The text of proposed rules and changes will appear under this heading. A 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 explanation is set out in the PURPOSE section of each rule. A citation of the legal authority to make rules is also required, and appears following the text of the rule, after the word "Authority."

Entirely 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 If an existing rule is to be amended or rescinded, it will have a heading of proposed amendment or proposed rescission.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 that are proposed to be amended will have new matter printed in boldface type and matter to be deleted placed in brackets.

An 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.

If 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*.

An 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.

If an agency decides to hold a public hearing after planning not to, it must withdraw the earlier notice, 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 1 – OFFICE OF ADMINISTRATION
Division 10 – Commissioner of Administration
Chapter 3 – Preapproval of Claims and Accounts

PROPOSED AMENDMENT

1 CSR 10-3.010 Preapproval of Claims/Accounts and Direct Deposit: Definitions/Examples. The Office of Administration is amending section (3).

PURPOSE: This proposed amendment modifies section (3) of the rule to clarify that an expense and equipment appropriation may be used for an unanticipated small dollar value maintenance, repair, minor modification, or capital improvement to a state-owned or leased facility or land, provided that such expenditure is approved by the directors of the Division of Facilities Management, Design and Construction and the Division of Accounting. This amendment increases the permissible amount of such expenditures, due to the cost of inflation. The amendment clarifies that expense and equipment funds may not be used for any maintenance, repair, minor modification, or capital improvement if an appropriation for such work was not approved by the General Assembly.

(3) The following are unallowable claims for the purpose of the appropriation charged:

(A) When the description of the claim indicates that the expenditure is not within the purpose of the appropriation being charged. For allowable claims, the following appropriation type definitions apply:

1. Expense and equipment – all expenditures for operating services, supplies, rentals, professional and technical services, other charges necessary to the operation of an agency, acquisition of equipment, and major repairs that extend the useful life of the equipment. *[This appropriation type also includes expenditures for operational repairs to state-owned facilities which do not increase their capacity or operating efficiency or enhance their function and are limited to ten thousand dollars ($10,000) per project. Expense and equipment appropriations may also be used for capital improvements to offices and buildings up to ten thousand dollars ($10,000) when no capital improvement appropriation exists and the expenditure is approved by the director of the Division of Facilities Management Design and Construction and the assistant director of the Division of Accounting. Expense and equipment appropriations do not include employee's wage/salaries, land acquisition, building acquisition, building construction, building demolition, and capital improvements other than those allowed above;]*

A. Expense and equipment may also include expenditures for unanticipated maintenance, repairs or minor modifications, or unanticipated capital improvements to a state-owned or leased facility or land that are limited to up to twenty thousand dollars ($20,000) per project. Such expenditures must be approved in advance by the director of the Division of Facilities Management, Design and Construction and the director of the Division of Accounting. If a qualifying project under this section is necessary for the health and safety of the public and/or state employees and exceeds the twenty thousand dollar ($20,000) threshold established above, the Commissioner of Administration may approve the use of an expense and equipment appropriation under this section up to thirty thousand dollars ($30,000) per project. An expense and equipment appropriation may not be used for any maintenance, repair, modification, or capital improvement of a facility for which an appropriation was requested and not approved by the General Assembly.

B. Expense and equipment appropriations do not include employee's wage/salaries, land acquisition, building acquisition, building construction, building demolition, and capital improvements other than those allowed above.

C. As used herein, the following definitions apply:

I. Maintenance – preventative, routine, cyclical, and/or emergency unscheduled work necessary to keep in good working condition any facility, land, or equipment;

II. Repair – any work necessary to restore to good working condition any facility, land, or equipment; and

III. Minor modification – any alteration or improvement to a facility, land, or equipment that does not increase its capacity or operating efficiency or enhance its function;

2. Capital improvements – substantial expenditures for the purchase of capital assets (land and buildings) and the extensive repairs and improvements to a capital asset which increases its capacity or operating efficiency by extending its useful life and/or enhancing its function*[. Purchase costs include purchase or contract price, delivered accessories, delivery*

charges, and other purchase-related costs. Extensive repair and improvement costs include materials and supplies directly related to the project and necessary to its completion and other related costs to the project];

3. Personal services – all expenditures for salaries, wages, and related employee benefits; and

4. Program/specific – expenses for a group of activities or services performed for an identifiable group to serve a specific purpose. This appropriation type allows any type of expenditure necessary to fulfill the intent of the program as defined in the corresponding house bill. Program appropriations may be broadly constructed or contain restrictive language for specific purposes;

AUTHORITY: sections 33.030(3), 33.103, 370.395, and 536.023, RSMo 2016. Original rule filed Aug. 15, 1994, effective Jan. 29, 1995. Amended: Filed Oct. 3, 2018, effective May 30, 2019. Emergency amendment filed Feb. 11, 2020, effective Feb. 27, 2020, expired Aug. 24, 2020. Amended: Filed Feb. 11, 2020, effective Aug. 30, 2020. Amended: Filed Nov. 29, 2022.

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

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

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Office of Administration, State Capitol Building, Room 125, PO Box 809, Jefferson City, MO 65102-0809. 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 2 – DEPARTMENT OF AGRICULTURE
Division 90 – Weights, Measures and Consumer Protection
Chapter 21 – Weighing and Measuring Devices

PROPOSED AMENDMENT

2 CSR 90-21.010 Registration of Servicepersons and Service Agencies. The department is amending sections (1) and (2), deleting sections (4) and (5), adding new sections (3) – (7), and renumbering as necessary.

PURPOSE: This amendment will update the current language of the regulation to include the most current issue of the NIST Handbook 130, supplies definitions regarding registrations, and sets the cost to register service agencies and service agency technicians.

(1) The rule for the Division of Weights, Measures and Consumer Protection for Voluntary Registration of Servicepersons and Service Agencies for Commercial Weighing and Measuring Devices shall incorporate by reference the section of the *NIST Handbook 130*, *[2020]* **2023** Edition, entitled "Uniform Regulation for the Voluntary Registration of Servicepersons and Service Agencies for Commercial Weighing and Measuring Devices." **NIST Handbook 130, 2023 Edition, is published by the Superintendent of Documents, U.S. Government Publishing Office, and is available free of charge online at www.NIST.gov or a hard copy may be purchased from the National Conference on Weights and Measures at www.NCWM.net.** This regulation does not include any later amendments or additions to *NIST Handbook 130*.

(2) *[Registration Fee. There is no registration fee for Servicepersons and Registered Service Agencies.]* **For the purposes of this regulation, the following terms shall mean –**

(A) Calibration certificate – a certificate that indicates a mass or volume standard has a traceable calibration.

(B) Registration card – a card issued by the Division of Weights, Measures and Consumer Protection that indicates a serviceperson's name, registration number, date of issuance, scope of work the person is allowed to perform, and the expiration date of the calibration certificate associated with the person's equipment.

(C) Service agency – a company performing installation, repair, or calibration on a weighing or measuring device.

(D) Service work – installation, repair, or calibration performed on a weighing or measuring device that is placed into service for commercial purposes.

(E) Serviceperson – an employee of a service agency performing installation, repair, or calibration on a weighing or measuring device.

(3) Registration of Servicepersons and Service Agencies. Any serviceperson or service agency that places a weighing and measuring device into service or restores a device to service shall be registered with the Division of Weights, Measures and Consumer Protection. All registration applications are due to the division annually by July 1 and are to include a one hundred dollar ($100) registration fee for any service agency and a twenty-five dollar ($25) fee for every serviceperson. No registration card will be issued to a serviceperson or service agency that does not show a calibration certificate evidencing proof that they possess properly calibrated equipment.

(4) New Registrations. Any unregistered serviceperson or service agency can register with the division at any time during the calendar year but must do so before performing service work in this state.

(5) Registration Card Expiration. Registration cards shall expire annually on June 30 and may be renewed by that date to avoid expiration.

(6) Registration Card Renewal. Any serviceperson or service agency may renew their registration card by providing the appropriate fee and calibration certificate described in section (3) of this regulation.

(7) All service work performed on a weighing or measuring device shall be performed with calibrated equipment or shall be deemed invalid. Should the division determine that a device has been improperly placed into service, an official rejection tag shall be placed on the device until a proper placed-in-service report is received by the department.

*[(3)]***(8)** Placed-in-Service Report. Within twenty-four (24) hours after a device is restored to service or placed in service, the original of the properly executed *[P]***p**laced-in-*[S]***s**ervice Report, together with any official rejection tag removed from the device, shall be forwarded to MDA – Weights, Measures and Consumer Protection Division, PO Box 630, Jefferson City, MO 65102-0630 or faxed to **(**573*[-]***)** 751-0281.

[(4) Certificate of Registration Exception. The "Certificate of Registration" will expire two (2) years from the date of issuance.

(5) NIST Handbook 130, 2020 Edition, is published by the Superintendent of Documents, U.S. Government Publishing Office, and is available free of charge online at NIST.gov or a hard copy may be purchased from the National Conference on

Weights and Measures at NCWM.net.]

AUTHORITY: section 413.065, RSMo 2016. Original rule filed Dec. 30, 1975, effective Jan. 9, 1976. For intervening history, please consult the ***Code of State Regulations****. Amended: Filed Nov. 23, 2022.*

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

PRIVATE COST: This proposed amendment will cost private entities thirty-two thousand two hundred fifty dollars ($32,250) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Jimmy Williams at the Department of Agriculture by email at jimmy.williams@mda.mo.gov. 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
PRIVATE COST

I. Department Title: Missouri Department of Agriculture
Division Title: Weights, Measures, and Consumer Protection
Chapter Title: Agriculture

Rule Number and Title:	2 CSR90-21
Type of Rulemaking:	Proposed Amendment

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:
140	**Fuel Dispenser and Scale Installers and Repairs**	**$14,000.00**
730	**Servicepersons affiliated with the companies above**	**$18,250.00**

III. WORKSHEET

86	Number of Scale device companies	$100 per Company	$8,600.00
429	Number of Scale device company Servicepersons	$25.00 per Serviceperson	$10,725.00
54	Number of Fuel device companies	$100 per Company	$5,400.00
301	Number of Fuel device company Servicepersons	$25.00 per Serviceperson	$7,525.00
		Total	$32,250.00

IV. ASSUMPTIONS

Using our current excel spreadsheet data we are able to determine how many companies are registered in Missouri and how many servicepersons are working in Missouri. These servicepersons install, repair, and/or calibrate weighing and measuring devices in Missouri and, by registering with the state, are allowed to place those devices into commercial use.

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

PROPOSED AMENDMENT

19 CSR 30-40.410 Definitions and Abbreviations Relating to Trauma Centers. The department is amending section (1).

PURPOSE: This amendment adds virtual reviews to the definitions for trauma centers.

(1) The following definitions and abbreviations shall be used in the interpretation of the rules in 19 CSR 30-40.400 to 19 CSR 30-40.450:

(II) Trauma team activation protocol is a hospital document outlining the criteria used to identify severely injured patients and the procedures for notification of trauma team members and indicating surgical and non-surgical specialty response times acceptable for treating major trauma patients; ***[and]***

(JJ) Trauma triage is an estimation of injury severity at the scene of an accident***[.]*****; and**

(KK) Virtual review means a type of review conducted through the use of secure virtual video and audio conferencing and secure file transfers in order to determine compliance with the rules of this chapter.

AUTHORITY: section 190.185, RSMo ***[Supp. 2007] 2016,*** *and section 190.241,* ***[HB 1790, 94th General Assembly, Second Regular Session, 2008] RSMo Supp. 2022.*** *Emergency rule filed Aug. 28, 1998, effective Sept. 7, 1998, expired March 5, 1999. Original rule filed Sept. 1, 1998, effective Feb. 28, 1999. Amended: Filed Jan. 16, 2007, effective Aug. 30, 2007. Amended: Filed May 19, 2008, effective Jan. 30, 2009. Emergency amendment filed Nov. 21, 2022, effective Dec. 7, 2022, expires June 4, 2023. Amended: Filed Nov. 21, 2022.*

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

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

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Nicole Gamm at Nicole.Gamm@health.mo.gov or Missouri Department of Health and Senior Services, PO Box 570, Jefferson City, MO 65102-0570. To be considered, comments must be received within thirty (30) days after publication of this notice in the ***Missouri Register****. No public hearing is scheduled.*

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

PROPOSED AMENDMENT

19 CSR 30-40.420 Trauma Center Designation Requirements. The department is amending sections (2) and (3), renumbering throughout sections (2) and (3), and updating the application for trauma center designation from.

PURPOSE: This amendment decreases validation reviews to every three (3) years, adds virtual review requirements, adds honorarium and payment requirements for virtual reviews and on-site reviews, adds qualified contractor requirements, updates language to be consistent with the House Bill 2331 amendment of sections 190.241 and 190.245, RSMo, that became effective August 28, 2022, adds a requirement that hospitals must provide the department with required medical records and quality improvement documentation or be revoked, allows hospitals to continue to be designated as long as the hospital has submitted an application, changes the requirements for hospitals participating in the local and regional emergency medical services systems, updates what the hospitals have to submit to the department to confirm verification or certification with national certifying bodies and when to submit changes of this verification or certification, removes the data submission requirement for hospitals verified by American College of Surgeons, and removes American College of Surgeons level IV trauma centers as an alternate designation since the American College of Surgeons has recently eliminated the level IV trauma center verification. This amendment also makes changes to the application for trauma center designation form included herein in subsection (3)(A) by removing the American College of Surgeons level IV trauma centers as an alternate designation and changing the certification section to reflect the new requirements for notification of changes and participation in the local and regional emergency medical services systems and removing the data submission requirement.

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

(F) The review of hospitals for trauma center designation shall include interviews with designated hospital staff, a review of the physical plant and equipment, and a review of records and documents as deemed necessary to assure compliance with the requirements of the rules of this chapter. **The department may conduct an on-site review, a virtual review or a combination thereof on the hospitals/trauma centers. For announced reviews that are scheduled with the hospitals/trauma centers, the department will make the hospitals/trauma centers aware at least thirty (30) days prior to the scheduled review whether the department intends that the review will be conducted on-site and/or virtually. Due to unforeseen circumstances, the department may need to change whether the review is conducted on-site and/or virtually less than thirty (30) days before the announced review. The department will contact the hospitals/trauma centers to make the hospitals/trauma centers aware of any changes about how the review will be conducted, either on-site and/or virtually, prior to the date of the announced review.** The cost of any and all site reviews shall be paid by each applicant hospital or renewing trauma center unless adequate funding is available to the department to pay for reviews***[;]*****. Hospitals/trauma centers shall be responsible for paying expenses related to the cost of the qualified contractors to review their respective hospitals/trauma 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/trauma center include –**

1. An honorarium shall be paid to each qualified contractor of the review team whether the review occurs on-site or virtually. Qualified contractors of the review team for levels I and II trauma center reviews shall be paid one thousand four hundred fifty dollars ($1,450) per reviewer. Qualified contractors of the review team for levels III and IV trauma center reviews shall be paid one thousand dollars ($1,000) per reviewer. This honorarium shall be paid to each qualified contractor of the review team at the time the site survey begins if on-site or prior

to the beginning of the review if the review is conducted virtually;

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

3. Lodging shall be paid for each qualified contractor of the review team, unless the review is conducted virtually. The hospital/trauma center shall secure the appropriate number of hotel rooms for the qualified contractors and pay the hotel directly; and

4. Incidental expenses, if applicable, for each qualified contractor of the review team shall not exceed two hundred fifty dollars ($250) and may include the following:

A. Airport parking;

B. Checking bag charges;

C. Meals during the review; and

D. Mileage to and from the review if no airfare was charged by the reviewer. If the reviewer solely participated virtually in the review and did not travel by vehicle to the review, then no mileage shall be paid. Mileage shall be paid at the federal mileage rate for business miles as set by the Internal Revenue Service (IRS). Federal mileage rates can be found at the website www.irs.gov;

(G) For the purpose of reviewing trauma centers and hospitals applying for trauma center designation, the department shall use review teams consisting of two (2) surgeons and one (1) emergency physician who are experts in trauma care and one (1) trauma nurse coordinator/trauma program manager experienced in trauma center review. The team shall be disinterested politically and financially in the hospitals to be reviewed. Out-of-state review teams shall conduct levels I and II reviews. In-state reviewers may conduct level III reviews. In the event that out-of-state reviewers are unavailable, level II reviews may be conducted by in-state reviewers from **emergency medical services (**EMS**)** regions other than the region being reviewed with approval of the director of the Department of Health and Senior Services or his/her designee. When utilizing in-state review teams, the level II trauma center shall have the right to refuse one (1) review team*[;]***.**

1. Any individual interested in becoming a qualified contractor to conduct reviews shall –

A. Send the department a curriculum vitae (CV) or résumé that includes his or her experience and expertise in trauma 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;

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

C. Submit a list to the department that details any ownership he or she may have in a Missouri hospital(s), whether he or she has been terminated from any Missouri hospital(s), any lawsuits he or she has currently or had in the past with any Missouri hospital(s), and any Missouri hospital(s) for which his or her hospital privileges have been revoked.

2. Qualified contractors for the department shall enter into a written agreement with the department indicating that, among other things, they agree to abide by Chapter 190, RSMo, and the rules in this chapter, during the review process;

(J) Validation reviews shall occur every *[five (5)]* **three (3)** years;

(K) Hospitals/trauma centers being reviewed through a virtual survey shall do the following:

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

2. Provide a live tour of the hospital;

3. Ensure the videoconferencing platform used during the review is compliant with state and federal laws for protected health information;

4. Assign an on-site visit coordinator for the review. The on-site visit coordinator role cannot be fulfilled by the trauma program manager. This on-site visit coordinator will be responsible for the logistical aspects of the virtual review. Responsibilities include, at least, the following:

A. Scheduling the videoconferencing meetings;

B. Sending out calendar invitations;

C. Providing electronic medical record (EMR) access to designated individuals;

D. Ensuring all required participants are on the videoconferencing line for the various parts of the review; and

E. Sending separate calendar invitations for each section of the virtual review to hospital staff, qualified contractors, and the department;

5. Assign one (1) staff navigator per qualified contractor to help remotely navigate the EMR, the patient performance improvement patient safety (PIPS) documentation, and supporting documentation. The staff navigator role cannot be fulfilled by the trauma program manager, the trauma program medical director, the trauma program registrar, or the on-site visit coordinator for the review. The individuals designated as the staff navigators shall be familiar with navigating through the EMR;

6. Provide the department with requested patient care report information for the review no later than thirty (30) days prior to the virtual review;

7. Provide the department with requested medical records, PIPS documentation, registry report and all supporting documentation at least seven (7) days prior to the virtual visit through a method that is compliant with state and federal laws for protected health information;

8. Schedule a pre-review call with the qualified contractors, the department, the trauma program medical director, the trauma program manager, the staff navigators, and the on-site visit coordinator approximately one (1) week prior to the virtual review;

9. Test the functionality of the videoconferencing platform for the live tour of the hospital prior to the pre-review call; and

10. Provide a list of attendees for the review meeting and their roles to the review team and the department prior to the virtual review;

(L) The department may conduct an on-site review of the hospital prior to the virtual review to ensure that the hospital meets the requirements for trauma designation;

*[(K)]***(M)** Upon completion of a review, the reviewers shall submit a report of their findings to the department. The report shall state whether the specific standards for trauma center designation have or have not been met; if not met, in what way they were not met. The report shall include the patient chart audits and a narrative summary to include pre-hospital, hospital, trauma service, emergency department, operating room, recovery room, clinical lab, intensive care unit, blood bank, rehabilitation, performance improvement and patient safety programs, education, outreach, research, chart review, and interviews. The department has final authority to determine compliance with the rules of this chapter;

*[(L)]***(N)** Within thirty (30) days after receiving a review report, the department shall return a copy of the report in whole to the chief executive officer of the hospital reviewed. Included with the report shall be notification indicating that the hospital has met the criteria for trauma center designation or has failed to meet the criteria for the designation level for which it applied and options the hospital may pursue;

*[(M)]***(O)** If a verification review is required, the hospital shall

be allowed a period of six (6) months to correct deficiencies. A plan of correction form shall be provided to the department and shall be completed by the hospital and returned to the department within thirty (30) days after notification of review findings;

*[(N)]***(P)** Once a review is completed, a final report shall be prepared by the department. The final report shall be public record and shall disclose the standards by which the reviews were conducted and whether the standards were met. The reports filed by the reviewers shall be held confidential and shall be disclosed only to the hospital's chief executive officer or an authorized representative;

*[(O)]***(Q)** The department shall have the authority to put on probation, suspend, revoke, or deny trauma center designation if *[there is reasonable cause to believe]* **the department has determined** that there has been a substantial failure to comply with the requirements of the rules in this chapter. Once designated as a trauma center, a hospital may voluntarily surrender the designation at any time without giving cause, by contacting the department. In these cases, the application and review process shall be completed again before the designation may be reinstated;

*[(P)]***(R)** Trauma center designation shall be valid for a period of *[five (5)]* **three (3)** years from the date the trauma center is designated. Expiration of the designation shall occur unless the trauma center applies for validation review within this *[five- (5-)]* **three- (3-)** year period. Trauma center designation shall be site specific and not transferable when a trauma center changes location; *[and]*

*[(Q)]***(S)** The department shall investigate complaints against trauma centers. Failure of the hospital to cooperate in providing documentation and interviews with appropriate staff may result in revocation of trauma center designation. Any hospital*[,]* which takes adverse action toward an employee for cooperating with the department regarding a complaint*[,]* is subject to revocation of trauma center designation*[.]***; and**

(T) Failure of a hospital/trauma center to provide all medical records and quality improvement documentation necessary for the department to conduct a trauma review in order to determine if the requirements of 19 CSR 30-40.430 have been met shall result in the revocation of the hospital/trauma center's designation as a trauma center.

(3) Hospitals seeking trauma center designation by the department based on their current verification as a trauma center by the American College of Surgeons shall meet the following requirements:

(B) *[Both sections A and B of t]***T**he application for trauma verified hospital designation form, included herein, shall be complete before the department designates a hospital/trauma center. The department shall notify the hospital/trauma center of any apparent omissions or errors in the completion of the application for trauma verified hospital designation form. Upon receipt of a completed and approved application, the department shall designate such hospital as follows:

1. The department shall designate a hospital as a level I trauma center if such hospital has been verified as a level I trauma center (adult and pediatric) by the American College of Surgeons;

2. The department shall designate a hospital as a level II trauma center if such hospital has been verified as a level II trauma center (adult and pediatric) by the American College of Surgeons;

3. The department shall designate a hospital as a level III trauma center if such hospital has been verified as a level III trauma center (adult and pediatric) by the American College of Surgeons;

[4. The department shall designate a hospital as a level IV trauma center if such hospital has been verified as a level IV trauma center (adult and pediatric) by the American College of Surgeons;]

*[5.]***4.** The department shall designate a hospital as a level I pediatric trauma center if such hospital has been verified as a level I pediatric trauma center (only treats children) by the American College of Surgeons;

*[6.]***5.** The department shall designate a hospital as a level II pediatric trauma center if such hospital has been verified as a level II pediatric trauma center (only treats children) by the American College of Surgeons;

*[7.]***6.** The department shall designate a hospital as a level I trauma center if such hospital has been verified as a level I trauma center (only treats adults) by the American College of Surgeons; and

*[8.]***7.** The department shall designate a hospital as a level II trauma center if such hospital has been verified as a level II trauma center (only treats adults) by the American College of Surgeons;

[(C) Annually from the date of designation by the department submit to the department proof of verification as a trauma center by the American College of Surgeons and the names and contact information of the medical director of the trauma center and the program manager of the trauma center;]

*[(D)]***(C)** Within thirty (30) days of any changes **or receipt of a verification, the hospital shall** submit to the department proof of verification as a trauma center by the American College of Surgeons and the names and contact information of the medical director of the trauma center and the program manager of the trauma center**. Verification as a trauma center by the American College of Surgeons shall accompany the application for trauma verified hospital designation form. A hospital shall report to the department in writing within thirty (30) days of the date the hospital no longer is verified as a trauma center by the American College of Surgeons for which the hospital used to receive its corresponding designation with the department as a trauma center, whether because the hospital voluntarily surrendered this verification or because the hospital's verification was suspended or revoked by the American College of Surgeons or expired**;

[(E) Submit to the department a copy of the verifying organization's final trauma center verification survey results within thirty (30) days of receiving such results;

(F) Submit to the department a completed application for trauma verified hospital designation form every three (3) years;

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

*[(H)]***(D)** Participate in local and regional emergency medical services systems *[by reviewing and sharing outcome data and]* **for purposes of** providing training *[and]***, sharing** clinical educational resources**, and collaborating on improving patient outcomes**;

[(I) Submit data to meet the data submission requirements in 19 CSR 30-40.430;]

*[(J)]***(E)** The designation of a hospital as a trauma center pursuant to section (3) shall continue if such hospital retains verification as a trauma center by the American College of Surgeons; and

*[(K)]***(F)** The department may remove a hospital's designation as a trauma center if requested by the hospital or **if** the department determines that the verification by the American College of Surgeons has been suspended or revoked. The department may also remove a hospital's designation as a trauma center if the department determines the hospital's verification with the American College of Surgeons has expired. Any decision made by the department to withdraw the designation of

a trauma center that is based on the revocation or suspension of a verification by the American College of Surgeons shall not be subject to judicial review.

MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES
SECTION OF HEALTH STANDARDS AND LICENSURE

APPLICATION FOR TRAUMA VERIFIED HOSPITAL DESIGNATION

In accordance with the requirements of Chapter 190, RSMo, and the applicable regulations, this application is hereby submitted for designation as a trauma center. Please complete all information.	ORGANIZATION'S TRAUMA IDENTIFICATION NUMBER

CURRENT TRAUMA VERIFICATION ORGANIZATION AND LEVEL

ADULT AND PEDIATRIC (TREATS ADULTS AND CHILDREN)	PEDIATRIC (TREATS CHILDREN ONLY)	ADULTS (TREATS ADULTS ONLY)
☐ Level I Trauma Center by the American College of Surgeons ☐ Level II Trauma Center by the American College of Surgeons ☐ Level III Trauma Center by the American College of Surgeons	☐ Level I Pediatric Trauma Center by the American College of Surgeons ☐ Level II Pediatric Trauma Center by the American College of Surgeons	☐ Level I Trauma Center by the American College of Surgeons ☐ Level II Trauma Center by the American College of Surgeons

HOSPITAL INFORMATION

NAME OF HOSPITAL (NAME TO APPEAR ON DESIGNATION CERTIFICATE)		TELEPHONE NUMBER
ADDRESS (STREET AND NUMBER)	CITY	ZIP CODE

PROFESSIONAL INFORMATION

CHIEF EXECUTIVE OFFICER	CHAIRMAN/PRESIDENT OF BOARD TRUSTEES
TRAUMA MEDICAL DIRECTOR (NAME, EMAIL, AND CONTACT PHONE NUMBER)	TRAUMA PROGRAM MANAGER (NAME, EMAIL, AND CONTACT PHONE NUMBER

The following should be submitted to the department as indicated

☐ Proof of trauma verification with the American College of Surgeons with the expiration date of the verification.

RESOURCE INFORMATION

E.D. TRAUMA CASELOAD	TRAUMA TEAM ACTIVATIONS	C.T. SCAN CAPABILITY	M.R.I. CAPABILITY
OPERATING ROOMS	ICU/CCU BEDS	BURN BEDS	REHAB. BEDS
TRAUMA SURGEONS	NEUROSURGEONS	ORTHOPAEDISTS	E.D. PHYSICIANS
ANESTHESIOLOGISTS	C.R.N.A.s	PEDIATRICIANS	PEDIATRIC SURGEONS

CERTIFICATION

We, the undersigned hereby certify that:

A. Within thirty (30) days of any changes or receipt of a verification, we will submit to the department proof of trauma verification with the American College of Surgeons.
B. Within thirty (30) days, we will submit to the department any changes in the names and/or contact information of our medical director and the program manager of our trauma center.
C. Within thirty (30) days of the date that our hospital is no longer verified by the American College of Surgeons, whether because we voluntarily surrendered our verification or because our verification has been suspended or revoked by the American College of Surgeons or has expired, we will report this change in writing to the department.
D. We will participate in local and regional emergency medical services systems for purposes of providing training, sharing clinical educational resources, and collaborating on improving patient outcomes.
E. We understand that our designation as a trauma center by the department shall continue only if our hospital remains verified as a trauma center by the American College of Surgeons.

DATE OF APPLICATION
SIGNED (CHAIRMAN/PRESIDENT OF BOARD OF TRUSTEES, OWNER, OR ONE PARTNER OF PARTNERSHIP)
SIGNED (HOSPITAL CHIEF EXECUTIVE OFFICER)
SIGNED (TRAUMA MEDICAL DIRECTOR)
SIGNED (DIRECTOR OF EMERGENCY MEDICINE)

MO 580-3238 (10-2022)

AUTHORITY: sections 190.176 and 190.185, RSMo 2016, and section 190.241, RSMo Supp. ***[2017] 2022****. Emergency rule filed Aug. 28, 1998, effective Sept. 7, 1998, expired March 5, 1999. Original rule filed Sept. 1, 1998, effective Feb. 28, 1999. For intervening history, please consult the* ***Code of State Regulations****. Emergency amendment filed Nov. 21, 2022, effective Dec. 7, 2022, expires June 4, 2023. Amended: Filed Nov. 21, 2022.*

PUBLIC COST: This proposed amendment will cost state agencies or political subdivisions eighty-two thousand one hundred fifty dollars ($82,150) during the three- (3-) year designation period.

PRIVATE COST: This proposed amendment will cost private entities twenty-six thousand two hundred dollars ($26,200) during the three- (3-) year designation period.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Nicole Gamm at Nicole.Gamm@health.mo.gov or Missouri Department of Health and Senior Services, PO Box 570, Jefferson City, Missouri 65102-0570. To be considered, comments must be received within thirty (30) days after publication of this notice in the ***Missouri Register****. No public hearing is scheduled.*

FISCAL NOTE
PUBLIC COST

I. Department Title: Department of Health and Senior Services
Division Title: Division of Regulation and Licensure
Chapter Title: 19 CSR 30-40.420 Trauma Center Designation Requirements.

Rule Number and Title:	**19 CSR 30-40.420 Trauma Center Designation Requirements**
Type of Rulemaking:	Proposed Amendment

II. SUMMARY OF FISCAL IMPACT

Affected Agency or Political Subdivision	Estimated Cost of Compliance in the Aggregate
5 hospitals/trauma centers virtual review costs	$1,250 during the 3 year designation period
2 hospitals/trauma centers cost of reviews for qualified contractors for Level I and II trauma centers	$2,900 during the 3 year designation period
3 hospitals/trauma centers cost of reviews for qualified contractors for Level II trauma centers	$3,000 during the 3 year designation period
Department reviewer for trauma reviews	$75,000
TOTAL COSTS =	**$82,150 during the 3 year designation period**

III. WORKSHEET

Five (5) public hospitals/trauma centers reviewed during the three (3) year designation period X $250.00 for virtual review cost = $1,250 for the hospitals/trauma centers reviewed during the three (3) year designation period.

Two (2) public hospitals/trauma centers reviewed during the three (3) year designation period X $1,450 for the cost of the reviews for the qualified contractors for Level I and II trauma centers = $2,900 during the three (3) year designation period.

Three (3) public hospitals/trauma centers reviewed during the three (3) year designation period X $1,000 for the cost of the reviews for the qualified contractors for Level III trauma centers = $3,000 during the three (3) year designation period.

Department reviewer X 1= $75,000.

IV. ASSUMPTIONS

There are currently twenty-two (22) Level I-III trauma centers designated with the department. Seventeen (17) of these hospitals/trauma centers are private.

All hospitals have internet capability, programs for the use of virtual meetings and the use of a secure means to send documents which contain information subject to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The department estimates that costs associated with the additional virtual survey requirements in 19 CSR 30-40.720 will cost hospitals/trauma centers approximately $250 based on the use of the computer programs to send this information and to utilize for virtual meetings and during the review (including the live tour).

There are two (2) public hospitals/trauma centers (Levels I and II) which will have to pay an additional $1,450 for an additional review since the review period decreased from five (5) years to three (3) years.

There are three (3) public hospitals/trauma centers (Level III) which will have to pay an additional $1,000 for an additional review since the review period decreased from five (5) years to three (3) years.

The department anticipates it will need one (1) additional nurse reviewer to complete the additional trauma reviews since the designation period decreased from five (5) years to (3) years. The department anticipates $75,000 for this position with benefits.

The department is not including the costs to pay the reviewers/qualified contractors in this fiscal note because hospitals were already required to pay the costs of the reviewers/qualified contractors in the regulation. Additionally, the amount that the hospitals were paying for the reviewers/qualified contractors is not changing. The department is only including more detail about the payment information with the change in the regulation.

FISCAL NOTE
PRIVATE COST

I. Department Title: Department of Health and Senior Services
Division Title: Division of Regulation and Licensure
Chapter Title: 19 CSR 30-40.420 Trauma Center Designation Requirements.

Rule Number and Title:	**19 CSR 30-40.420 Trauma Center Designation Requirements**
Type of Rulemaking:	Proposed Amendment

II. SUMMARY OF FISCAL IMPACT

Affected Agency or Political Subdivision	Estimated Cost of Compliance in the Aggregate
17 hospitals/trauma centers virtual review costs	$4,250 during the 3 year designation period
11 hospitals/trauma centers cost of reviews for qualified contractors for Level I and II trauma centers	$15,950 during the 3 year designation period
6 hospitals/trauma centers cost of reviews for qualified contractors for Level III trauma centers	$6,000 during the 3 year designation period
TOTAL COSTS =	**$26,200 during the 3 year designation period**

III. WORKSHEET

Seventeen (17) private hospitals/trauma centers reviewed during the three (3) year designation period X $250.00 for virtual review cost = $4,250 for the hospitals/trauma centers reviewed during the three (3) year designation period.

Eleven (11) private hospitals/trauma centers reviewed during the three (3) year designation period X $1,450 for the cost of the reviews for the qualified contractors for Level I and II trauma centers = $15,950 during the three (3) year designation period.

Six (6) private hospitals/trauma centers reviewed during the three (3) year designation period X $1,000 for the cost of the reviews for the qualified contractors for Level III trauma centers = $6,000 during the three (3) year designation period.

IV. ASSUMPTIONS

There are currently twenty-two (22) Level I-III trauma centers designated with the department. Seventeen (17) of these hospitals/trauma centers are private.

All hospitals have internet capability, programs for the use of virtual meetings and the use of a secure means to send documents which contain information subject to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The department estimates that costs associated with the additional virtual survey requirements in 19 CSR 30-40.720 will cost hospitals/trauma centers approximately $250 based on the use of the computer programs to send this information and to utilize for virtual meetings and during the review (including the live tour).

There are eleven (11) private hospitals/trauma centers (Levels I and II) which will have to pay an additional $1,450 for an additional review since the review period decreased from five (5) years to three (3) years.

There are six (6) private hospitals/trauma centers (Level III) which will have to pay an additional $1,000 for an additional review since the review period decreased from five (5) years to three (3) years.

The department is not including the costs to pay the reviewers/qualified contractors in this fiscal note because hospitals were already required to pay the costs of the reviewers/qualified contractors in the regulation. Additionally, the amount that the hospitals were paying for the reviewers/qualified contractors is not changing. The department is only including more detail about the payment information with the change in the regulation.

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

PROPOSED AMENDMENT

19 CSR 30-40.430 Standards for Trauma Center Designation. The department is amending sections (1), (3), and (4) and renumbering as necessary.

PURPOSE: *This amendment changes continuing education hours/credentialing requirements to be consistent with required continuing education/credentialing requirements by the national verifying body for trauma centers, adds credentialing courses for nurses, changes EMS Bureau to department's time critical diagnosis unit, requires nurses in the ICU to be current in ATLS, updates the publication date for the National Trauma Data Standard, removes continuing medical education requirements for physicians who are emergency medicine board certified or board eligible through the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine and who are practicing in the emergency department of a trauma center, removes requirements relating to the operation or construction of a helipad at trauma centers, and adds an option for trauma centers to enter trauma data into a national data registry or databank that will allow the trauma center to perform its performance improvement and patient safety program requirements.*

(1) General Standards for Trauma Center Designation.

[(D) There shall be a lighted designated helicopter landing area at the trauma center to accommodate incoming medical helicopters. (I-R, II-R, III-R)

1. 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, III-R)

2. The landing area shall be on the hospital premises no more than three (3) minutes from the emergency room. (I-R, II-R, III-R)]

(D) The trauma center shall have a helicopter landing area. (I-R, II-R, III-R)

(E) The hospital shall appoint a board-certified surgeon to serve as the trauma medical director. (I-R, II-R, III-R)

1. There shall be a job description and organization chart depicting the relationship between the trauma medical director and other services. (I-R, II-R, III-R)

2. The trauma medical director shall be a member of the surgical trauma call roster. (I-R, II-R, III-R)

3. The trauma medical director shall be responsible for the oversight of the education and training of the medical and nursing staff in trauma care. (I-R, II-R, III-R)

4. The trauma medical director shall document *[a minimum average of sixteen (16)]* **thirty-six (36)** hours of continuing medical education (CME) in trauma care every **three (3)** years. (I-R, II-R, III-R)

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

(F) There shall be a trauma nurse coordinator/trauma program manager. (I-R, II-R, III-R)

1. There shall be a job description and organization chart depicting the relationship between the trauma nurse coordinator/trauma program manager and other services. (I-R, II-R, III-R)

2. The trauma nurse coordinator/trauma program manager shall document *[a minimum average of sixteen (16)]* **thirty-six (36)** hours of continuing nursing education in trauma care every **three (3)** years. (I-R, II-R, III-R)

[(H) All members of the surgical trauma call roster and emergency medicine physicians including liaisons for anesthesiology, neurosurgery, and orthopedic surgery shall document a minimum average of eight (8) hours of CME in trauma care every year. In hospitals designated as adult/pediatric trauma centers, providing care to injured children fourteen (14) years of age and younger, four (4) of the eight (8) hours of education per year must be applicable to pediatric trauma. (I-R, II-R, III-R)]

*[(I)]***(H)** The hospital shall demonstrate that there is a plan for adequate post-discharge follow-up on trauma patients, including rehabilitation. (I-R, II-R, III-R)

*[(J)]***(I)** A *[Missouri]* trauma registry shall be completed on each patient who sustains a traumatic injury and meets the following criteria: Includes at least one (1) code within the range of the following injury diagnostic codes as defined in the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9)-(CM) 800-959.9**,** which is incorporated by reference in this rule as published by the Centers for Disease Control and Prevention in 2006 and is available at National Center for Health Statistics, 1600 Clifton Road, Atlanta, GA 30333. This rule does not incorporate any subsequent amendments or additions. Excludes all diagnostic codes within the following code ranges: 905–909.9 (late effects of injury), 910–924.9 (superficial injuries, including blisters, contusions, abrasions, and insect bites), 930–939.9 (foreign bodies), and must include one **(1)** of the following criteria: hospital admission, patient transfer out of facility, or death resulting from the traumatic injury (independent of hospital admission or hospital transfer status). *[The registry shall be submitted electronically in a format defined by the Department of Health and Senior Services.]* **Trauma centers shall enter trauma care data elements for each patient who meets these criteria. The trauma care data elements shall be those identified and defined by the National Trauma Data Standard, which is incorporated by reference in this rule as published by the American College of Surgeons in 2022 and is available at the American College of Surgeons, 633 N. St. Clair St., Chicago, IL 60611. This rule does not incorporate any subsequent amendments or additions. (I-R, II-R, III-R)**

1. Trauma centers shall enter trauma care data elements for each patient who meets the criteria above into the following:

A. Trauma centers shall submit data into the department's Missouri trauma registry. The data required in subsection (1)(I) above shall be submitted electronically into the Missouri trauma registry via the department's website at www.health.mo.gov; or (I-R, II-R, III-R)

B. Trauma centers shall submit data into a national data registry or data bank capable of being used by the trauma center to perform its ongoing performance improvement and patient safety program requirements for its trauma patients. The trauma center shall submit data for each data element included in the national data registry or data bank's data system. (I-R, II-R, III-R)

2. Electronic data shall be submitted quarterly, ninety (90) days after the quarter ends. The trauma registry must be current and complete. **(I-R, II-R, III-R)**

3. Information provided by hospitals on the trauma registry shall be subject to the same confidentiality requirements and procedures contained in section 192.067, RSMo. (I-R, II-R, III-R)

(J) A patient log **of those patients entered into the trauma registry** with admission date, patient name, and injuries must be available for use during the site review process. *[Information*

provided by hospitals on the trauma registry shall be subject to the same confidentiality requirements and procedures contained in section 192.067, RSMo. The trauma care data elements shall be those identified and defined by the National Trauma Data Standard which is incorporated by reference in this rule as published by the American College of Surgeons in 2008 and is available at the American College of Surgeons, 633 N. St. Clair St., Chicago, IL 60611. This rule does not incorporate any subsequent amendments or additions.] (I-R, II-R, III-R)

(3) Standards for Special Facilities/Resources/Capabilities for Trauma Center Designation.

(A) The hospital shall meet emergency department standards for trauma center designation.

1. The emergency department staffing shall ensure immediate and appropriate care of the trauma patient. (I-R, II-R, III-R)

A. The physician director of the emergency department shall be board-certified or board-admissible in emergency medicine. (I-R, II-R)

B. There shall be a physician trained in the care of the critically injured as evidenced by credentialing in ATLS *[and current in trauma CME]* in the emergency department twenty-four (24) hours a day. ATLS is incorporated by reference in this rule as published by the American College of Surgeons in 2003 and is available at American College of Surgeons, 633 N. St. Clair St., Chicago, IL 60611. This rule does not incorporate any subsequent amendments or additions. (I-R, II-R, III-R)

C. All emergency department physicians shall be certified in ATLS at least once. Physicians who are certified by boards other than emergency medicine who treat trauma patients in the emergency department are required to have current ATLS status. (I-R, II-R, III-R)

D. There shall be written protocols defining the relationship of the emergency department physicians to other physician members of the trauma team. (I-R, II-R, III-R)

E. All registered nurses assigned to the emergency department shall be credentialed in trauma nursing by the hospital within one (1) year of assignment. (I-R, II-R, III-R)

[(I) Registered nurses credentialed in trauma nursing shall document a minimum of eight (8) hours of trauma-related continuing nursing education per year. (I-R, II-R, III-R)]

*[(II)]***(I)** Registered nurses credentialed in trauma care shall maintain current provider status in the **Trauma Care After Resuscitation (TCAR),** Trauma Nurse Core Curriculum **(TNCC),** or Advanced Trauma Care for Nurses **(ATCN)** and either **Pediatric Care After Resuscitation (PCAR),** Pediatric Advanced Life Support (PALS), Advanced Pediatric Life Support (APLS), or Emergency Nursing Pediatric Course (ENPC) within one (1) year of employment in the emergency department. The requirement for **Pediatric Care After Resuscitation,** Pediatric Advanced Life Support, Advanced Pediatric Life Support, or Emergency Nursing Pediatric Course may be waived in centers where policy exists diverting injured children to a pediatric trauma center and where a pediatric trauma center is adjacent and a performance improvement filter reviewing any children seen is maintained. The Trauma Nurse Core Curriculum is incorporated by reference in this rule as published in 2007 by the Emergency Nurses Association and is available at the Emergency Nurses Association, 915 Lee Street, Des Plaines, IL 60016-9659. This rule does not incorporate any subsequent amendments or additions. Advanced Trauma Care for Nurses is incorporated by reference in this rule as published in 2003 by the Society of Trauma Nurses and is available at the Society of Trauma Nurses, 1926 Waukegan Road, Suite 100, Glenview, IL 60025. This rule does not incorporate any subsequent amendments or additions. Pediatric Advanced Life Support is incorporated by reference in this rule as published in 2005 by the American Heart Association and is available at the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231. This rule does not incorporate any subsequent amendments or additions. The Emergency Nursing Pediatric Course is incorporated by reference in this rule as published by the Emergency Nurses Association in 2004 and is available at the Emergency Nurses Association, 915 Lee Street, Des Plaines, IL 60016-9659. This rule does not incorporate any subsequent amendments or additions. **Trauma Care After Resuscitation and Pediatric Care After Resuscitation are incorporated by reference in this rule as published in 2022 by TCAR Education Programs and are available at TCAR Education Programs, 33456 Havlik Drive, Scappoose, Oregon 97056. This rule does not incorporate any subsequent amendments or additions.** (I-R, II-R, III-R)

2. Equipment for resuscitation and life support with age appropriate sizes for the critically or seriously injured shall include the following:

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

B. Suction devices – I-R, II-R, III-R;

C. Electrocardiograph, cardiac monitor, and defibrillator – I-R, II-R, III-R;

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

E. All standard intravenous fluids and administration devices including intravenous catheters – I-R, II-R, III-R;

F. Sterile surgical sets for procedures standard for the emergency department—I-R, II-R, III-R;

G. Gastric lavage equipment – I-R, II-R, III-R;

H. Drugs and supplies necessary for emergency care – I-R, II-R, III-R;

I. Two-way radio linked with emergency medical service (EMS) vehicles – I-R, II-R, III-R;

J. End-tidal carbon dioxide monitor – I-R, II-R, III-R and mechanical ventilators – I-R, II-R;

K. Temperature control devices for patient, parenteral fluids, and blood – I-R, II-R, III-R; and

L. Rapid infusion system for parenteral infusion – I-R, II-R, III-R.

3. There shall be documentation that all equipment is checked according to the hospital preventive maintenance schedule. (I-R, II-R, III-R)

4. There shall be a designated trauma resuscitation area in the emergency department. (I-R, II-R)

5. There shall be X-ray capability with twenty-four (24)-hour coverage by technicians. (I-IH, II-IH, III-IA)

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

(B) The hospital shall meet intensive care unit (ICU) standards for trauma center designation.

1. There shall be a designated surgeon medical director for the ICU. (I-R, II-R, III-R)

2. A physician who is not the emergency department physician shall be on duty in the ICU or available in-house twenty-four (24) hours a day in a level I trauma center and shall be on call and available within twenty (20) minutes in a level II trauma center.

3. The minimum registered nurse/trauma patient ratio used shall be one to two (1:2). (I-R, II-R, III-R)

4. Registered nurses shall be credentialed in trauma care within one (1) year of assignment *[documenting a minimum of eight (8) hours of trauma-related continuing nursing education per year]*. (I-R, II-R, III-R)

5. Nursing care documentation shall be on a patient flow sheet. (I-R, II-R, III-R)

6. **Nurses assigned to the ICU shall maintain current provider status in ACLS.** At the time of the initial review, nurses assigned to ICU shall have successfully completed or be registered for a provider ACLS course. The requirement for ACLS may be waived in pediatric centers where policy exists diverting injured adults to an adult trauma center and where an adult trauma center is adjacent to the affected pediatric facilities, and a performance improvement filter reviewing any adult trauma patients seen is maintained**.** (I-R, II-R, III-R)*[.]*

7. There shall be separate pediatric and adult ICUs or a combined ICU with nurses trained in pediatric intensive care. In ICUs providing care to children, registered nurses shall maintain credentialing in PALS, APLS, or ENPC. (I-R, II-R)

8. There shall be beds for trauma patients or comparable level of care provided until space is available in ICU. (I-R, II-R, III-R)

9. Equipment for resuscitation and to provide life support for the critically or seriously injured shall be available for the intensive care unit. In ICUs providing care for the pediatric patient, equipment with age appropriate sizes shall also be available. This equipment shall include*[,]* but not be limited to*[:]* **–**

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

B. Oxygen source with concentration controls – I-R, II-R, III-R;

C. Cardiac emergency cart, including medications – I-R, II-R, III-R;

D. Temporary transvenous pacemakers – I-R, II-R, III-R;

E. Electrocardiograph, cardiac monitor, and defibrillator – I-R, II-R, III-R;

F. Cardiac output monitoring – I-R, II-R;

G. Electronic pressure monitoring and pulse oximetry – I-R, II-R;

H. End-tidal carbon dioxide monitor and mechanical ventilators – I-R, II-R, III-R;

I. Patient weighing devices – I-R, II-R, III-R;

J. Temperature control devices – I-R, II-R, III-R;

K. Drugs, intravenous fluids, and supplies – I-R, II-R, III-R; and

L. Intracranial pressure monitoring devices – I-R, II-R.

10. There shall be documentation that all equipment is checked according to the hospital preventive maintenance schedule. (I-R, II-R, III-R)

(4) Standards for Programs in Performance Improvement and Improvement Patient Safety Program, Outreach, Public Education, and Training for Trauma Center Designation.

(F) There shall be a hospital-approved procedure for credentialing nurses in trauma care. (I-R, II-R, III-R)

1. All nurses providing care to severely injured patients and assigned to the emergency department or ICU shall complete a *[minimum of sixteen (16) hours of]* trauma nursing course*[s]* **in order** to become credentialed in trauma care. (I-R, II-R, III-R)

2. The content and format of any trauma nursing courses developed and offered by a hospital shall be developed in cooperation with the trauma medical director. A copy of the course curriculum used shall be filed with the *[EMS Bureau]* **department's time critical diagnosis unit**. (I-R, II-R, III-R)

3. Trauma nursing courses offered by institutions of higher education in Missouri such as the Advanced Trauma Care for Nurses, Emergency Nursing Pediatric Course, **Trauma Care After Resuscitation, Pediatric Care After Resuscitation,** or the Trauma Nurse Core Curriculum may be used to fulfill this requirement. To receive credit for this course, a nurse shall obtain advance approval for the course from the trauma medical director and trauma nurse coordinator/trauma program manager and shall present evidence of satisfactory completion of the course. (I-R, II-R, III-R)

AUTHORITY: section 190.185, RSMo ***[Supp. 2007] 2016,*** *and section 190.241,* ***[HB 1790, 94th General Assembly, Second Regular Session, 2008] RSMo Supp. 2022****. Emergency rule filed Aug. 28, 1998, effective Sept. 7, 1998, expired March 5, 1999. Original rule filed Sept. 1, 1998, effective Feb. 28, 1999. Amended: Filed Jan. 16, 2007, effective Aug. 30, 2007. Amended: Filed May 19, 2008, effective Jan. 30, 2009. Emergency amendment filed Nov. 21, 2022, effective Dec. 7, 2022, expires June 4, 2023. Amended: Filed Nov. 21, 2022.*

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

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

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Nicole Gamm at Nicole.Gamm@health.mo.gov or Missouri Department of Health and Senior Services, PO Box 570, Jefferson City, MO 65102-0570. To be considered, comments must be received within thirty (30) days after publication of this notice in the ***Missouri Register****. No public hearing is scheduled.*

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

PROPOSED AMENDMENT

19 CSR 30-40.710 Definitions and Abbreviations Relating to Stroke Centers. The department is amending section (1).

PURPOSE: This amendment adds virtual reviews to the definitions for stroke centers.

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

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

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

(XX) Virtual review – a type of review conducted through the use of secure virtual video and audio conferencing and secure file transfers in order to determine compliance with the rules of this chapter.

*AUTHORITY: section***s** *192.006* ***and 190.185****, RSMo* ***[2000] 2016****, and section****[s 190.185 and]*** *190.241, RSMo Supp.* ***[2012] 2022****. Original rule filed Nov. 15, 2012, effective June 30, 2013. Emergency amendment filed Nov. 21, 2022, effective Dec. 7, 2022, expires June 4, 2023. Amended: Filed Nov. 21, 2022.*

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

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

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Nicole Gamm at Nicole.Gamm@health.mo.gov or Missouri Department of Health and Senior Services, PO Box 570, Jefferson City, MO 65102-0570. To be considered, comments must be received within thirty (30) days after publication of this notice in the ***Missouri Register****. No public hearing is scheduled.*

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

PROPOSED AMENDMENT

19 CSR 30-40.720 Stroke Center Designation Application and Review. The department is amending sections (2) and (3), renumbering as necessary, and amending the application for stroke center designation form.

PURPOSE: This amendment decreases validation reviews to every three (3) years, adds virtual review requirements, clarifies honorarium and payment requirements for virtual reviews, updates language to be consistent with the House Bill 2331 amendment of sections 190.241 and 190.245, RSMo, that became effective August 28, 2022, adds primary stroke center with thrombectomy capability as a type of certification or verification that hospitals may have in order for the department to designate hospitals as level II stroke centers, adds a requirement that hospitals must provide the department with required medical records and quality improvement documentation or be revoked, allows hospitals to continue to be designated as long as the hospital has submitted an application and the department has not yet been able to conduct a review, changes the requirements for hospitals participating in local and regional emergency medical services systems, removes the data submission requirement for hospitals certified or verified by department-approved national bodies and updates what the hospitals have to submit to the department to confirm verification or certification with national certifying bodies and when to submit changes of this verification or certification. This amendment also makes changes to the application for stroke center designation form included herein in subsection (3)(A) by adding primary stroke center with thrombectomy capability, changing the certification section to reflect the new requirements for notification of changes and participation in the local and regional emergency medical services systems, and removing the data submission requirement.

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

(D) **The department may conduct an on-site review, a virtual review, or a combination thereof on the hospitals/stroke centers. For announced reviews that are scheduled with the hospitals/stroke centers, the department will make the hospitals/stroke centers aware at least thirty (30) days prior to the scheduled review whether the department intends that the review will be conducted on-site and/or virtually. Due to unforeseen circumstances, the department may need to change whether the review is conducted on-site and/or virtually less than thirty (30) days before the announced review. The department will contact the hospitals/stroke centers to make the hospitals/stroke centers aware of any changes about how the review will be conducted, either on-site and/or virtually, prior to the date of the announced review.** The different types of ***[site]*** reviews to be conducted on hospitals/stroke centers seeking stroke center designation by the department include***[:]*****—**

1. An initial review shall occur on a hospital applying to be initially designated as a stroke center. An initial review shall include interviews with designated hospital staff, a review of the physical plant and equipment, and a review of records and documents as deemed necessary to assure compliance with the requirements of the rules of this chapter**. This review may occur on-site and/or virtually**;

2. A validation review shall occur on a designated stroke center applying for renewal of its designation as a stroke center. Validation reviews shall occur no less than every ***[four (4)]*** **three (3)** years. A validation review shall include interviews with designated stroke center staff, a review of the physical plant and equipment, and a review of records and documents as deemed necessary to assure compliance with the requirements of the rules of this chapter**. This review may occur on-site and/or virtually**; and

3. A focus review shall occur on a designated stroke center in which an initial or validation review was conducted and substantial deficiency(ies) were cited. A review of the physical plant will not be necessary unless a deficiency(ies) was cited in the physical plant in the preceding validation review. The focus review team shall be comprised of a representative from the department and may include a qualified contractor(s) with the required expertise to evaluate corrections in areas where deficiencies were cited**. This review may occur on-site and/or virtually**;

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

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

2. Once designated as a stroke center, a stroke center may voluntarily surrender the designation at any time without giving cause, by contacting the department in writing. In these cases, the application and review process shall be completed again before the designation may be reinstated;

(H) Hospitals/stroke centers shall be responsible for paying expenses related to the cost of the qualified contractors to review their respective hospitals/stroke centers during initial, validation, and focus reviews. The department shall be responsible for paying the expenses of its representative. Costs of the review to be paid by the hospital/stroke center include***[:]*****—**

1. An honorarium shall be paid to each qualified contractor of the review team **whether the review occurs on-site or virtually**. Qualified contractors of the review team for levels I and II stroke center reviews shall be paid ***[six hundred dollars ($600) for the day of travel per reviewer and eight hundred fifty dollars ($850) for the day of the review]*** **one thousand four hundred fifty dollars ($1,450)** per reviewer. Qualified contractors of the review team for levels III and IV stroke center reviews shall be paid ***[five hundred dollars ($500) for the day of travel per reviewer and five hundred dollars ($500) for the day of the review]*** **one thousand dollars ($1,000)** per reviewer. This honorarium shall be paid to each qualified contractor of the review team at the time the site survey begins **if on-site or prior to the review beginning if the review is conducted virtually**;

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

3. Lodging shall be paid for each qualified contractor of the review team**, unless the review is conducted virtually**.

The hospital/stroke center shall secure the appropriate number of hotel rooms for the qualified contractors and pay the hotel directly; and

4. Incidental expenses, if applicable, for each qualified contractor of the review team shall not exceed two hundred fifty dollars ($250) and may include the following:

A. Airport parking;

B. Checking bag charges;

C. Meals during the review; and

D. Mileage to and from the review if no airfare was charged by the reviewer. **If the reviewer solely participated virtually in the review and did not travel by vehicle to the review, then no mileage shall be paid.** Mileage shall be paid at the federal mileage rate for business miles as set by the Internal Revenue Service (IRS). Federal mileage rates can be found at the website www.irs.gov;

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

1. Provide an audio and videoconferencing platform to be used for the hospital/stroke center virtual review;

2. Provide a live tour of the hospital;

3. Ensure the video and audio conferencing service used during the review is compliant with state and federal laws for protected health information;

4. Assign an on-site visit coordinator for the review. The on-site visit coordinator role cannot be fulfilled by the stroke program manager. This on-site visit coordinator will be responsible for the logistical aspects of the virtual review. Responsibilities include, at least, the following:

A. Scheduling the videoconferencing meetings;

B. Sending out calendar invitations;

C. Providing electronic medical record (EMR) access to designated individuals;

D. Ensuring all required participants are on the videoconferencing line for the various parts of the review; and

E. Sending separate calendar invitations for each section of the virtual review to hospital staff, qualified contractors, and the department;

5. Assign one (1) staff navigator per qualified contractor to help remotely navigate the EMR, the patient performance improvement patient safety (PIPS) documentation, and supporting documentation. The staff navigator role cannot be fulfilled by the stroke program manager, the stroke program medical director, the stroke program registrar, or the on-site visit coordinator for the review. The individuals designated as the staff navigators shall be familiar with navigating through the EMR;

6. Provide the department with requested patient care report information for the review through a method that is compliant with state and federal laws for protected health information no later than thirty (30) days prior to the virtual review;

7. Provide the department with requested medical records, PIPS documentation, registry report, and all supporting documentation at least seven (7) days prior to the virtual visit through a method that is compliant with state and federal laws for protected health information;

8. Schedule a pre-review call with the qualified contractors, the department, the stroke program medical director, the stroke program manager, the staff navigators, and the on-site visit coordinator approximately one (1) week prior to the virtual review;

9. Test the functionality of the audio and videoconferencing service for the live tour of the hospital prior to the pre-review call; and

10. Provide a list of attendees for the review meeting and their roles to the review team and the department prior to the virtual review;

(J) The department may conduct an on-site review of the hospital prior to the virtual review to ensure that the hospital meets the requirements for stroke designation;

*[(I)]***(K)** Upon completion of a review, the qualified contractors from the review team shall submit a report of their findings to the department. This report shall state whether the specific standards for stroke center designation have or have not been met and if not met, in what way they were not met. This report shall detail the hospital/stroke center's strengths, weaknesses, deficiencies, and recommendations for areas of improvement. This report shall also include findings from patient chart audits and a narrative summary of the following areas: prehospital, hospital, stroke service, emergency department, operating room, angiography suites, recovery room, clinical lab, intensive care unit, rehabilitation, performance improvement and patient safety programs, education, outreach, research, chart review, and interviews. The department shall have the final authority to determine compliance with the rules of this chapter;

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

*[(K)]***(M)** When the hospital/stroke center is found to have deficiencies, the hospital/stroke center shall submit a plan of correction to the department. The plan of correction shall include identified deficiencies, actions to be taken to correct deficiencies, time frame in which the deficiencies are expected to be resolved, and the person responsible for the actions to resolve the deficiencies. A plan of correction form shall be completed by the hospital and returned to the department within thirty (30) days after notification of review findings and designation. If a focus review is required, then the stroke center shall be allowed a minimum period of six (6) months to correct deficiencies;

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

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

*[(M)]***(P)** Any person aggrieved by an action of the Department of Health and Senior Services affecting the stroke center designation pursuant to Chapter 190, RSMo, including the revocation, the suspension, or the granting of, refusal to grant, or failure to renew a designation, may seek a determination thereon by the Administrative Hearing Commission under Chapter 621, RSMo. It shall not be a condition to such determination that the person aggrieved seek reconsideration, a rehearing, or exhaust any other procedure within the department; and

*[(N)]***(Q)** The department may deny, place on probation, suspend, or revoke such designation in any case in which it has *[reasonable cause to believe]* **determined** that there has been a substantial failure to comply with the provisions of Chapter

190, RSMo, or any rules or regulations promulgated pursuant to this chapter. If the Department of Health and Senior Services has *[reasonable cause to believe]* **determined** that a hospital is not in compliance with such provisions or regulations, it may conduct additional announced or unannounced site reviews of the hospital to verify compliance. If a stroke center fails two (2) consecutive on-site reviews because of substantial noncompliance with standards prescribed by sections 190.001 to 190.245, RSMo, or rules adopted by the department pursuant to sections 190.001 to 190.245, RSMo, its center designation shall be revoked.

(3) Hospitals seeking stroke center designation by the department based on their current certification **or verification** as a stroke center by the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program shall meet the following requirements:

(A) An application for stroke center designation by the department for hospitals that have been certified **or verified** as a stroke center by the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program shall be made upon forms prepared or prescribed by the department and shall contain information the department deems necessary to make a determination of eligibility for review and designation in accordance with the rules of this chapter. The application for stroke certified hospital designation form, included herein, is available at the Health Standards and Licensure (HSL) office, or online at the department's website at www.health.mo.gov, or may be obtained by mailing a written request to the Missouri Department of Health and Senior Services, HSL, PO Box 570, Jefferson City, MO 65102-0570. The application for stroke center designation shall be submitted to the department no less than sixty (60) days and no more than one hundred twenty (120) days prior to the desired date of the initial designation *[or expiration of the current designation]*;

(B) Both sections A and B of the application for stroke certified hospital designation form, included herein, shall be complete before the department designates a hospital/stroke center. The department shall notify the hospital/stroke center of any apparent omissions or errors in the completion of the application for stroke certified hospital designation form. Upon receipt of a completed and approved application, the department shall designate such hospital as follows:

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

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

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

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

*[(D)]***(C)** Within thirty (30) days of any changes **or receipt of a certificate or verification, the hospital shall** submit*[,]* to the department proof of certification or verification as a stroke center by the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program and the names and contact information of the medical director of the stroke center and the program manager of the stroke center**. A certificate or verification as a stroke center by the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program shall accompany the application for stroke certified hospital designation form. A hospital shall report to the department in writing within thirty (30) days of the date the hospital no longer is certified or verified as a stroke center by the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program for which the hospital used to receive its corresponding designation with the department as a stroke center, whether because the hospital voluntarily surrendered this certificate or verification or because the hospital's certificate or verification was suspended or revoked by the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program or expired**;

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

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

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

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

*[(I)]***(E)** Participate in local and regional emergency medical services systems *[by reviewing and sharing outcome data and]* **for purposes of** providing training *[and]***, sharing** clinical educational resources**, and collaborating on improving patient outcomes**;

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

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

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

MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES
SECTION OF HEALTH STANDARDS AND LICENSURE

APPLICATION FOR STROKE CERTIFIED HOSPITAL DESIGNATION

SECTION A

In accordance with the requirements of the Chapter 190, RSMo, and the applicable regulations, this application is hereby submitted for designation as a stroke center. Please complete all information.	ORGANIZATION'S STRO E IDENTIFICATION NO.

CURRENT STROKE CERTIFICATION ORGANIZATION

☐ The Joint Commission ☐ DNV-GL Healthcare ☐ Healthcare Facilities Accreditation Program

CURRENT STROKE CERTIFICATION LEVEL

☐ Comprehensive Stroke Center ☐ Primary Stroke Center with Thrombectomy Capability ☐ Primary Stroke Center
☐ Acute Stroke-Ready Center

HOSPITAL INFORMATION

NAME OF HOSPITAL (NAME TO APPEAR ON DESIGNATION CERTIFICATE)		TELEPHONE NUMBER
ADDRESS (STREET AND NUMBER)	CITY	ZIP CODE

PROFESSIONAL INFORMATION

CHIEF EXECUTIVE OFFICER	CHAIRMAN/PRESIDENT OF BOARD OF TRUSTEES
STROKE MEDICAL DIRECTOR (NAME, EMAIL, AND CONTACT PHONE NUMBER)	STROKE PROGRAM MANAGER (NAME, EMAIL, AND CONTACT PHONE NUMBER)

SECTION B

The following should be submitted to the department as indicated:

☐ Proof of stroke certification with the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program.

If applying for Acute Stroke-Ready/Level III Stroke Center designation, the following should be submitted to the Department:

☐ Formal agreement with Level I or Level II stroke center for physician consultative services for evaluation of stroke patients for thrombolytic therapy and the care of the patients' post-thrombolytic therapy.

CERTIFICATION

We, the undersigned, hereby certify that:

A. Within thirty (30) days of any changes or receipt of a certificate or verification, we will submit to the department proof of stroke certification with the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program.
B. Within thirty (30) days, we will submit to the department any changes in the names and/or contact information of our medical director and the program manager of our stroke center.
C. Within thirty (30) days of the date that our hospital is no longer certified or verified by the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program, whether because we voluntarily surrendered our certification or verification or because our certification or verification has been suspended or revoked by the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program or expired, we will report this change in writing to the department.
D. We will participate in local and regional emergency medical services systems for purposes of providing training, sharing clinical educational resources, and collaborating on improving patient outcomes.
E. We understand that our designation as a stroke center by the department shall continue only if our hospital remains certified as a stroke center by the Joint Commission, DNV-GL Healthcare or Healthcare Facilities Accreditation Program.

SIGNATURE OF CHAIRMAN/PRESIDENT OF BOARD OF TRUSTEES, OWNER, OR ONE PARTNER OF PARTNERSHIP	
SIGNATURE OF HOSPITAL CHIEF EXECUTIVE OFFICER	
SIGNATURE OF STROKE MEDICAL DIRECTOR	
SIGNATURE OF DIRECTOR OF EMERGENCY MEDICINE	DATE

MO 580-3189 (10-2022)

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

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

PRIVATE COST: This proposed amendment will cost private entities twenty-seven thousand two hundred fifty dollars ($27,250) during the three- (3-) year designation period.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Nicole Gamm at Nicole.Gamm@health.mo.gov or Missouri Department of Health and Senior Services, PO Box 570, Jefferson City, MO 65102-0570. To be considered, comments must be received within thirty (30) days after publication of this notice in the ***Missouri Register****. No public hearing is scheduled.*

FISCAL NOTE
PUBLIC COST

I. Department Title: Department of Health and Senior Services
Division Title: Division of Regulation and Licensure
Chapter Title: 19 CSR 30-40.720 Stroke Center Designation Application and Review.

Rule Number and Title:	**19 CSR 30-40.720 Stroke Center Designation Application and Review**
Type of Rulemaking:	Proposed Amendment

II. SUMMARY OF FISCAL IMPACT

Affected Agency or Political Subdivision	Estimated Cost of Compliance in the Aggregate
Seventeen (17) hospitals/stroke centers for virtual review costs	$4,250 during the 3 year designation period
3 hospitals/stroke centers cost of reviews for qualified contractors for Level I and II reviews	$4,350 during the 3 year designation period
14 hospitals/stroke centers cost of reviews for qualified contractors for Level III and IV reviews	$14,000 during the 3 year designation period
Department reviewer for stroke reviews	$75,000
TOTAL COSTS =	**$97,600 during the 3 year designation period**

III. WORKSHEET

Seventeen (17) public hospitals/stroke centers reviewed during the three (3) year designation period X $250.00 for the virtual review costs = $4,250 for the hospitals/stroke centers reviewed during the three (3) year designation period.

Three (3) public hospitals/stroke centers reviewed during the three (3) year designation period X $1,450 for the cost of the reviews for the qualified contractors for Level I and II reviews = $4,350 during the three (3) year designation period.

Fourteen (14) public hospitals/stroke centers reviewed during the three (3) year designation period X $1,000 for the cost of the reviews for the qualified contractors for Level III and IV reviews = $14,000 during the three (3) year designation period.

Department reviewer X 1= $75,000.

IV. ASSUMPTIONS

There are currently thirty-seven (37) Level I-IV stroke centers designated with the department. Seventeen (17) of those hospitals are public hospitals and will be reviewed during the three (3) year designation period.

All hospitals have internet capability, programs for the use of virtual meetings and the use of a secure means to send documents which contain information subject to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The department estimates that costs associated with the additional virtual survey requirements in 19 CSR 30-40.720 will cost hospitals/stroke centers approximately $250 based on the use of the computer programs to send this information and to utilize for virtual meetings and during the review (including the live tour).

There are three (3) public hospitals/stroke centers (Levels I and II) which will have to pay an additional $1,450 for an additional review since the review period decreased from four (4) years to three (3) years.

There are fourteen (14) public hospitals/stroke centers (Levels III and IV) which will have to pay an additional $1,000 for an additional review since the review period decreased from four (4) years to three (3) years.

The department anticipates it will need one (1) additional nurse reviewer to complete the additional stroke reviews since the designation period decreased from four (4) years to (3) years. The department anticipates $75,000 for this position with benefits.

FISCAL NOTE
PRIVATE COST

I. Department Title: Department of Health and Senior Services
Division Title: Division of Regulation and Licensure
Chapter Title: 19 CSR 30-40.720 Stroke Center Designation Application and Review.

Rule Number and Title:	**19 CSR 30-40.720 Stroke Center Designation Application and Review**
Type of Rulemaking:	Proposed Amendment

II. SUMMARY OF FISCAL IMPACT

Affected Agency or Political Subdivision	Estimated Cost of Compliance in the Aggregate
Twenty (20) hospitals/stroke centers for virtual review costs	$5,000 during the 3 year designation period
Five (5) hospitals/stroke centers for Level I and II reviews	$7,250 during the 3 year designation period
Fifteen (15) hospitals/stroke centers for Level III and IV reviews	$15,000 during the 3 year designation period
TOTAL COSTS =	**$27,250 during the 3 year designation period**

III. WORKSHEET

Twenty (20) private hospitals/stroke centers reviewed during the three (3) year designation period X $250.00 for virtual review costs = $5,000 for the hospitals/stroke centers reviewed during the three (3) year designation period.

Five (5) private hospitals/stroke centers reviewed during the three (3) year designation period X $1,450 for the cost of the reviews for the qualified contractors for Level I and II reviews= $7,250 during the three (3) year designation period.

Fifteen (15) private hospitals/stroke centers reviewed during the three (3) year designation period X $1,000 for the cost of the reviews for the qualified contractors for Level III and IV reviews = $15,000 during the three (3) year designation period.

IV. ASSUMPTIONS

There are currently thirty-seven (37) Level I-IV stroke centers designated with the department. Twenty (20) of those hospitals are private hospitals and will be reviewed during the three (3) year designation period. Five (5) of the private hospitals are Level I and II stroke centers designated by the department and will be required to pay $1,450 for

a review every three (3) years. Fifteen (15) of the private hospitals are Level III and IV stroke centers and will be required to pay $1,000 for a review every three (3) years.

All hospitals have internet capability, programs for the use of virtual meetings and the use of a secure means to send documents which contain information subject to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The department estimates that costs associated with the additional virtual survey requirements in 19 CSR 30-40.720 will cost hospitals/stroke centers approximately $250 based on the use of the computer programs to send this information and to utilize for virtual meetings and during the review (including the live tour).