-R, IV-R)

A. The multidisciplinary team shall include a suitable representative from hospital units as appropriate for care of each stroke patient. The hospital units represented on the multidisciplinary team may include, but not be limited to: administration, emergency medical services, intensive care unit, radiology, pharmacy, laboratory, stroke unit, stroke rehabilitation, and discharge planning. (I-R, II-R, III-R, IV-R)

B. The multidisciplinary team members or their representatives shall attend at least half of the stroke program performance improvement and patient safety program meetings which shall be documented in the meeting minutes and/or meeting attendance documents. (I-R, II-R, III-R, IV-R)

(D) A level I stroke center shall provide the services of a neuro-interventional laboratory staffed twenty-four (24) hours a day, seven (7) days a week.

1. The staff of the neuro-interventional laboratory, referred to as the neuro-interventional laboratory team, shall consist of at least the following:

A. Neuro-interventional specialist(s); and (I-R/PA)

B. Other clinical staff as deemed necessary. (I-R/PA)

2. The stroke center neuro-interventional laboratory team shall maintain core competencies annually as required by the stroke center. (I-R/PA)

3. The hospital credentialing committee shall document that the neuro-interventional specialist(s) have completed appropriate training and conducted sufficient neuro-interventional procedures. (I-R/PA)

4. The stroke center neuro-interventional laboratory team shall remain up to date in their continuing education requirements which are set forth in section (4) of this rule. (I-R/PA)

5. Resuscitation equipment shall be available in the neuro-interventional lab. (I-R)

(E) It is recommended that a level I stroke center meet the volume for stroke patient cases that is required for eligibility by The Joint Commission in its Advanced Certification of Comprehensive Stroke Centers as posted on January 31, 2012, which is incorporated by reference in this rule and is available at The Joint Commission, One Renaissance Boulevard, Oakbrook Terrace, IL 60181 or on The Joint Commission's website at [www.jointcommission.org](http://www.jointcommission.org). This rule does not incorporate any subsequent amendments or additions.

(F) The stroke center shall appoint a physician to serve as the stroke medical director. A stroke medical director shall be appointed

at all times with no lapses. (I-R, II-R, III-R, IV-R)

1. A level I stroke medical director shall have appropriate qualifications, experience, and training. A board-certified or board-admissible neurologist or other neuro-specialty trained physician is recommended. If the stroke medical director is board-certified or board-admissible, then one (1) of the following additional qualifications shall be met and documented. If the stroke medical director is not board-certified, then two (2) of the following additional qualifications shall be met and documented:

A. Completion of a stroke fellowship; (I-R)

B. Participation (as an attendee or faculty) in one (1) national or international stroke course or conference each year or two (2) regional or state stroke courses or conferences each year; or (I-R)

C. Five (5) or more peer-reviewed publications on stroke. (I-R)

2. A level II stroke medical director shall have appropriate qualifications, experience, and training. A board-certified or board-admissible physician with training and expertise in cerebrovascular disease is recommended. If the stroke medical director is board-certified or board-admissible, then one (1) of the following additional qualifications shall be met. If the stroke medical director is not board-certified, then two (2) of the following additional qualifications shall be met and documented:

A. Completion of a stroke fellowship; (II-R)

B. Participation (as an attendee or faculty) in one (1) national or international stroke course or conference each year or two (2) regional or state stroke courses or conferences each year; or (II-R)

C. Five (5) or more peer-reviewed publications on stroke. (II-R)

3. A level III and IV stroke medical director shall have the appropriate qualifications, experience, and training. A board-certified or board-admissible physician is recommended. If the stroke medical director is not board-certified or board-admissible, then the following additional qualifications shall be met and documented:

A. Complete a minimum of ten (10) hours of continuing medical education (CME) in the area of cerebrovascular disease every other year; and (III-R, IV-R)

B. Attend one (1) national, regional, or state meeting every three (3) years in cerebrovascular disease. Continuing medical education hours earned at these meetings can count toward the ten (10) required continuing medical education hours. (III-R, IV-R)

4. The stroke medical director shall meet the department's continuing medical education requirements for stroke medical directors as set forth in section (4) of this rule. (I-R, II-R, III-R, IV-R)

5. The stroke center shall have a job description and organizational chart depicting the relationship between the stroke medical director and the stroke center services. (I-R, II-R, III-R, IV-R)

6. The stroke medical director is encouraged to be a member of the stroke call roster. (I-R, II-R, III-R, IV-R)

7. The stroke medical director shall be responsible for the oversight of the education and training of the medical and clinical staff in stroke care. This includes a review of the appropriateness of the education and training for the practitioner's level of responsibility. (I-R, II-R, III-R, IV-R)

8. The stroke medical director shall participate in the stroke center's research and publication projects. (I-R)

(G) The stroke center shall have a stroke program manager/coordinator who is a registered nurse or qualified individual. The stroke center shall have a stroke program manager/coordinator at all times with no lapses. (I-R, II-R, III-R, IV-R)

1. The stroke center shall have a job description and organizational chart depicting the relationship between the stroke program manager/coordinator and the stroke center services. (I-R, II-R, III-R, IV-R)

2. The stroke program manager/coordinator shall—

A. Meet continuing education requirements as set forth in section (4) of this rule; and (I-R, II-R, III-R, IV-R)

B. Participate in the performance improvement and patient



safety program. (I-R, II-R, III-R, IV-R)

(H) The stroke center shall have a specific and well-organized system to notify and rapidly activate the stroke team to evaluate patients presenting at the stroke center with symptoms suggestive of an acute stroke. (I-R, II-R, III-R, IV-R)

(I) The stroke center shall have a one- (1-) call stroke team activation protocol. This protocol shall establish the following:

1. The criteria used to triage stroke patients shall include, but not be limited to, the time of symptom onset; (I-R, II-R, III-R, IV-R)

2. The persons authorized to notify stroke team members when a suspected stroke patient is in route and/or when a suspected stroke patient has arrived at the stroke center; (I-R, II-R, III-R, IV-R)

3. The method for immediate notification and the response requirements for stroke team members when a suspected stroke patient is in route to the stroke center and/or when a suspected stroke patient has arrived at the stroke center; and (I-R/IA, II-R/IA, III-R/IA, IV-R/IA)

4. All members of the stroke call roster shall comply with the availability and response requirements per the stroke center's protocols and be in communication within fifteen (15) minutes of notification of the patient. If not on the stroke center's premises, stroke call roster members who are on call shall carry electronic communication devices at all times to permit contact by the hospital. It is recommended that one (1) member of the stroke team, per stroke center protocol, be at the patient's bedside within fifteen (15) minutes of notification of the patient. (I-R, II-R, III-R, IV-R)

(J) The stroke center shall have a fibrinolysis protocol for cases when fibrinolysis is achievable. (I-R, II-R, III-R)

(K) The stroke center shall have transfer agreements between referring and receiving facilities that address the following:

1. A one- (1-) call transfer protocol that establishes the criteria used to triage stroke patients and identifies persons authorized to notify the designated stroke center; and (I-R, II-R, III-R, IV-R)

2. A rapid transfer process in place to transport a stroke patient to a higher level of stroke care when needed. (II-R, III-R, IV-R)

(L) The stroke center shall have rehabilitation services that are directed by a physician with board certification in physical medicine and rehabilitation or by other properly trained individuals (e.g., neurologist experienced in stroke rehabilitation). (I-R, II-R)

(M) The stroke center shall have consults for physical medicine and rehabilitation, physical therapy, occupational therapy, and speech therapy requested and completed when deemed medically necessary within forty-eight (48) hours of admission. (I-R, II-R)

(N) The stroke center shall demonstrate that there is a plan for adequate post-discharge and post-transfer follow-up on stroke patients, including rehabilitation and repatriation, if indicated. (I-R, II-R, III-R, IV-R)

(O) The stroke center shall maintain a stroke patient log. The log information shall be kept for a period of five (5) years and made available to the Department of Health and Senior Services (department) during reviews for all stroke patients which contains the following:

1. Response times; (I-R, II-R, III-R, IV-R)

2. Patient diagnosis; (I-R, II-R, III-R, IV-R)

3. Treatment/actions; (I-R, II-R, III-R, IV-R)

4. Outcomes; (I-R, II-R, III-R, IV-R)

5. Number of patients; and (I-R, II-R, III-R, IV-R)

6. Benchmark indicators. (I-R, II-R, III-R, IV-R)

(P) The stroke center shall have a helicopter landing area. (I-R, II-R, III-R, IV-R)

1. Level I and II stroke centers shall have a lighted designated helicopter landing area at the stroke center to accommodate incoming medical helicopters. (I-R, II-R)

A. The landing area shall serve solely as the receiving and take-off area for medical helicopters and shall be cordoned off at all times from the general public to assure its continual availability and safe operation. (I-R, II-R)

B. The landing area shall be on the hospital premises no more

than three (3) minutes from the emergency room. (I-R, II-R)

2. Level III and IV stroke centers shall have a lighted designated helicopter landing area that meets the following requirements:

A. Accommodates incoming medical helicopters; (III-R, IV-R)

B. Serves as the receiving and take-off area for medical helicopters; (III-R, IV-R)

C. Be cordoned off when in use from the general public; (III-R, IV-R)

D. Be managed to assure its continual availability and safe operation; and (III-R, IV-R)

E. Though not required, it is recommended the landing area be no more than three (3) minutes from the emergency department. (III-R, IV-R)

(Q) Stroke centers shall enter data into the Missouri stroke registry as follows:

1. All stroke centers shall submit data into the department's Missouri stroke registry on each stroke patient who is admitted to the stroke center, transferred out of the stroke center, or dies as a result of the stroke (independent of hospital admission or hospital transfer status). The data required to be submitted into the Missouri stroke registry by the stroke centers is listed and explained in the document entitled "Time Critical Diagnosis Stroke Center Registry Data Elements" dated March 1, 2012, which is incorporated by reference in this rule and is available at the Missouri Department of Health and Senior Services, PO Box 570, Jefferson City, MO 65102-0570 or on the department's website at [www.health.mo.gov](http://www.health.mo.gov). This rule does not incorporate any subsequent amendments or additions; (I-R, II-R, III-R, IV-R)

2. The data required in paragraph (1)(Q)1. above shall be submitted electronically into the Missouri stroke registry via the department's website at [www.health.mo.gov](http://www.health.mo.gov); (I-R, II-R, III-R, IV-R)

3. The data required in paragraph (1)(Q)1. above shall be submitted electronically into the Missouri stroke registry on at least a quarterly basis for that calendar year. Stroke centers have ninety (90) days after the quarter ends to submit the data electronically into the Missouri stroke registry; (I-R, II-R, III-R, IV-R)

4. The data submitted by the stroke centers shall be complete and current; and (I-R, II-R, III-R, IV-R)

5. The data shall be managed in compliance with the confidentiality requirements and procedures contained in section 192.067, RSMo. (I-R, II-R, III-R, IV-R)

(R) A stroke center shall maintain a diversion protocol for the stroke center that is designed to allow best resource management within a given area. The stroke center shall create criteria for diversion in this diversion protocol and shall detail a performance improvement and patient safety process in the diversion protocol to review and validate the criteria for diversion created by the stroke center. The stroke center shall also collect, document, and maintain diversion information that includes at least the date, length of time, and reason for diversion. This diversion information shall be readily retrievable by the stroke center during a review by the department and shall be kept by the stroke center for a period of five (5) years. (I-R, II-R, III-R, IV-R)

(2) Medical Staffing Standards for Stroke Center Designation.

(A) The stroke center's medical staff credentialing committee shall provide a delineation of privileges for neurologists, neurosurgeons, and neuro-interventionalists, as applicable to the stroke center. (I-R, II-R)

(B) The stroke center shall credential and shall have the following types of physicians available as listed below:

1. A neurologist shall be available for consultation within fifteen (15) minutes of patient notification; (I-R)

2. A physician with experience and expertise in diagnosing and treating patients with cerebrovascular disease shall be available for consultation within fifteen (15) minutes of patient notification; (II-R)

3. A neurosurgeon as follows:

A. Neurosurgeon and back-up coverage on the call roster; (I-R/PA)

B. Neurosurgeon and back-up coverage on the call roster or available within two (2) hours by transfer agreement if not on staff; and (II-R/PA)

C. The neurosurgery staffing requirement may be fulfilled by a surgeon who has been approved by the chief of neurosurgery for care of stroke patients and shall be capable of initiating measures to stabilize the patient and perform diagnostic procedures; (I-R, II-R)

4. A neuro-interventional specialist; (I-R/PA)

5. An emergency department physician; (I-R/IH, II-R/IH, III-R/IH; IV-R/IA)

6. An internal medicine physician; (I-R/PA, II-R/PA, III-R/PA)

7. A diagnostic radiologist; and (I-R/IA, II-R/IA, III-R/IA)

8. An anesthesiologist. (I-R/PA, II-R/PA)

A. Anesthesiology staffing requirements may be fulfilled by anesthesiology residents, certified registered nurse anesthetists (CRNA), or anesthesia assistants capable of assessing emergent situations in stroke patients and of providing any indicated treatment including induction of anesthesia. When anesthesiology residents or CRNAs are used to fulfill availability requirements, the staff anesthesiologist on call will be advised and promptly available and present for all operative interventions and emergency airway conditions. The CRNA may proceed with life preserving therapy while the anesthesiologist is in route under the direction of the neurosurgeon, including induction of anesthesia. An anesthesiologist assistant shall practice only under the direct supervision of an anesthesiologist who is physically present or immediately available as this term is defined in section 334.400, RSMo. (I-R, II-R)

(3) Standards for Hospital Resources and Capabilities for Stroke Center Designation.

(A) The stroke center shall meet emergency department standards listed below. (I-R, II-R, III-R, IV-R)

1. The emergency department staffing shall meet the following requirements:

A. The emergency department in the stroke center shall provide immediate and appropriate care for the stroke patient; (I-R, II-R, III-R, IV-R)

B. A level I stroke center shall have a medical director of the emergency department who shall be board-certified or board-admissible in emergency medicine by the American Board of Medical Specialties, the Bureau of Osteopathic Specialties and Boards of Certification, or the Royal College of Physicians and Surgeons of Canada; (I-R)

C. A level II stroke center shall have a medical director of the emergency department who shall be a board-certified or board-admissible physician; (II-R)

D. A level III and IV stroke center shall have a medical director of the emergency department who is recommended to be a board-certified or board-admissible physician; (III-R, IV-R)

E. There shall be an emergency department physician credentialed for stroke care by the stroke center covering the emergency department twenty-four (24) hours a day, seven (7) days a week; (I-R/IH, II-R/IH, III-R/IH, IV-R/IA)

F. The emergency department physician who provides coverage shall be current in continuing medical education in the area of cerebrovascular disease; (I-R, II-R, III-R, IV-R)

G. There shall be a written policy defining the relationship of the emergency department physicians to other physician members of the stroke team; (I-R, II-R, III-R, IV-R)

H. Registered nurses in the emergency department shall be current in continuing education requirements as set forth in section (4) of this rule; (I-R, II-R, III-R, IV-R)

I. All registered nurses assigned to the emergency department shall be determined to be credentialed in the care of the stroke patient by the stroke center within one (1) year of assignment and remain current in continuing education requirements as set forth in section

(4) of this rule; and (I-R, II-R, III-R, IV-R)

J. The emergency department in stroke centers shall have written care protocols for identification, triage, and treatment of acute stroke patients that are available to emergency department personnel, reviewed annually, and revised as needed. (I-R, II-R, III-R, IV-R)

2. Nursing documentation for the stroke patient shall be on a stroke flow sheet approved by the stroke medical director and the stroke program coordinator/manager. (I-R, II-R, III-R, IV-R)

3. The emergency department shall have at least the following equipment for resuscitation and life support available to the unit:

A. Airway control and ventilation equipment including:

(I) Laryngoscopes; (I-R, II-R, III-R, IV-R)

(II) Endotracheal tubes; (I-R, II-R, III-R, IV-R)

(III) Bag-mask resuscitator; (I-R, II-R, III-R, IV-R)

(IV) Sources of oxygen; and (I-R, II-R, III-R, IV-R)

(V) Mechanical ventilator; (I-R, II-R, III-R)

B. Suction devices; (I-R, II-R, III-R, IV-R)

C. Electrocardiograph (ECG), cardiac monitor, and defibrillator; (I-R, II-R, III-R, IV-R)

D. Central line insertion equipment; (I-R, II-R, III-R)

E. All standard intravenous fluids and administration devices including intravenous catheters and intraosseous devices; (I-R, II-R, III-R, IV-R)

F. Drugs and supplies necessary for emergency care; (I-R, II-R, III-R, IV-R)

G. Two- (2-) way communication link with emergency medical service (EMS) vehicles; (I-R, II-R, III-R, IV-R)

H. End-tidal carbon dioxide monitor; and (I-R, II-R, III-R, IV-R)

I. Temperature control devices for patient and resuscitation fluids. (I-R, II-R, III-R IV-R)

4. The stroke center emergency department shall maintain equipment following the hospital's preventive maintenance schedule and document when this equipment is checked. (I-R, II-R, III-R, IV-R)

(B) The stroke center shall have a designated intensive care unit (ICU). (I-R, II-R)

1. The intensive care unit shall ensure staffing to provide appropriate care of the stroke patient. (I-R, II-R)

A. The stroke center intensive care unit shall have a designated intensive care unit medical director who has twenty-four (24) hours a day, seven (7) days a week access to a physician knowledgeable in stroke care and who meets the stroke call roster continuing medical education requirements as set forth in section (4) of this rule. (I-R, II-R)

B. The stroke center intensive care unit shall have a physician on duty or available twenty-four (24) hours a day, seven (7) days a week who is not the emergency department physician. This physician shall have access to a physician on the stroke call roster. (I-R/IA, II-R/IA)

C. The stroke center intensive care unit shall have a one to one (1:1) or one to two (1:2) registered nurse/patient ratio used for critically ill patients requiring intensive care unit level care. (I-R, II-R)

D. The stroke center intensive care unit shall have registered nurses in the intensive care unit who are current in continuing education requirements as set forth in section (4) of this rule. (I-R, II-R)

E. The stroke center intensive care unit shall have registered nurses in the intensive care unit who meet at least the following core credentials for care of stroke patients on a yearly basis:

(I) Care of patients after thrombolytic therapy; (I-R, II-R)

(II) Treatment of blood pressure abnormalities with parenteral vasoactive agents; (I-R, II-R)

(III) Management of intubated/ventilated patients; (I-R, II-R)

(IV) Detailed neurologic assessment and scales (e.g., National Institutes of Health Stroke Scale, Glasgow Coma Scale); (I-R, II-R)

(V) Care of patients with intracerebral hemorrhage and subarachnoid hemorrhage at all level I centers and all level II centers with neurosurgical capability; (I-R, II-R)

(VI) Function of ventriculostomy and external ventricular drainage apparatus in all level I centers and all level II centers with neurosurgical capability; and (I-R, II-R)

(VII) Treatment of increased intracranial pressure in all level I centers and all level II centers with neurosurgical capability. (I-R, II-R)

2. The stroke center intensive care unit shall have written care protocols for identification and treatment of acute stroke patients which are available to intensive care unit personnel, reviewed annually, and revised as needed. (I-R, II-R)

3. The stroke center intensive care unit shall have intensive care unit beds for stroke patients or, if space is not available in the intensive care unit, the stroke center shall make arrangements to provide the comparable level of care until space is available in the intensive care unit. (I-R, II-R)

4. The stroke center intensive care unit shall have equipment available for resuscitation and to provide life support for the stroke patient. This equipment shall include at least the following:

A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes, bag-mask resuscitator, and a mechanical ventilator; (I-R, II-R)

B. Oxygen source with concentration controls; (I-R, II-R)

C. Cardiac emergency cart, including medications; (I-R, II-R)

D. Telemetry, ECG capability, cardiac monitor, and defibrillator; (I-R, II-R)

E. Electronic pressure monitoring and pulse oximetry; (I-R, II-R)

F. End-tidal carbon dioxide monitor; (I-R, II-R)

G. Patient weighing devices; (I-R, II-R)

H. Drugs, intravenous fluids, and supplies; and (I-R, II-R)

I. Intracranial pressure monitoring devices. (I-R, II-R)

5. The intensive care unit shall check all equipment according to the hospital preventive maintenance schedule and the stroke center shall document when it is checked. (I-R, II-R)

(C) Level I and level II stroke centers shall provide a stroke unit. A level III stroke center that has an established plan for admitting and caring for stroke patients under a supervised relationship with a level I or II stroke center pursuant to subparagraph (1)(C)3.H. above shall also provide a stroke unit. (I-R, II-R, III-R)

1. The stroke center shall have a designated medical director for the stroke unit who has access to a physician knowledgeable in stroke care and who meets the stroke call roster continuing medical education requirements as set forth in section (4) of this rule. (I-R, II-R, III-R)

2. The stroke center stroke unit shall have a physician on duty or available twenty-four (24) hours a day, seven (7) days a week who is not the emergency department physician. This physician shall have access to a physician on the stroke call roster. (I-R/IA, II-R/IA, III-R/IA)

3. The stroke center stroke unit shall have registered nurses and other essential personnel on duty twenty-four (24) hours a day, seven (7) days a week. (I-R, II-R, III-R)

4. The stroke center stroke unit shall have registered nurses who are current in continuing education requirements as set forth in section (4) of this rule. (I-R, II-R, III-R)

5. The stroke center stroke unit shall annually credential registered nurses that work in the stroke unit. (I-R, II-R, III-R)

6. The stroke center stroke unit shall have written care protocols for identification and treatment of acute stroke patients (e.g., lytic and post-lytic management, hemorrhagic conversion according to current best evidence) which are available to stroke unit personnel, reviewed annually, and revised as needed. (I-R, II-R, III-R)

7. The stroke center stroke unit shall have equipment to support the care and resuscitation of the stroke patient that includes at least

the following:

A. Airway control and ventilation equipment including:

(I) Laryngoscopes, endotracheal tubes of all sizes; (I-R, II-R, III-R)

(II) Bag-mask resuscitator and sources of oxygen; and (I-R, II-R, III-R)

(III) Suction devices; (I-R, II-R, III-R)

B. Telemetry, electrocardiograph, cardiac monitor, and defibrillator; (I-R, II-R, III-R)

C. All standard intravenous fluids and administration devices and intravenous catheters; and (I-R, II-R, III-R)

D. Drugs and supplies necessary for emergency care. (I-R, II-R, III-R)

8. The stroke center stroke unit shall maintain equipment following the hospital preventive maintenance schedule and document when it is checked. (I-R, II-R, III-R)

(D) The stroke center shall provide radiological and diagnostic capabilities. (I-R, II-R, III-R)

1. The radiological and diagnostic capabilities shall include a documented mechanism for prioritization of stroke patients and timely interpretation to aid in patient management. (I-R, II-R, III-R)

2. The radiological and diagnostic capabilities shall include the following equipment and staffing capabilities:

A. Angiography with interventional capability available twenty-four (24) hours a day, seven (7) days a week; (I-R/PA)

B. Cerebroangiography technologist on call and available within thirty (30) minutes for emergent procedures, and on call and available within sixty (60) minutes for routine procedures, and available twenty-four (24) hours a day, seven (7) days a week; (I-R)

C. In-house computerized tomography; (I-R/IA, II-R/IA, III-R/IA)

D. Computerized tomography perfusion; (I-R/IA)

E. Computerized tomography angiography; (I-R/IA)

F. Computerized tomography technologist; (I-R/IH, II-R/IH, III-R/IA)

G. Magnetic resonance imaging; (I-R, II-R)

H. Magnetic resonance angiogram/magnetic resonance venography; (I-R, II-R)

I. Magnetic resonance imaging technologist on call and available within sixty (60) minutes, twenty-four (24) hours a day, seven (7) days a week; (I-R, II-R)

J. Extracranial ultrasound; (I-R, II-R)

K. Equipment and clinical staff to evaluate for vasospasm available within thirty (30) minutes for emergent evaluation, and available within sixty (60) minutes for routine evaluation, and available twenty-four (24) hours a day, seven (7) days a week; (I-R)

L. Transthoracic echo; (I-R, II-R)

M. Transesophageal echo; and (I-R, II-R)

N. Resuscitation equipment available to the radiology department. (I-R, II-R, III-R)

3. The radiological and diagnostic capabilities shall include adequate physician and nursing personnel available with monitoring equipment to fully support the acute stroke patient and provide documentation of care during the time the patient is physically present in the radiology department and during transportation to and from the radiology department. (I-R, II-R, III-R)

4. The radiological and diagnostic capabilities shall include the stroke center maintaining all radiology and diagnostic equipment according to the hospital preventive maintenance schedule and documenting when it is checked. (I-R, II-R, III-R)

(E) All level I stroke centers shall have operating room personnel, equipment, and procedures. Those level II stroke centers with neurosurgical capability shall also meet operating room personnel, equipment, and procedure requirements. (I-R, II-R)

1. Operating room staff shall be available twenty-four (24) hours a day, seven (7) days a week. (I-R/PA, II-R/PA)

2. Registered nurses shall annually maintain core competencies as required by the stroke center.

3. Operating rooms shall have at least the following equipment:
  - A. Operating microscope; (I-R, II-R)
  - B. Thermal control equipment for patient and resuscitation fluids; (I-R, II-R)
  - C. X-ray capability; (I-R, II-R)
  - D. Instruments necessary to perform an open craniotomy; (I-R, II-R)
  - E. Monitoring equipment; and (I-R, II-R)
  - F. Resuscitation equipment available to the operating room. (I-R, II-R)

4. The operating room shall maintain all equipment according to the hospital preventive maintenance schedule and document when it is checked. (I-R, II-R)

(F) All level I stroke centers shall meet post-anesthesia recovery room (PAR) requirements listed below. Those level II stroke centers with neurosurgical capability shall also have a post-anesthesia recovery room and meet the requirements below—

1. The stroke center post-anesthesia recovery room shall have registered nurses and other essential personnel on call and available within sixty (60) minutes twenty-four (24) hours a day, seven (7) days a week; (I-R, II-R)

2. The stroke center post-anesthesia recovery room's registered nurses shall annually maintain core competencies as required by the stroke center; (I-R, II-R)

3. The stroke center post-anesthesia recovery room shall have at least the following equipment for resuscitation and to provide life support for the stroke patient:

A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes of all sizes, bag-mask resuscitator, sources of oxygen, and mechanical ventilator; (I-R, II-R)

B. Suction devices; (I-R, II-R)

C. Telemetry, ECG capability, cardiac monitor, and defibrillator; (I-R, II-R)

D. All standard intravenous fluids and administration devices, including intravenous catheters; and (I-R, II-R)

E. Drugs and supplies necessary for emergency care; and (I-R, II-R)

4. The stroke center post-anesthesia recovery room shall maintain all equipment according to the hospital preventive maintenance schedule and document when it is checked. (I-R, II-R)

(G) The stroke center shall have clinical laboratory services available twenty-four (24) hours a day, seven (7) days a week that meet the following requirements:

1. Written protocol to provide timely availability of results; (I-R, II-R, III-R, IV-R)

2. Standard analyses of blood, urine, and other body fluids; (I-R, II-R, III-R, IV-R)

3. Blood typing and cross-matching; (I-R, II-R, III-R)

4. Coagulation studies; (I-R, II-R, III-R, IV-R)

5. Comprehensive blood bank or access to a community central blood bank and adequate hospital blood storage facilities; (I-R, II-R, III-R)

6. Blood bank or access to a community central blood bank and adequate hospital blood storage facilities; (IV-R)

7. Blood gases and pH determinations; (I-R, II-R, III-R, IV-R)

8. Blood chemistries; and (I-R, II-R, III-R, IV-R)

9. Written protocol for prioritization of the stroke patient with other time critical patients. (I-R, II-R, III-R, IV-R)

(H) The stroke center shall have support services to assist the patient's family from the time of entry into the facility to the time of discharge and records to document that these services were provided. (I-R, II-R, III-R, IV-R)

(I) The stroke center shall have a stroke rehabilitation program or a plan to refer those stroke patients that require rehabilitation to another facility or community agency that can provide necessary services. (I-R, II-R, III-R)

(4) Continuing Medical Education (CME) and Continuing Education

Standards for Stroke Center Designation.

(A) The stroke center shall ensure that staff providing services to stroke patients receives required continuing medical education and continuing education and document this continuing medical education and continuing education for each staff member. The department shall allow up to one (1) year from the date of the hospital's initial stroke center designation for stroke center staff members to complete all of the required continuing medical education and continuing education if the stroke center staff complete and document that at least half of the required continuing medical education and/or continuing education hours have been completed for each stroke center staff member at the time of on-site initial application review. The stroke center shall submit documentation to the department within one (1) year of the initial designation date that all continuing medical education and continuing education requirements for stroke center staff members have been met in order to maintain the stroke center's designation. (I-R, II-R, III-R, IV-R)

(B) The stroke call roster members shall complete the following continuing education requirements:

1. Level I core team members of the stroke call roster shall complete a minimum of ten (10) hours of continuing education in cerebrovascular disease every year, and it is recommended that a portion of those hours shall be on stroke care. All other members of the stroke call roster in level I stroke centers shall complete a minimum average of ten (10) hours of continuing education in cerebrovascular disease every year. This continuing education shall be reviewed for appropriateness to the practitioner's level of responsibility by the stroke medical director; (I-R)

2. Level II core team members of the stroke call roster shall complete a minimum of eight (8) hours of continuing education in cerebrovascular disease every year, and it is recommended that a portion of those hours be in stroke care. All other members of the stroke call roster in level II stroke centers shall complete a minimum average of eight (8) hours of continuing education in cerebrovascular disease every year. This continuing education shall be reviewed for appropriateness to the practitioner's level of responsibility by the stroke medical director; and (II-R)

3. Level III and IV stroke call roster members shall complete a minimum average of eight (8) hours of continuing education in cerebrovascular disease every two (2) years. This continuing education shall be reviewed for appropriateness to the practitioner's level of responsibility by the stroke medical director. (III-R, IV-R)

(C) The stroke medical director shall complete the following continuing medical education requirements:

1. Level I stroke medical directors shall complete a minimum of twelve (12) hours of continuing medical education every year in the area of cerebrovascular disease; (I-R)

2. Level II stroke medical directors shall complete a minimum of eight (8) hours of continuing medical education every year in the area of cerebrovascular disease; and (II-R)

3. Level III and IV stroke medical directors shall complete a minimum of eight (8) hours of continuing medical education every two (2) years in the area of cerebrovascular disease. (III-R, IV-R)

(D) The stroke center's stroke program manager/coordinator shall complete the following continuing education requirements:

1. Level I program managers/coordinators shall:

A. Complete a minimum of ten (10) hours of continuing education every year in cerebrovascular disease. This continuing education shall be reviewed by the stroke medical director for appropriateness to the stroke program manager/coordinator's level of responsibility; and (I-R)

B. Attend one (1) national, regional, or state meeting every two (2) years focused on the area of cerebrovascular disease. If the national or regional meeting provides continuing education, then that continuing education may count toward the annual requirement; (I-R)

2. Level II program managers/coordinators shall—

A. Complete a minimum average of eight (8) hours of continuing education every year in cerebrovascular disease. This continuing education shall be reviewed for appropriateness by the stroke

medical director to the stroke program manager/coordinator's level of responsibility; and (II-R)

B. Attend one (1) national, regional, or state meeting every three (3) years focused on the area of cerebrovascular disease. If the national, regional, or state meeting provides continuing education, then that continuing education may count toward the annual requirement; and (II-R)

3. Level III and IV center program managers/coordinators shall complete a minimum average of eight (8) hours of continuing education in cerebrovascular disease every two (2) years. This continuing education shall be reviewed by the stroke medical director for appropriateness to the stroke program manager/coordinator's level of responsibility. (III-R, IV-R)

(E) Emergency department personnel in stroke centers shall complete the following continuing education requirements:

1. Emergency department physicians in stroke centers shall complete—

A. Level I and II emergency department physicians providing stroke coverage shall complete a minimum average of four (4) hours of continuing medical education in cerebrovascular disease every year; or (I-R, II-R)

B. Level III and IV emergency department physicians providing stroke coverage shall complete a minimum average of six (6) hours of continuing medical education in cerebrovascular disease every two (2) years; and (III-R, IV-R)

2. Registered nurses assigned to the emergency departments in stroke centers shall complete—

A. Level I and II registered nurses shall complete a minimum of four (4) hours of cerebrovascular disease continuing education every year; (I-R, II-R)

B. Level III and IV registered nurses shall complete a minimum of six (6) hours of cerebrovascular disease continuing education every two (2) years; and (III-R, IV-R)

C. Registered nurses shall maintain core competencies in the care of the stroke patient annually as determined by the stroke center. Training to maintain these competencies may count toward continuing education requirements. (I-R, II-R, III-R, IV-R)

(F) Registered nurses assigned to the intensive care unit in the stroke centers who care for stroke patients shall complete the following continuing education requirements:

1. Level I intensive care unit registered nurses shall complete a minimum of ten (10) hours of cerebrovascular related continuing education every year; (I-R)

2. Level II intensive care unit registered nurses shall complete a minimum of eight (8) hours of cerebrovascular related continuing education every year; and (II-R)

3. The stroke medical director shall review the continuing education for appropriateness to the practitioner's level of responsibility. (I-R, II-R)

(G) Stroke unit registered nurses in the stroke centers shall complete the following continuing education requirements:

1. All level I stroke unit registered nurses shall complete a minimum of ten (10) hours of cerebrovascular disease continuing education every year; (I-R)

2. All level II stroke unit registered nurses shall complete a minimum of eight (8) hours of cerebrovascular disease continuing education every year; (II-R)

3. All level III stroke centers caring for stroke patients under an established plan for admitting and caring for stroke patients under a supervised relationship with a physician affiliated with a level I or II stroke center shall require registered nurses in the stroke unit complete a minimum of eight (8) hours of cerebrovascular disease continuing education every two (2) years; and (III-R)

4. The stroke medical director shall review the continuing education for appropriateness to the practitioner's level of responsibility. (I-R, II-R, III-R)

(5) Standards for Hospital Performance Improvement and Patient

Safety, Outreach, Public Education, and Training Programs for Stroke Center Designation.

(A) The stroke center shall maintain an ongoing performance improvement and patient safety program designed to objectively and systematically monitor, review, and evaluate the quality, timeliness, and appropriateness of patient care; resolve problems; and improve patient care. (I-R, II-R, III-R, IV-R)

1. The stroke center shall collect, document, trend, maintain for at least five (5) years, and make available for review by the department at least the following data elements:

A. Door-to-needle time; (I-R, II-R, III-R)

B. Number of patients presenting within the treatment window; and (I-R, II-R, III-R)

C. Number of eligible patients treated with thrombolytics. (I-R, II-R, III-R)

2. The stroke center shall at least quarterly conduct a regular morbidity and mortality review meeting which shall be documented in the meeting minutes and/or the meeting attendance documents. (I-R, II-R, III-R, IV-R)

3. The stroke center shall review the reports generated by the department from the Missouri stroke registry. (I-R, II-R, III-R, IV-R)

4. The stroke center shall conduct monthly reviews of pre-hospital stroke care including inter-facility transfers. (I-R, II-R, III-R, IV-R)

5. The stroke center shall 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. (I-R, II-R, III-R, IV-R)

6. The stroke center shall document review of its cases of stroke patients who received U.S. Food and Drug Administration-approved thrombolytics and who remained at the referring hospital greater than ninety (90) minutes prior to transfer. (I-R, II-R, III-R)

7. The stroke center shall document its review of cases of stroke patients who did not receive U.S. Food and Drug Administration-approved thrombolytics and who remained greater than sixty (60) minutes at the referring hospital prior to transfer. (II-R, III-R, IV-R)

8. The stroke center shall review and monitor the core competencies of the physicians, practitioners, and nurses and document these core competencies have been met. (I-R, II-R, III-R, IV-R)

(B) The stroke center shall establish a patient and public education program to promote stroke prevention and stroke symptoms awareness. (I-R, II-R, III-R, IV-R)

(C) It is recommended that level I, II, and III stroke centers establish a professional education outreach program in catchment areas to provide training and other supports to improve care of stroke patients. (I-R, II-R, III-R)

(D) Each stroke center shall establish a training program for professionals on caring for stroke patients in the stroke center that includes at least the following:

1. A procedure for training nurses and clinical staff to be credentialed in stroke care; (I-R, II-R, III-R, IV-R)

2. A mechanism to assure that all nurses providing care to stroke patients complete a minimum of required continuing education as set forth in section (4) of this rule to become credentialed in stroke care; and (I-R, II-R, III-R, IV-R)

3. The content and format of any stroke continuing education courses developed and offered by the stroke center shall be developed with the oversight of the stroke medical director. (I-R, II-R, III-R, IV-R)

(E) The stroke center shall provide and monitor timely feedback to the emergency medical service providers and referring hospital, if involved. This feedback shall include, at least, diagnosis, treatment, and disposition of the patients. It is recommended that the feedback be provided within seventy-two (72) hours of admission to the hospital. When emergency medical services does not provide patient care data on patient arrival or in a timely fashion (recommended

within three (3) hours of patient delivery), this time frame shall not apply. (I-R, II-R, III-R, IV-R)

(F) Stroke centers shall be actively involved in local and regional emergency medical services systems by providing training and clinical educational resources. (I-R, II-R, III-R, IV-R)

(6) Standards for the Programs in Stroke Research for Stroke Center Designation.

(A) Level I stroke centers shall support an ongoing stroke research program as evidenced by any of the following:

1. Production of evidence-based reviews of the stroke program's process and clinical outcomes; (I-R)
2. Publications in peer-reviewed journals; (I-R)
3. Reports of findings presented at regional, state, or national meetings; (I-R)
4. Receipt of grants for study of stroke care; (I-R)
5. Participation in multi-center studies; and (I-R)
6. Epidemiological studies and individual case studies. (I-R)

(B) The stroke center shall agree to cooperate and participate with the department in developing stroke prevention programs. (I-R, II-R, III-R, IV-R)

*AUTHORITY: section 192.006, RSMo 2000, and sections 190.185 and 190.241, RSMo Supp. 2012. Original rule filed Nov. 15, 2012.*

*PUBLIC COST: This proposed rule will cost state agencies or political subdivisions \$177,449,044 for the initial four- (4-) year period and \$50,413,398 annually thereafter.*

*PRIVATE COST: This proposed rule will cost private entities \$354,807,289 for the initial four- (4-) year period and \$92,504,758 annually thereafter.*

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with Teresa Generous, Director, Division of Regulation and Licensure, Missouri Department of Health and Senior Services, 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.*