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SALUS POPULI SUPREMA LEX ESTO

"The welfare of the people shall be the supreme law."

JASON KANDER

SECRETARY OF STATE

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

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HOW TO CITE RULES AND RSMo

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

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

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

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

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

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

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

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 which 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 and file a new notice of proposed rulemaking and schedule a hearing for a date not less than thirty (30) days from the date of publication of the new notice.

Proposed Amendment Text Reminder:
Boldface text indicates new matter.
[Bracketed text indicates matter being deleted.]

Title 10—DEPARTMENT OF NATURAL RESOURCES
Division 10—Air Conservation Commission
Chapter 6—Air Quality Standards, Definitions, Sampling and Reference Methods and Air Pollution Control Regulations for the Entire State of Missouri

PROPOSED AMENDMENT

10 CSR 10-6.040 Reference Methods. The commission proposes to amend sections (1) through (5) and sections (7) and (8). If the commission adopts this rule action, it will be the department's intention to submit this rule amendment to the U.S. Environmental Protection Agency to replace the current rule that is in the Missouri State Implementation Plan. The evidence supporting the need for this proposed rulemaking is available for viewing at the Missouri Department of Natural Resources' Air Pollution Control Program at the address listed in the Notice of Public Hearing at the end of this rule. More information concerning this rulemaking can be found at the Missouri Department of Natural Resources' Environmental Regulatory Agenda website, www.dnr.mo.gov/regs/index.html.

PURPOSE: This rule provides reference methods for determining data and information necessary for the enforcement of air pollution control regulations throughout Missouri. This amendment updates the incorporation by reference in section (4) to include the latest ***Federal Register*** *promulgation dates. Recent* ***Federal Register*** *Notices add Federal Equivalency Methods (FEMs) for ambient monitoring of nitrogen dioxide and fine particulate matter; and two (2) FEMs for laboratory analysis of lead. Adding the latest* ***Federal Register*** *promulgation dates to this rule will allow the latest FEMs to be used to meet state requirements. The ASTM Methods for determining parameters such as fuel sulfur and heat content are also being updated to the latest versions available. Any source that emits nitrogen dioxide, lead, or fine particulate matter or relies on any of the ASTM methods being updated with this rulemaking could be affected. The evidence supporting the need for this proposed rulemaking, per 536.016, RSMo, is a rule comment form dated June 6, 2012, from Missouri Department of Natural Resources staff noting new federal equivalency methods promulgated in a* ***Federal Register*** *Notice 77 FR 32632, dated June 1, 2012.*

(1) The percent sulfur in solid fuels shall be determined as specified by American Society of Testing and Materials (ASTM) *[Method D(3177-75) Total Sulfur in the Analysis Sample of Coal and Coke.]* **D4239 - 12** ***Standard Test Method for Sulfur in the Analysis Sample of Coal and Coke Using High Temperature Tube Furnace Combustion*****, as approved and published February 1, 2012. This standard is incorporated by reference in this rule, as published by American Society for Testing and Materials (ASTM) International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959. This rule does not incorporate any subsequent amendments or additions.**

(2) The heat content or higher heating value (HHV) of solid fuels shall be determined by use of the Adiabatic Bomb Calorimeter as specified by ASTM *[Method D(2015-66) Gross Calorific Value of Solid Fuel by the Adiabatic Bomb Calorimeter.]* ***D5865 - 12 Standard Test Method for Gross Calorific Value of Coal and Coke*****, as approved and published December 1, 2012. This standard is incorporated by reference in this rule, as published by American Society for Testing and Materials (ASTM) International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959. This rule does not incorporate any subsequent amendments or additions.**

(3) The heat content or HHV of liquid hydrocarbons shall be determined as specified by ASTM *[Method D(240-64) Heat of Combustion of Liquid Hydrocarbon by Bomb Calorimeter.]* **D240 - 09** ***Standard Test Method for Heat of Combustion of Liquid Hydrocarbon Fuels by Bomb Calorimeter*****, as approved and published July 1, 2009. This standard is incorporated by reference in this rule, as published by American Society for Testing and Materials (ASTM) International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959. This rule does not incorporate any subsequent amendments or additions.**

(4) **The methods for determining the concentrations of the following air contaminants in the ambient air shall be as specified in 40 CFR 50, Appendices A–R or equivalent methods as specified in 40 CFR 53.** The provisions of 40 CFR *[part]* 50, Appendices A–R and 40 CFR *[part]* 53, promulgated as of *[June 30, 2008]* **July 1, 2012**, and *Federal Register* Notice *[73 FR 67051–67062]* **77 FR 55832-55834**, promulgated *[November 12, 2008]* **September 11, 2012**, shall apply and are hereby incorporated by reference in this

rule, as published by the Office of the Federal Register, U.S. National Archives and Records, 700 Pennsylvania Avenue NW, Washington, DC 20408. This rule does not incorporate any subsequent amendments or additions. *[The methods for determining the concentrations of the following air contaminants in the ambient air shall be as specified in 40 CFR part 50, Appendices A–R or equivalent methods as specified in 40 CFR part 53:]*

(A) The concentration of sulfur dioxide shall be determined as specified in 40 CFR *[part]* 50, Appendix A—*Reference Method for the Determination of Sulfur Dioxide in the Atmosphere (Pararosaniline Method)* or an equivalent method as approved by 40 CFR *[part]* 53*[;]***.**

(B) The concentration of total suspended particulate shall be determined as specified in 40 CFR *[part]* 50, Appendix B—*Reference Method for the Determination of Suspended Particulates in the Atmosphere (High Volume Method)[;]***.**

(C) The concentration of carbon monoxide in the ambient air shall be determined as specified in 40 CFR *[part]* 50, Appendix C—*Measurement Principle and Calibration Procedure for the Continuous Measurement of Carbon Monoxide in the Atmosphere (Non-Dispersive Infrared Spectrometry)* or equivalent methods as approved by 40 CFR *[part]* 53*[;]***.**

(D) The concentration of photochemical oxidants (ozone) in the ambient air shall be determined as specified in 40 CFR *[part]* 50, Appendix D—*Measurement Principle and Calibration Procedure for the Measurement of Ozone in the Atmosphere* or equivalent methods as approved by 40 CFR *[part]* 53*[;]***.**

(F) The concentration of nitrogen dioxide in the ambient air shall be determined as specified in 40 CFR *[part]* 50, Appendix F—*Measurement Principle and Calibration Procedure for the Measurement of Nitrogen Dioxide in the Atmosphere (Gas Phase Chemiluminescence)* or equivalent methods as approved by 40 CFR *[part]* 53*[;]***.**

(G) The concentration of lead in the ambient air shall be determined as specified in 40 CFR *[part]* 50, Appendix G—*Reference Method for the Determination of Lead in Suspended Particulate Matter Collected From Ambient Air* or in 40 CFR *[part]* 50, Appendix Q—*Reference Method for the Determination of Lead in Particulate Matter as PM_{10} Collected From Ambient Air* or equivalent methods as approved by 40 CFR *[part]* 53*[;]***.**

(H) Compliance with the one (1) hour ozone standard shall be determined as specified in 40 CFR *[part]* 50, Appendix H—*Interpretation of the National Ambient Air Quality Standards for Ozone[;]***.**

(I) Compliance with the eight (8) hour ozone standards shall be determined as specified in 40 CFR *[part]* 50, Appendix I—*Interpretation of the 8-Hour Primary and Secondary National Ambient Air Quality Standards for Ozone[;]***.**

(J) The concentration of particulate matter 10 micron (PM_{10}) in the ambient air shall be determined as specified in 40 CFR *[part]* 50, Appendix J—*Reference Method for the Determination of Particulate Matter as PM_{10} in the Atmosphere*, or an equivalent method as approved in 40 CFR *[part]* 53*[;]***.**

(K) Compliance with particulate matter 10 PM_{10} standards shall be determined as specified in 40 CFR *[part]* 50, Appendix K—*Interpretation of the National Ambient Air Quality Standards for Particulate Matter[;]***.**

(L) The concentration of particulate matter 2.5 micron ($PM_{2.5}$) in the ambient air shall be determined as specified in 40 CFR *[part]* 50, Appendix L—*Reference Method for the Determination of Fine Particulate Matter as $PM_{2.5}$ in the Atmosphere*, or an equivalent method as approved in 40 CFR *[part]* 53*[;]***.**

(M) Compliance with particulate matter 2.5 ($PM_{2.5}$) standards shall be determined as specified in 40 CFR *[part]* 50, Appendix N—*Interpretation of the National Ambient Air Quality Standards for Particulate Matter[;]***.**

(N) Compliance with the eight (8)-hour ozone standards shall be determined as specified in 40 CFR *[part]* 50, Appendix P—*Interpretation of the Primary and Secondary National Ambient Air Quality Standards for Ozone[; and]***.**

(O) Compliance with the lead standards shall be determined as specified in 40 CFR *[Part]* 50, Appendix R—*Interpretation of the National Ambient Air Quality Standards for Lead.*

(5) The concentration of hydrogen sulfide (H_2S) in the ambient air shall be determined by scrubbing all sulfur dioxide (SO_2) present in the sample and then converting each molecule of H_2S to SO_2 with a thermal converter so that the resulting SO_2 is detected by an analyzer as specified in 40 CFR *[part]* 50, Appendix A—*Reference Method for the Determination of Sulfur Dioxide in the Atmosphere (Pararosaniline Method)* or an equivalent method approved by 40 CFR *[part]* 53, in which case the calibration gas used must be National Institute of Standards and Technology traceable H_2S gas.

(7) The percent sulfur in liquid hydrocarbons shall be determined as specified by ASTM *[D(2622-98), Sulfur in Petroleum Products by X-Ray Fluorescence Spectrometry.]* ***D2622 - 10 Standard Test Method for Sulfur in Petroleum Products by Wavelength Dispersive X-ray Fluorescence Spectrometry*****, as approved and published February 15, 2010. This standard is incorporated by reference in this rule, as published by American Society for Testing and Materials (ASTM) International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959. This rule does not incorporate any subsequent amendments or additions.**

(8) The amount of solvent present in earth filters and distillation wastes shall be determined as specified by ASTM *[Method D(322-67), Standard Test Method for Gasoline Diluent in Used Gasoline Engine Oils by Distillation.]* ***D322 - 97(2012) Standard Test Method for Gasoline Diluent in Used Gasoline Engine Oils by Distillation*****, as approved and published November 1, 2012. This standard is incorporated by reference in this rule, as published by American Society for Testing and Materials (ASTM) International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959. This rule does not incorporate any subsequent amendments or additions.**

AUTHORITY: section 643.050, RSMo [2000] ***Supp. 2012****. Original rule filed Aug. 16, 1977, effective Feb. 11, 1978. For intervening history, please consult the* ***Code of State Regulations****. Amended: Filed March 18, 2013.*

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 OF PUBLIC HEARING AND NOTICE TO SUBMIT COMMENTS: A public hearing on this proposed amendment will begin at 9:00 a.m., June 27, 2013. The public hearing will be held at the Sheraton St. Louis City Center, Colonnade Salon D, 400 South 14th Street, St. Louis, Missouri. Opportunity to be heard at the hearing shall be afforded any interested person. Interested persons, whether or not heard, may submit a written or email statement of their views until 5:00 p.m., July 5, 2013. Written comments shall be sent to Chief, Air Quality Planning Section, Missouri Department of Natural Resources' Air Pollution Control Program, PO Box 176, Jefferson City, MO 65102-0176. Email comments shall be sent to apcprulespn@dnr.mo.gov.

Title 11—DEPARTMENT OF PUBLIC SAFETY
Division 45—Missouri Gaming Commission
Chapter 8—Accounting Records and Procedures; Audits

PROPOSED AMENDMENT

11 CSR 45-8.010 Definition of Licensee. The commission is amending section (1).

PURPOSE: This rule updates the classification designation.

(1) For purposes of this chapter, licensee shall mean a holder of a Class *[A]* **B** license.

AUTHORITY: sections 313.004[,] ***and*** *313.825,* ***RSMo 2000,*** *and* ***section*** *313.805, RSMo* ***Supp. [1994] 2012****. Emergency rule filed Sept. 1, 1993, effective Sept. 20, 1993, expired Jan. 17, 1994. Emergency rule filed Jan. 5, 1994, effective Jan. 18, 1994, expired Jan. 30, 1994. Original rule filed Sept. 1, 1993, effective Jan. 31, 1994. Amended: Filed May 13, 1998, effective Oct. 30, 1998. Amended: Filed March 28, 2013.*

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 OF PUBLIC HEARING AND NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri Gaming Commission, PO Box 1847, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the ***Missouri Register****. A public hearing is scheduled for June 12, 2013, at 10:00 a.m., in the Missouri Gaming Commission's Hearing Room, 3417 Knipp Drive, Jefferson City, Missouri.*

Title 11—DEPARTMENT OF PUBLIC SAFETY
Division 45—Missouri Gaming Commission
Chapter 8—Accounting Records and Procedures; Audits

PROPOSED AMENDMENT

11 CSR 45-8.060 Audits. The commission is amending sections (1), (9), and (10).

PURPOSE: This amendment updates audit procedures.

(1) Independent certified public accountants (C.P.A.s) registered or licensed in Missouri under Chapter 326, RSMo, *[selected by the commission from a list of at least three (3) C.P.A.s submitted by the applicant or licensee,]* shall conduct quarterly and annual audits of each licensee, as follows:

(A) On a quarterly calendar basis, except as noted—

1. Audit the respective quarter's adjusted gross receipts and related taxes from gambling games, and total number and amount of fees received from admissions in order to report on the fair presentation of such amounts. A reconcilement of these audited amounts to similar amounts in monthly financial reports required by 11 CSR 45-8.050 shall be provided;

2. Consider, in connection with the audit of adjusted gross receipts and admission fees referred to in paragraph (1)(A)1., the related internal control structure and report whether there exists any material weaknesses and report any reportable conditions identified. This evaluation shall include, at a minimum, walk-throughs of the internal control system, inquiries of licensee personnel, examination of supporting documents and unannounced observations of pit activity and table games and electronic gaming device drop and count procedures. For purposes of these procedures, unannounced means that no officers, directors or employees of the licensee are given advance information regarding the dates or times of the observations; and

3. Report on compliance of the licensee's operating procedures and written system of internal controls with the requirements of 11 CSR 45-9*[.030 and 11 CSR 45-9.040(1)]*. Whenever, in the opinion of the independent C.P.A., the licensee's operating procedures or written system of internal controls has deviated from the minimum internal control standards or variations to the standards approved by the commission, the report shall enumerate these deviations, regardless of materiality; and

(B) On an annual basis—

1. Report on reportable conditions found during the annual audit of the licensee's financial statements. A reportable condition shall be defined as a significant deficiency in the design or operation of the internal control structure, which would adversely affect the licensee's ability to record, process, summarize and report financial data consistent with the assertions of management in the financial statements. Reportable conditions that are also material weaknesses shall be identified as such in the report; and

2. Audit, in accordance with generally accepted auditing standards, the licensee's annual financial statements covering all financial activities of the licensee's operation**, including a physical count of all assets inventoried on the Main Bank/Vault Accountability form** in order to report on the fair presentation of the financial statements in conformity with generally accepted accounting principles. **The annual count of assets shall be performed within thirty (30) days of the fiscal year end. The commission shall be notified at least thirty (30) days prior to the annual count.** The audited annual financial statements must be prepared in a format consistent with the reporting requirements under 11 CSR 45-8.050(2). Unless the commission approves otherwise in writing, these statements must be prepared on a comparative basis. If the licensee or a person controlling, controlled by or under common control with the licensee owns or operates room, food or beverage facilities at the establishment, the financial statements must cover those operations as well as gaming operations;

(C) Sixty (60) days prior to the commencement of the annual financial audit, the independent C.P.A. shall submit to the commission a detailed written audit plan *[for approval]*. The audit plan shall include a complete description of procedures to be performed by the licensee's internal auditor, if applicable. At its discretion, the commission may require the independent C.P.A. to perform additional testing and/or procedures; and

(9) Any audits conducted in accordance with this rule*[,]* shall be conducted by independent C.P.A.s registered or licensed in Missouri under Chapter 326, RSMo*.[, and selected by the commission. The commission shall consider the following:*

(A) Prior experience of the firm in auditing gaming entities of similar size;

(B) Availability of sufficient numbers of qualified personnel;

(C) Submission of the firm to a peer review, and successful results; and

(D) Other factors as determined by the commission.]

(10) The term independent as used in section (9) of this rule is consistent with *[that set forth in 4 CSR 10-3.020, and]* definitions set forth by the American Institute of Certified Public Accountants or the rules of the Securities and Exchange Commission, or both, to the extent applicable.

AUTHORITY: sections 313.004[,] and 313.825, RSMo 2000, ***and***

***section** 313.805**, RSMo Supp. 2012**. Emergency rule filed Sept. 1, 1993, effective Sept. 20, 1993, expired Jan. 17, 1994. Emergency rule filed Jan. 5, 1994, effective Jan. 18, 1994, expired Jan. 30, 1994. Original rule filed Sept. 1, 1993, effective Jan. 31, 1994. For intervening history, please consult the **Code of State Regulations**. Amended: Filed March 28, 2013.*

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 OF PUBLIC HEARING AND NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri Gaming Commission, PO Box 1847, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. A public hearing is scheduled for June 12, 2013, at 10:00 a.m., in the Missouri Gaming Commission's Hearing Room, 3417 Knipp Drive, Jefferson City, Missouri.*

Title 11—DEPARTMENT OF PUBLIC SAFETY
Division 45—Missouri Gaming Commission
Chapter 8—Accounting Records and Procedures; Audits

PROPOSED AMENDMENT

11 CSR 45-8.090 Mandatory Count Procedure. The commission is amending sections (1) and (2).

PURPOSE: This amendment updates drop device terminology, and replaces the Social Security number with the occupational license number.

(1) Each licensee shall report to the commission, the time(s) when drop *[boxes and slot drop buckets]* **devices** will be removed and the contents counted. All drop *[boxes and slot drop buckets]* **devices** must be removed and counted at the time(s) previously designated to the commission. Removal and counting of contents at other than the designated time(s) is prohibited unless the licensee provides advance written notice to the commission of a change in time(s) or the commission requires a change of authorized times.

(2) Within ten (10) days after the end of each calendar quarter, each licensee shall submit a list to the commission of employees authorized to participate in the count and those employees who are authorized to be in the count room during the count (count personnel list) during and as of the end of the calendar quarter. The count personnel list shall indicate those persons, if any, who hold an interest in the licensee and shall indicate what relationship by blood or marriage, if any, exists between any person on this list or any interest holder or employee of the gaming establishment. The count personnel list shall also indicate the *[Social Security]* **occupational license** number of each count employee and the job position held by each count employee.

*AUTHORITY: sections 313.004[,] and 313.825, **RSMo 2000, and section** 313.805, RSMo Supp. [1993] **2012**. Emergency rule filed Sept. 1, 1993, effective Sept. 20, 1993, expired Jan. 17, 1994. Emergency rule filed Jan. 5, 1994, effective Jan. 18, 1994, expired Jan. 30, 1994. Original rule filed Sept. 1, 1993, effective Jan. 31, 1994. Amended: Filed March 28, 2013.*

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 OF PUBLIC HEARING AND NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri Gaming Commission, PO Box 1847, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. A public hearing is scheduled for June 12, 2013, at 10:00 a.m., in the Missouri Gaming Commission's Hearing Room, 3417 Knipp Drive, Jefferson City, Missouri.*

Title 11—DEPARTMENT OF PUBLIC SAFETY
Division 45—Missouri Gaming Commission
Chapter 8—Accounting Records and Procedures; Audits

PROPOSED AMENDMENT

11 CSR 45-8.100 Count Room—Characteristics. The commission is amending sections (1) and (3).

PURPOSE: This amendment updates count room characteristics.

(1) Each casino shall have a room(s) specifically designated for counting the contents of drop *[boxes and drop buckets]* **devices** which shall be known as the count room.

(3) The *[security department]* **key custodian** shall establish a sign-out procedure for all count room keys. An alarm device **(audible, visual, or both)** shall be connected to the entrance of the count room that causes a signaling to the monitors of the closed circuit television system and to the commission office on the boat whenever the door to the count room is opened.

*AUTHORITY: section[s] 313.004, **RSMo 2000, and sections** 313.800 and 313.805, RSMo Supp. [1993] **2012**. Emergency rule filed Sept. 1, 1993, effective Sept. 20, 1993, expired Jan. 17, 1994. Emergency rule filed Jan. 5, 1994, effective Jan. 18, 1994, expired Jan. 30, 1994. Original rule filed Sept. 1, 1993, effective Jan. 31, 1994. Amended: Filed March 28, 2013.*

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 OF PUBLIC HEARING AND NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri Gaming Commission, PO Box 1847, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. A public hearing is scheduled for June 12, 2013, at 10:00 a.m., in the Missouri Gaming Commission's Hearing Room, 3417 Knipp Drive, Jefferson City, Missouri.*

Title 11—DEPARTMENT OF PUBLIC SAFETY
Division 45—Missouri Gaming Commission
Chapter 8—Accounting Records and Procedures; Audits

PROPOSED AMENDMENT

11 CSR 45-8.150 Cash Reserve Requirements. The commission is amending Appendix A.

PURPOSE: This amendment updates the classification designation in Appendix A.

Appendix A
Commission Formula Minimum Bankroll Requirements

The Class *[A]* **B** licensee shall maintain the following minimum bankroll requirements to insure payment of patrons' win.

First month of operation one hundred percent (100%) of licensee's projected payout to patrons (electronic gaming device and table game drop minus licensee win) for a weekly period, defined as seven (7) gaming days, based on the average daily payout multiplied by seven (7).

Second and subsequent months of operation one hundred percent (100%) of licensee's actual payout to patrons (electronic gaming device and table game drop minus licensee win) for a weekly period, based on the average daily payout multiplied by seven (7) from the previous month's operation.

*AUTHORITY: section[s] 313.004, **RSMo 2000, and sections** 313.800 and 313.805, RSMo [1994] **Supp. 2012**. Emergency rule filed Sept. 1, 1993, effective Sept. 20, 1993, expired Jan. 17, 1994. Emergency rule filed Jan. 5, 1994, effective Jan. 18, 1994, expired Jan. 30, 1994. Original rule filed Sept. 1, 1993, effective Jan. 31, 1994. For intervening history, please consult the **Code of State Regulations**. Amended: Filed March 28, 2013.*

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 OF PUBLIC HEARING AND NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri Gaming Commission, PO Box 1847, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. A public hearing is scheduled for June 12, 2013, at 10:00 a.m., in the Missouri Gaming Commission's Hearing Room, 3417 Knipp Drive, Jefferson City, Missouri.*

Title 11—DEPARTMENT OF PUBLIC SAFETY
Division 45—Missouri Gaming Commission
Chapter 9—Internal Control System

PROPOSED RULE

11 CSR 45-9.107 Minimum Internal Control Standards (MICS)—Chapter G

*PURPOSE: This rule establishes the internal controls for Chapter G of the **Minimum Internal Control Standards**.*

*PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here. The **Minimum Internal Control Standards** may also be accessed at http://www.mgc.dps.mo.gov.*

(1) The commission shall adopt and publish minimum standards for internal control procedures that in the commission's opinion satisfy 11 CSR 45-9.020, as set forth in *Minimum Internal Control Standards* (MICS) Chapter G—Drops and Counts, which has been incorporated by reference herein, as published by the Missouri Gaming Commission, 3417 Knipp Dr., PO Box 1847, Jefferson City, MO 65102. Chapter G does not incorporate any subsequent amendments or additions as adopted by the commission on March 27, 2013.

AUTHORITY: section 313.004, RSMo 2000, and sections 313.800 and 313.805, RSMo Supp. 2012. Original rule filed March 28, 2013.

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

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

*NOTICE OF PUBLIC HEARING AND NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with the Missouri Gaming Commission, PO Box 1847, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. A public hearing is scheduled for June 12, 2013, at 10:00 a.m., in the Missouri Gaming Commission's Hearing Room, 3417 Knipp Drive, Jefferson City, Missouri.*

Title 13—DEPARTMENT OF SOCIAL SERVICES
Division 70—MO HealthNet Division
Chapter 10—Nursing Home Program

PROPOSED RULE

13 CSR 70-10.017 Nursing Facility Invasive Ventilator Program

PURPOSE: This rule sets forth the requirements for participation in the MO HealthNet Invasive Ventilator Program and the per diem add-on amounts to be applied to nursing facility reimbursement rates, established in 13 CSR 70-10.015 and 13 CSR 70-10.016. The services provided under the Invasive Ventilator Program are in addition to the nursing facility services already provided by the facility and as such are subject to all policies, rules, regulations, and provider agreements applicable to providing nursing facility services to MO HealthNet participants.

(1) The Invasive Ventilator Program is limited to—

(A) Nursing facilities licensed by the Department of Health and Senior Services (DHSS) and certified for participation in the MO HealthNet program and enrolled in the MO HealthNet Invasive Ventilator Program; and

(B) Services provided to adult MO HealthNet participants who are dependent on an invasive ventilator as a means of life support. An invasive ventilator generates breath delivered to the participant through an artificial airway positioned in the participant's trachea.

(2) Reimbursement for Invasive Ventilator Care. Providers approved for participation in the Invasive Ventilator Program will receive payment in the form of a per diem add-on to their reimbursement rate established in accordance with 13 CSR 70-10.015. The per diem add-on amount will be one hundred fifty dollars ($150.00) will be paid for MO HealthNet participants who are dependent on a ventilator full time as a means of life support.

(3) Provider Requirements for Participation in the Invasive Ventilator Program.

(A) Nursing facilities seeking to participate in the Invasive

Ventilator Program must submit the following information to Missouri Medicaid Audit and Compliance (MMAC), Provider Enrollment Unit:

1. A completed Invasive Ventilator Program Provider application; and

2. Any other information or documentation requested by MMAC to assist in determining enrollment status.

(B) MMAC may enter into agreements with facilities for the participation in the MO HealthNet Invasive Ventilator Program through the provider enrollment process only if the provider agrees to the following terms:

1. The provider must maintain and provide documentation demonstrating—

A. Medicaid (Title XIX) Certification;

B. The provider has the capacity and capability to provide invasive ventilator medical care as documented by DHSS, MO HealthNet Division (MHD), and MMAC records;

C. Adherence to regulatory requirements established by DHSS, MHD, and MMAC;

D. The medical condition of the participant to verify they meet the criteria for participation in this program; and

E. The provider has the following written agreements:

(I) A written agreement with an enrolled MO HealthNet Durable Medical Equipment (DME) provider which must include a service contract for invasive ventilator equipment. DME providers will bill MO HealthNet for the necessary ventilator;

(II) A written agreement with a local emergency transportation provider;

(III) A written agreement with a local hospital capable of providing the necessary care for invasive ventilator-dependent participants, when appropriate;

(IV) Presence of written emergency procedures including but not limited to the following:

(a) Procedures to care for and transport invasive ventilator-dependent participants in the event of an emergency evacuation;

(b) Procedures to care for invasive ventilator-dependent participants in the event of power failure; and

(c) Procedures to care for invasive ventilator-dependent participants in the event of equipment failure;

2. Individuals qualifying for participation in the Invasive Ventilator Program must be placed in contiguous rooms; and

3. In addition to the covered items and services included in the reimbursement rate set forth in 13 CSR 70-10.015—

A. The nursing facility must purchase one (1) Ambu bag per invasive ventilator dependent participant and place it in a designated location readily accessible at the bedside to ensure access in the event of an emergency;

B. The provider must ensure the necessary equipment to accommodate the needs of the invasive ventilator-dependent participants is provided by the DME provider. The equipment and supplies covered under the MO HealthNet DME program will be payable directly to the DME provider;

C. Proper invasive ventilator and tracheostomy supplies and equipment are provided to the participant;

D. Each invasive ventilator is equipped with an alarm on both the pressure valve and the volume valve; and

E. Each invasive ventilator is equipped with internal batteries to provide a short term back-up system in case of a total loss of power**,** and the battery must be checked as recommended by the manufacturer.

(C) Termination of Participation in Invasive Ventilator Program.

1. Providers desiring to discontinue providing invasive ventilator services shall notify MMAC Provider Enrollment Unit in writing, at least sixty (60) days prior to the date of termination. Payment for invasive ventilator participants already residing in facilities who wish to discontinue providing invasive ventilator services will remain at the previous invasive ventilator rate as long as the participant meets the invasive ventilator criteria and as long as all related criteria are met by the provider or the participant is discharged.

(4) Participant Eligibility for Participation in Invasive Ventilator Program.

(A) Pre-certification must be obtained through MO HealthNet in order to receive payment under the Invasive Ventilator Program. The pre-certification must be initiated by an authorized medical assistance provider who has evaluated the medical needs of the individual. Authorized providers include physicians, advanced practice nurses, respiratory therapists, hospitals, and nursing facilities.

1. The pre-certification application will be available by contacting the Clinical Services Unit/Invasive Ventilator Program.

2. The pre-certification period will be approved for the duration of the physician's prescription for invasive ventilation. If the invasive ventilator is used for weaning purposes**,** a pre-certification must be completed every ninety (90) days to ensure individuals still meet the requirements for participation in this program. An approved pre-certification request does not guarantee payment. The provider must verify participant eligibility on the date of service using the Interactive Voice Response (IVR) System at (573) 635-8908 or by logging onto the MO HealthNet Internet Web portal at www.emomed.com.

(B) Accessibility to Records. The provider must make accessible to MHD, MMAC, and/or DHSS all provider, participant, and other records necessary to determine that the needs of the participant are being met and to determine the appropriateness of invasive ventilator services.

(C) In the event that it is determined through the pre-certification process that the participant is no longer in need of or receiving invasive ventilator services, MHD shall discontinue the add-on per diem authorized by this regulation for the participant and reduce the rate of payment to the provider to the provider's standard MO HealthNet per diem rate established under 13 CSR 70-10.015.

(5) Cost Reporting Requirements.

(A) Providers will be required to separately identify the invasive ventilator-dependent patient days regardless of payer source that relate to dates of service within the cost reporting time period by completing a supplemental schedule as provided by MHD.

(B) Due to the complex record-keeping requirements needed to identify the specific cost of this program, MHD will remove the cost as a revenue offset determined as follows. The days from each category identified above will be multiplied by the related Invasive Ventilator add-on amount and offset against the expenses. This will ensure the additional cost of caring for these participants will be removed from the allowable cost in determining the prospective reimbursement rate. The offset will be allocated among the cost components as follows: Patient Care—sixty percent (60%), Ancillary—thirty percent (30%), and Administrative—five percent (5%). The remaining five percent (5%) will not be offset because the capital costs are easily identified and will be removed as non-allowable.

AUTHORITY: section 208.159, RSMo 2000, and sections 208.153 and 208.201, RSMo Supp. 2012. Original rule filed April 1, 2013.

PUBLIC COST: This proposed rule will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate for SFY 2013. There is a fiscal note attached that describes the estimated savings from this rule.

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

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with the Department of Social Services, MO HealthNet Division, 615 Howerton Court, Jefferson City, MO 65109. To be considered, comments must be delivered by regular mail, express or overnight mail, in person, or by courier within thirty (30) days after publication of this notice in the ***Missouri Register****. If to be hand-delivered, comments must be brought to the MO HealthNet Division at 615 Howerton Court, Jefferson City, Missouri. No public hearing is scheduled.*

FISCAL NOTE
PUBLIC COST

I. Department Title: Title 13 - Department of Social Services
Division Title: Division 70 - MO HealthNet Division
Chapter Title: Chapter 10 - Nursing Home Program

Rule Number and Name:	13 CSR 70-10.017 Nursing Facility Invasive Ventilator Program
Type of Rulemaking:	Proposed Rule

II. SUMMARY OF FISCAL IMPACT

Affected Agency or Political Subdivision	Estimated Cost of Compliance in the Aggregate
Department of Social Services MO HealthNet Division	Estimated cost savings for SFY 2013 – $9,888

III. WORKSHEET

Ventilator Full Time		Full Time
Average In-State Proposed Per Diem Rate		$297.41
Add Per Day amount for DME Cost		$27.12
Total Proposed Cost Per Day		$324.53
Out of State Average Rate Paid		$346.50
Savings Per Day Compared to Out of State Payment		($21.97)
Estimated MO HealthNet Participants	5	
Average Number of Days Paid	90	
Total Estimated Patient Days in SFY 2013		450
Estimated Range of Savings SFY 2013		$9,888

Future Years
Approximately 10,000 Patient Days Paid to Out of State Facilities for Ventilator Care:

Per Patient Days Savings	$21.97
Estimated Ventilator Patient Days	10,000
Annualized Range of Savings	$219,700

IV. ASSUMPTIONS

The estimated average MO HealthNet nursing facility rate for SFY 2013 is increased for the add-on per diem amount of $150.00 for full time ventilator need. The DME cost is a computed per patient day amount based on the monthly MO HealthNet DME provider payment of $825.00 for ventilator equipment. The out of state average rate paid is based on July 2012 out of state facility rates being paid for 28 MO HealthNet participants in those facilities.

There will not be a requirement for MO HealthNet participants to move from an out of state facility into a Missouri facility offering invasive ventilator care. The estimated number of 5

participants would be new participants requiring invasive ventilator care. The 90 days would be average number of days paid over 6 months of SFY 13 assuming equal entry into the program from January 2013 to June 2013.

The 10,000 patient days for future years is estimated based on the current number of MO HealthNet participants placed in out of state facilities for nursing facility invasive ventilator care. There are 28 participants which multiplied by 365 days equals 10,220 patient days and then reduced to 10,000 to account for possible hospital stays or other discharges which would reduce the nursing facility days.

This section will contain the final text of the rules proposed by agencies. The order of rulemaking is required to contain a citation to the legal authority upon which the order of rulemaking is based; reference to the date and page or pages where the notice of proposed rulemaking was published in the *Missouri Register*; an explanation of any change between the text of the rule as contained in the notice of proposed rulemaking and the text of the rule as finally adopted, together with the reason for any such change; and the full text of any section or subsection of the rule as adopted which has been changed from that contained in the notice of proposed rulemaking. The effective date of the rule shall be not less than thirty (30) days after the date of publication of the revision to the *Code of State Regulations*.

The agency is also required to make a brief summary of the general nature and extent of comments submitted in support of or opposition to the proposed rule and a concise summary of the testimony presented at the hearing, if any, held in connection with the rulemaking, together with a concise summary of the agency's findings with respect to the merits of any such testimony or comments which are opposed in whole or in part to the proposed rule. The ninety- (90-) day period during which an agency shall file its Order of Rulemaking for publication in the *Missouri Register* begins either: 1) after the hearing on the Proposed Rulemaking is held; or 2) at the end of the time for submission of comments to the agency. During this period, the agency shall file with the secretary of state the order of rulemaking, either putting the proposed rule into effect, with or without further changes, or withdrawing the proposed rule.

Title 6—DEPARTMENT OF HIGHER EDUCATION
Division 10—Commissioner of Higher Education
Chapter 2—Student Financial Assistance Program

ORDER OF RULEMAKING

By the authority vested in the Commissioner of Higher Education under section 160.545, RSMo Supp. 2012, as transferred to the Missouri Department of Higher Education by Executive Order 10-16, dated January 29, 2010, the commissioner amends a rule as follows:

6 CSR 10-2.190 A+ Scholarship Program **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on January 15, 2013 (38 MoReg 174–176). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The commissioner of higher education received comments on the proposed amendment from three (3) sources.

COMMENT #1: Pat Rooney, A+ Coordinator at Mt. Vernon High School, expressed general concern about the amendment in its entirety because the changes will make the program more complex for families to understand. This commenter specifically expressed concern about the ACT or COMPASS exam alternative to the Algebra I end-of-course exam requirement. This commenter recommended this provision be revised to ensure that eligibility for all students is determined prior to high school graduation, regardless of whether eligibility is established through the Algebra I end-of-course exam or the alternative.
RESPONSE: The department respectfully disagrees with these comments. This amendment is necessary to clarify A+ Scholarship eligibility policy, ensuring that all students are treated as equitably as possible. While the department appreciates the commenter's concern with increased complexity, the department believes it is in the best interest of students to provide an alternative to the end-of-course exam requirement. Because the COMPASS exam is not available to all high school students, this eligibility criterion, which was suggested to the department from A+ participating institutions, necessitates extending the period beyond high school graduation. The addition of a requirement that eligibility be determined for all students prior to high school graduation would limit eligibility for some students based solely on the postsecondary institution they plan to attend. No changes have been made to this rule as a result of these comments.

COMMENT #2: J. Terry Gates, president/CEO of The Hoenny Center, supported the proposed amendment but opposed the option of allowing up to twenty-five percent (25%) of the required fifty (50) hours of tutoring or mentoring to include job shadowing. This commenter recommended replacing job shadowing with community service. This commenter also recommended the department consider adding a Communication Arts minimum requirement.
RESPONSE: The comments relating to the tutoring or mentoring provision and the inclusion of a minimum Communication Arts requirement are outside of the scope of this proposed amendment. No changes have been made to this rule as a result of this comment. The department will retain these comments for consideration in future amendments.

COMMENT #3: Eric Sclesky, A+ Coordinator at Raymore-Peculiar High School, recommended amendment of the Algebra I end-of-course exam requirement to clarify the provision that students may achieve a qualifying score on a higher level DESE approved end-of-course exam in the field of mathematics by specifying the Geometry and Algebra II end-of-course exams.
RESPONSE: The department respectfully disagrees with this comment. The proposed amendment includes language to allow students to meet the end-of-course requirement by achieving qualifying scores on the Geometry and Algebra II end-of-course exams. Identifying these courses and tests by name within the rule would require the department to revise these provisions any time a new mathematics test is added or if the existing tests are revised by the Department of Elementary and Secondary Education. The proposed approach will provide the department with flexibility to adapt more quickly as the end-of-course exams evolve in the future. No changes have been made to this rule as a result of this comment.

Title 11—DEPARTMENT OF PUBLIC SAFETY
Division 45—Missouri Gaming Commission
Chapter 9—Internal Control System

ORDER OF RULEMAKING

By the authority vested in the Missouri Gaming Commission (MGC) under section 313.805, RSMo Supp. 2012, the commission amends a rule as follows:

11 CSR 45-9.106 Minimum Internal Control Standards (MICS)—Chapter F **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 3,

2012 (37 MoReg 1770). No changes have been made to the *Minimum Internal Control Standards* (MICS) as incorporated by reference in Chapter F. No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: A public hearing was held on this proposed amendment on January 9, 2013. No one attended the public hearing. No written comments were received.

Title 11—DEPARTMENT OF PUBLIC SAFETY
Division 45—Missouri Gaming Commission
Chapter 9—Internal Control System

ORDER OF RULEMAKING

By the authority vested in the Missouri Gaming Commission (MGC) under section 313.805, RSMo Supp. 2012, the commission amends a rule as follows:

11 CSR 45-9.120 Minimum Internal Control Standards (MICS)—Chapter T **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 3, 2012 (37 MoReg 1770). No changes have been made to the *Minimum Internal Control Standards* (MICS) as incorporated by reference in Chapter T. No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: A public hearing was held on this proposed amendment on January 9, 2013. No one attended the public hearing. No written comments were received.

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

ORDER OF RULEMAKING

By the authority vested in the Missouri Department of Health and Senior Services under section 192.006, RSMo 2000, and sections 190.185 and 190.241, RSMo Supp. 2012, the department adopts a rule as follows:

19 CSR 30-40.710 is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on December 17, 2012 (37 MoReg 1889–1891). Changes have been made in the text of the proposed rule, so it is reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The Department of Health and Senior Services received four (4) comments.

COMMENT #1: Robert C. Scanlon, II, D.O., with the Missouri Association of Osteopathic Physicians & Surgeons commented that the definition of board-certified under subsection (1)(D) that currently reads "the Bureau of Osteopathic Specialties and Boards of Certification" should actually read "American Osteopathic Association Board of Osteopathic Specialists."
RESPONSE AND EXPLANATION OF CHANGE: The department agrees and has amended subsections (1)(C) and (1)(D).

COMMENT #2: Thomas L. Holloway, with the Missouri State Medical Association suggests that under paragraph (1)(B)1. which defines anesthesiologist assistant the word "American" should come before the phrase "Medical Association's Committee on Allied Health Education."
RESPONSE AND EXPLANATION OF CHANGE: The department agrees and has amended the proposed rule.

COMMENT #3: Thomas L. Holloway, with the Missouri State Medical Association suggests that under subsection (1)(F) which defines a certified registered nurse anesthetist (CRNA) additional language should be added to specify that a CRNA must be licensed pursuant to Chapter 335, RSMo.
RESPONSE AND EXPLANATION OF CHANGE: The department agrees and has amended the proposed rule.

COMMENT #4: Thomas L. Holloway with the Missouri State Medical Association comments that proposed rule 19 CSR 30-40.720(4) refers to neurologist(s)/neuro-interventionalist(s) but there is no definition for these terms. Mr. Holloway suggests that it might be prudent to clarify that a neurologist or neuro-interventionalist are licensed physicians with the appropriate specialty training.
RESPONSE AND EXPLANATION OF CHANGE: The department agrees and has added new subsections (1)(V) defining "neurologist" and (1)(W) defining "neuro-interventionalist" and renumbered the subsections thereafter.

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

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

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

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

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

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

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

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

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

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

(F) Certified registered nurse anesthetist (CRNA)—a registered nurse who—

1. Has graduated from a school of nurse anesthesia accredited by the Council on Accreditation of Education Programs of Nurse Anesthesia or its predecessor;

2. Has been certified as a nurse anesthetist by the Council on Certification of Nurse Anesthetists; and

3. Has been licensed in Missouri pursuant to Chapter 335, RSMo;

(V) Neurologist—a licensed physician with the appropriate specialty training;

(W) Neuro-interventionalist—a licensed physician with the appropriate specialty training;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(UU) Telemedicine—the use of medical information exchanged from one (1) site to another via electronic communications to improve patient's health status. A neurology specialist will assist the physician in the center in rendering a diagnosis. This may involve a patient "seeing" a specialist over a live, remote consult or the transmission of diagnostic images and/or video along with patient data to the specialist;

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

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

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

ORDER OF RULEMAKING

By the authority vested in the Missouri Department of Health and Senior Services under section 192.006, RSMo 2000, and sections

190.185 and 190.241, RSMo Supp. 2012, the department adopts a rule as follows:

19 CSR 30-40.720 is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on December 17, 2012 (37 MoReg 1891–1906). Changes have been made in the text of the proposed rule, so it is reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The Department of Health and Senior Services received sixteen (16) comments.

COMMENT #1: Shane Lockard, with the Johnson County Ambulance District commented about his concern with the fiscal impact of the time critical diagnosis (TCD) regulations on the many hospitals that are interested in seeking formal designation as a stroke center. Mr. Lockard commented that the federal Medicare program is seeking to cut funding to healthcare, the Affordable Care Act has cut several billion dollars from the funding stream for hospitals, and the Missouri Medicaid program inadequately funds healthcare services. Mr. Lockard is concerned that some hospitals will be unable to seek designation due to the high cost to participate combined with other unrelated funding cuts creating fiscal challenges for hospitals. Finally, Mr. Lockard encourages the department to evaluate the fiscal impact of the proposed regulations on the hospitals which could seek designation in order to balance the various factors needed to assure an adequate number of facilities in the TCD system.
RESPONSE: The department understands this concern. The option as to whether or not a hospital chooses to apply to the department to become a designated stroke center is voluntary. In addition, the department has tiered the requirements of each level of stroke center based on the level of resources it is able to provide for the care of the stroke patient. For example, a level IV stroke center which is typically a smaller hospital in a rural area will not be required to have the healthcare staff and resources compared to a level I stroke center. Finally, many representatives from hospitals throughout Missouri met with the department to create these regulations and during these meetings the costs to the hospitals were considered as well as what resources the hospitals already had for a stroke program (e.g., emergency department, helipad, etc.). No changes have been made to this rule as a result of this comment.

COMMENT #2: Dr. David Gustafson, with the Kansas City Regional Emergency Medical Services (EMS) Committee and Ben Chlapek, with the Mid-America Regional Council Emergency Rescue Committee (MARCER) commented that they are concerned with the fiscal impact of the TCD regulations on the many hospitals they believe are interested in seeking formal designation as a stroke center. Dr. Gustafson and Mr. Chlapek are aware that many hospitals have indicated concern regarding the fiscal note related to designation. Dr. Gustafson and Mr. Chlapek are concerned that some hospitals that were seriously considering seeking designation will decide to not seek designation due to the high cost to participate. Finally, Dr. Gustafson and Mr. Chlapek believe the department should evaluate the fiscal impact of the proposed regulations on the hospitals that could seek designation in order to balance the various factors needed to assure an adequate number of facilities in the system.
RESPONSE: The department understands this concern. The option as to whether or not a hospital chooses to apply to the department to become a designated stroke center is voluntary. In addition, the department has tiered the requirements of each level of stroke center based on the level of resources it is able to provide for the care of the stroke patient. For example, a level IV stroke center which is typically a smaller hospital in a rural area will not be required to have the healthcare staff and resources compared to a level I stroke center. Finally, many representatives from hospitals throughout Missouri met with the department to create these regulations and during these meetings the costs to the hospitals were considered as well as what resources the hospitals already had for a stroke program (e.g., emergency department, helipad, etc.). No changes have been made to this rule as a result of this comment.

COMMENT #3: Thomas L. Holloway, with the Missouri State Medical Association comments that section (4) refers to "neurologist(s)/neuro-interventionalist(s)" but those terms appear to not be defined in the proposed rules. Mr. Holloway suggests that the department define theses terms as a licensed physician with the appropriate specialty training.

RESPONSE: The department agrees and has added definitions of "neurologist" and "neuro-interventionalist" to 19 CSR 30-40.710 Definitions and Abbreviations Relating to Stroke Centers. No changes have been made to this rule as a result of this comment.

COMMENT #4: Daniel Landon, with the Missouri Hospital Association (MHA) commented that section (3) states that the stoke center designation shall be valid for a period of four (4) years from the date the stroke center/hospital is designated. This proposed designation period is inconsistent with the current trauma center designation period of five (5) years as detailed in 19 CSR 30-40.420(4)(A). The proposed four- (4-) year period is also inconsistent with the three- (3-) year time period as proposed in 19 CSR 30-40.750(3). The department does not specify the rationale for the differing length of designation. The disparate timing of revalidation activities may create undue burden on both the hospital and the department as they try to manage the appropriate cycles for revalidation of hospitals that participate in more than one (1) center across all designated centers and correspond with the existing standard of five (5) years as detailed in the trauma center regulations. Mr. Landon recommends that the department modify its proposal to be consistent across all designated centers and correspond with the existing standard of five (5) years as detailed in the trauma center designation regulations.

RESPONSE: The department understands this concern. The department and representatives of the healthcare community felt that a five- (5-) year designation period was too long of a period. The department with a consensus from the healthcare community decided to designate STEMI centers for a period of three (3) years to correlate with the American College of Surgeons' three- (3-) year accreditation cycle, a vetted national standard for trauma centers which by design STEMI centers closely resemble. This three- (3-) year designation period has also been raised in trauma system discussions with trauma care professionals in Missouri for consensus driven changes to the department's trauma designation program in order for the designation time to more closely align with the American College of Surgeons' three- (3-) year accreditation cycle. The department decided to designate stroke centers for a period of four (4) years in order to correlate with the Joint Commission's stroke certification process which is every two (2) years. The department felt that two (2) years was too short of a designation time period, but the four- (4-) year time frame allows the department to accommodate a hospital's request to conduct a stroke center designation review during a similar time frame that the Joint Commission will visit a hospital that is also a Joint Commission stroke certified center. No changes have been made to this rule as a result of this comment.

COMMENT #5: Judy Aslin, with Southeast Health comments that the assumptive statements in both the private and public fiscal notes should be clarified because it is unclear if the assumptions of how many hospitals will apply to become a designated stroke center are stating the maximum capacity the department can review each year. Ms. Aslin suggests these assumptive statements be clarified to clearly state the number of annual reviews for which the department has capacity.

RESPONSE: The assumptive statements in the fiscal note are estimates of how many hospitals might apply to become a designated stroke center during the time frames discussed in the fiscal notes. This estimate is not based on the maximum capacity the department can review to become designated stroke centers during the time frames discussed in the fiscal notes. No changes have been made to this rule as a result of this comment.

COMMENT #6: Judy Aslin, with Southeast Health recommends that the assumptive statements in the private and public fiscal notes clearly state the process planned for releasing level designations to the public.
RESPONSE: A process planned for releasing level designations to the public would not go into fiscal notes. No changes have been made to this rule as a result of this comment.

COMMENT #7: Judy Aslin, with Southeast Health comments that it is unclear in the assumptive statements for the fiscal note if a stroke center would be recognized as a designated stroke center by the state after the end of the on-site review, at the end of each year or at the end of the first five- (5-) year period. Ms. Aslin requests clarification of this process.
RESPONSE: As outlined in the proposed rule, after a hospital applies to become a stroke center then a review by a department staff member and qualified contractors will occur. Following the review, the qualified contractors will submit a report of their findings to the department. The department then gives a copy of this report to the hospital. This report indicates whether a hospital has met the criteria to be designated as a stroke center, or in the case of renewal of stroke center designation, whether the hospital will be redesignated as a stroke center. If a stroke center has met the requirements to be designated by the department as a stroke center, then it will be designated as a stroke center for a period of four (4) years from the date that it was designated or redesignated following the issuance of the report confirming that the hospital has met the criteria to be designated as a stroke center. No changes have been made to this rule as a result of this comment.

COMMENT #8: Jace Smith, with the American Heart Association, Midwest Affiliate; Sharon Pulver, with SSM Neurosciences Institute; Rebekah Terrell; Natalie Mills; Todd Sampson; Sascha Haley; Cammie Johnson; Sharon Spero; John Paul Pe; Ronnie Gibbs; Pat Kueny; Rona Frey; Vickie Brown; Cynthia Rasdall; Ashlea Serri; Sheila Beck; Mary Jane Beck; Deborah Gieselman; Sandra Pelletier; Justin Blomquist; Kelly Minnis; Rita Phillips; Shelly Wright; April Dimas; Dianna Smith; Frank Scharsch; Annette Long; Jeffrey Hasty; Jill Snider; Jessica Powell; Jacob Roach; Hillis Doyel; Linda Duncan; Amber Boes; Kathy Fidler; Corrine Everson; Becky Madonia; Brian Marriott; Mary Murphy; Juli Christopher; Michael Dieker; Grace Sumption; Greg Simpson; Tina York; Kathryn Hedges; Carla Di Maggio; Brandi King; Connie Horne; Tracy Thellman; Janet Frye; Tina Johnson; Cie Cascone; Hannah Earhart; Rebecca Froese; Debra Smith; Sandra Shipman; Gina Gregg; Rachelle Mellor; Doris Owens; Patricia Doyel; Shawn Kegley; John Young; Deborah Popp; Kevin Johnson; Wayne Arndt; Elizabeth Martin; Greg Carson; Deanna Bailey; Cheryl Allen; Randal Moberg; Heath King; Jackie De Souza; Larry Todd; and Michele Kueny question whether, as drafted in the proposed rules, the department is going to be the accrediting body and will not be accepting Joint Commission (stroke) status from applying hospital facilities. If that is so, then this will mean that if a hospital wants to be certified as a primary stroke center or comprehensive stroke center receiving facility, then it will need to go through a separate department accreditation process in addition to the Joint Commission process. As drafted it appears the rules could potentially create an environment that would keep facilities from ever pursuing Joint Commission or other national accreditation because it would not "count" toward state accreditation. They also feel that is an unwarranted cost to the state, since the standards for stroke care in Missouri have already been set by the Joint Commission. It is also cost prohibitive for facilities to pursue Joint Commission certification. Finally, they recommend that the Joint Commission be the standard accreditation the department uses. They comment that this will also help accelerate the implementation of the Missouri stroke center program by allowing the department to focus on hospitals that are new to the certification process.

RESPONSE AND EXPLANATION OF CHANGE: The department understands this concern. The department did not intend to accept Joint Commission stroke certification status from hospitals who apply to the department to become a stroke center. During these past several years the department met with many representatives from the healthcare community in Missouri to create this proposed rule and proposed rule 19 CSR 30-40.730 which sets forth the requirements for a stroke center. During these meetings, the healthcare representatives came to a consensus on the requirements for a stroke center. The requirements set forth in 19 CSR 30-40.730 are not identical to the Joint Commission's stroke certification process. For example, sections 190.200 and 190.241, RSMo, mandate the department to promulgate rules to create stroke centers in Missouri and to create a transport protocol in order to route stroke patients in Missouri to these stroke centers. This system of routing patients in Missouri to appropriate stroke centers is not part of the Joint Commission's stroke center certification process. As such, the proposed rules integrate the stroke centers into the larger system of care that includes components that precede and follow hospital based care for these patients. Thus, the consensus of healthcare representatives decided to create a proposed rule on the requirements of a stroke center instead of accepting the Joint Commission's stroke certification process for the state stroke designation program. The department also felt that to accept the Joint Commission stroke certification status instead of creating state requirements would eliminate the smaller and more rural hospitals from being able to participate as stroke designated centers because these hospitals would most likely not qualify for Joint Commission stroke certification and the hospitals might not be able to afford such a certification. For example, the Joint Commission Advanced Certification for Comprehensive Stroke Centers would be similar to the department designated level I stroke center. The Advanced Certification for Primary Stroke Centers would be similar to the department's designated level II stroke center. There are no Joint Commission stroke certifications which would be similar to the department designated level III and IV stroke centers. The requirements created in 19 CSR 30-40.730 set up four (4) levels of stroke centers which can provide appropriate care to stroke patients and set requirements based on the evidence and resources and size of the facility. These differing levels of stroke centers allow smaller hospitals to be able to receive stroke center designation. The department also seriously considered whether to conduct a joint review with the Joint Commission for comprehensive and primary stroke centers. Currently, the department conducts joint reviews with the American College of Surgeons in the department's trauma designation system for those hospitals that wish to be a state designated trauma center and also accredited by the American College of Surgeons. There was no consensus reached between the Joint Commission and the department after the department contacted the Joint Commission about conducting joint reviews. Taking into account all of the reasons, the department agrees to amend section (4) to reflect that the department will only send out one (1) department staff liaison and may send out one (1) qualified contractor to conduct an initial review on a Joint Commission certified Comprehensive Stroke Center which applies to become a level I stroke center with the department. Similarly, the department will only send out one (1) department staff liaison and may also send one (1) qualified contractor to conduct an initial review on a Joint Commission certified Primary Stroke Center which applies to become a level II stroke center with the department. This change will save the Joint Commission stroke certified facilities money and time, since the department will not be sending out the maximum of four (4) qualified contractors plus the department's staff liaison as originally proposed. The department will not rely on Joint

Commission stroke certifications status for validation reviews when the stroke centers apply for renewal of their stroke center designation because the department is not able to conduct a joint review with the Joint Commission stroke certified facilities to ensure that the department's requirements are met. The department has amended section (4) to reflect this change and the application for stroke centers.

COMMENT #9: Judy Aslin, with Southeast Health recommends both STEMI center and stroke center designations be valid for a period of four (4) years from the date the center/hospital is designated. Ms. Aslin points out that the current three- (3-) year validation period for STEMI centers and the four- (4-) year validation period for stroke centers are asynchronous. Ms. Aslin states the regulations do not state the rationale for the different validation period lengths. Facilities with dedicated internal resources for this work could create efficiencies if both center reviews had the same validation period.

RESPONSE: The department understands this concern. The department and representatives of the healthcare community felt that a five- (5-) year designation period was too long of a period. The department with a consensus from the healthcare community decided to designate STEMI centers for a period of three (3) years to correlate with the American College of Surgeons' three- (3-) year accreditation cycle, a vetted national standard for trauma centers which by design STEMI centers closely resemble. This three- (3-) year designation period has also been raised in trauma system discussions with trauma care professionals in Missouri for consensus driven changes to the department's trauma designation program in order for the designation time to more closely align with the American College of Surgeons' three- (3-) year accreditation cycle. The department decided to designate stroke centers for a period of four (4) years in order to correlate with the Joint Commission's stroke certification process which is every two (2) years. The department felt that two (2) years was too short of a designation time period, but the four- (4-) year time frame allows the department to accommodate a hospital's request to conduct a stroke center designation review during a similar time frame that the Joint Commission will visit a hospital that is also a Joint Commission stroke certified center. No changes have been made to this rule as a result of this comment.

COMMENT #10: Susan Law, with Midwest Health Systems comments that many Missouri healthcare facilities have pursued and maintained Joint Commission stroke center certification. Much work has been done on achieving Joint Commission certification and the on-going requirements are rigorous. Ms. Law points out that the current proposed rule states that the department is going to be the accrediting body for stroke certification and that the state will not be accepting Joint Commission stroke center certification status as the basis for Missouri state designation. This means that if a hospital wants to be certified as a primary stroke certified/comprehensive stroke certified receiving facility, then it will need to go through a separate department accreditation process in addition to the Joint Commission process. The proposed rule will potentially create an environment that could place facilities in the position of choosing state designation instead of Joint Commission or other national accreditation because the state will not recognize the vast amount of work that is required to achieve and maintain Joint Commission certification. Ms. Law states Joint Commission stroke certification program is nationally recognized as the gold standard. Ms. Law recommends that the Joint Commission stroke certification be the accreditation standard used by the department.

RESPONSE AND EXPLANATION OF CHANGE: The department understands this concern. The department did not intend to accept Joint Commission stroke certification status from hospitals who apply to the department to become a stroke center. During these past several years the department met with many representatives from the healthcare community in Missouri to create this proposed rule and proposed rule 19 CSR 30-40.730 which sets forth the requirements for a stroke center. During these meetings, the healthcare representatives came to a consensus on the requirements for a stroke center. These requirements set forth in 19 CSR 30-40.730 are not identical to the Joint Commission's stroke certification process. For example, sections 190.200 and 190.241, RSMo, mandate the department to promulgate rules to create stroke centers in Missouri and to create a transport protocol in order to route stroke patients in Missouri to these stroke centers. This system of routing patients in Missouri to appropriate stroke centers is not part of the Joint Commission's stroke center certification process. As such, the proposed rules integrate the stroke centers into the larger system of care that includes components that precede and follow hospital based care for these patients. Thus, the consensus of healthcare representatives decided to create a proposed rule on the requirements of a stroke center instead of accepting Joint Commission's stroke certification process for the state stroke designation program. The department also felt that to accept the Joint Commission stroke certification status instead of creating state requirements would eliminate the smaller and more rural hospitals from being able to participate as stroke designated centers because these hospitals would most likely not qualify for Joint Commission stroke certification and the hospitals might not be able to afford such a certification. For example, the Joint Commission Advanced Certification for Comprehensive Stroke Centers would be similar to the department designated level I stroke center. The Advanced Certification for Primary Stroke Centers would be similar to the department's designated level II stroke center. There are no Joint Commission stroke certifications which would be similar to the department designated level III and IV stroke centers. The requirements created in 19 CSR 30-40.730 set up four (4) levels of stroke centers which can provide appropriate care to stroke patients and set requirements based on the evidence and resources and size of the facility. These differing levels of stroke centers allow smaller hospitals to be able to receive stroke center designation. The department also seriously considered whether to conduct a joint review with the Joint Commission for comprehensive and primary stroke centers. Currently, the department conducts joint reviews with the American College of Surgeons in the department's trauma designation system for those hospitals that wish to be a state designated trauma center and also accredited by the American College of Surgeons. There was no consensus reached between the Joint Commission and the department after the department contacted the Joint Commission about conducting joint reviews. Taking into account all of the reasons, the department agrees to amend section (4) in that the department will only send out one (1) department staff liaison and may send out one (1) qualified contractor to conduct an initial review on a Joint Commission certified Comprehensive Stroke Center which applies to become a level I stroke center with the department. Similarly, the department will only send out one (1) department staff liaison and may also send one (1) qualified contractor to conduct an initial review on a Joint Commission certified Primary Stroke Center which applies to become a level II stroke center with the department. This change will save the Joint Commission stroke certified facilities money and time, since the department will not be sending out the maximum of four (4) qualified contractors plus the department's staff liaison as originally proposed. The department will not rely on Joint Commission stroke certifications status for validation reviews when the stroke centers apply for renewal of their stroke center designation because the department is not able to conduct a joint review with the Joint Commission stroke certified facilities to ensure that the department's requirements are met. The department has amended section (4) to reflect this change and the application for stroke centers.

COMMENT #11: Susan Law, with Midwest Health Systems comments that instituting a state designation program will create duplication of survey processes competing directly with the Joint Commission, the American Heart Association, and the American Stroke Association surveys in which many facilities already participate.

RESPONSE: The Missouri stroke designation program is voluntary. No hospital is required to go through the designation process. Sections 190.200 and 190.241, RSMo, mandated that the department promulgate rules to create stroke centers in Missouri and to create transport protocols in order to route stroke patients in Missouri to these stroke centers. The department created these rules as mandated by sections 190.200 and 190.241, RSMo. No changes have been made to this rule as a result of this comment.

COMMENT #12: Dr. David Gustafson, with the Kansas City Regional Emergency Medical Services (EMS) Committee; Ken Koch, with the Missouri Emergency Medical Services Association (MEMSA); Art Maxwell, with the Missouri Ambulance Association; and Ben Chlapek, with Mid-America Regional Council Emergency Rescue Committee (MARCER) comment that they support the proposed regulations which will establish the critical hospital based system.

RESPONSE: No changes have been made to this rule as a result of this comment.

COMMENT #13: Jace Smith, with the American Heart Association, Midwest Affiliate, comments that it was his understanding that the department would recognize the Joint Commission certification for stroke centers, but would grant the official state level designation. Mr. Smith comments the language also states that the hospitals would be responsible for paying the reviewer. It is not clear in the language if this will be a much easier process for hospitals already designated as a primary stroke center by the Joint Commission or other certifying bodies like Healthcare Facilities Accreditation Program (HFAP), etc.

RESPONSE AND EXPLANATION OF CHANGE: During these past several years the department met with many representatives from the healthcare community in Missouri to create this proposed rule and proposed rule 19 CSR 30-40.730 which sets forth the requirements for a stroke center. During these meetings, the healthcare representatives came to a consensus on the requirements for a stroke center. The requirements set forth in 19 CSR 30-40.730 are not identical to the Joint Commission's stroke certification process. For example, sections 190.200 and 190.241, RSMo, mandate the department to promulgate rules to create stroke centers in Missouri and to create a transport protocol in order to route stroke patients in Missouri to these stroke centers. This system of routing patients in Missouri to appropriate stroke centers is not part of the Joint Commission's stroke center certification process. As such, the proposed rules integrate the stroke centers into the larger system of care that includes components that precede and follow hospital based care for these patients. Thus, the consensus of healthcare representatives decided to create a proposed rule on the requirements of a stroke center instead of accepting the Joint Commission's stroke certification process for the state stroke designation program. The department also felt that to accept the Joint Commission stroke certification status instead of creating state requirements would eliminate the smaller and more rural hospitals from being able to participate as stroke designated centers because these hospitals would most likely not qualify for Joint Commission stroke certification and the hospitals might not be able to afford such a certification. For example, the Joint Commission Advanced Certification for Comprehensive Stroke Centers would be similar to the department designated level I stroke center. The Advanced Certification for Primary Stroke Centers would be similar to the department's designated level II stroke center. There are no Joint Commission stroke certifications which would be similar to the department designated level III and IV stroke centers. The requirements created in 19 CSR 30-40.730 set up four (4) levels of stroke centers which can provide appropriate care to stroke patients and set requirements based on the evidence and resources and size of the facility. These differing levels of stroke centers allow smaller hospitals to be able to receive stroke center designation. The department also seriously considered whether to conduct a joint review with the Joint Commission for comprehensive and primary stroke centers. Currently, the department conducts joint reviews with the American College of Surgeons in the department's trauma designation system for those hospitals that wish to be a state designated trauma center and also accredited by the American College of Surgeons. There was no consensus reached between the Joint Commission and the department after the department contacted the Joint Commission about conducting joint reviews. Taking into account all of the reasons, the department agrees to amend section (4) in that the department will only send out one (1) department staff liaison and may send out one (1) qualified contractor to conduct an initial review on a Joint Commission certified Comprehensive Stroke Center which applies to become a level I stroke center with the department. Similarly, the department will only send out one (1) department staff liaison and may also send one (1) qualified contractor to conduct an initial review on a Joint Commission certified Primary Stroke Center which applies to become a level II stroke center with the department. This change will save the Joint Commission stroke certified facilities money and time, since the department will not be sending out the maximum of four (4) qualified contractors plus the department's staff liaison as originally proposed. The department will not rely on Joint Commission stroke certifications status for validation reviews when the stroke centers apply for renewal of their stroke center designation because the department is not able to conduct a joint review with the Joint Commission stroke certified facilities to ensure that the department's requirements are met. The department has amended section (4) to reflect this change and the application for stroke centers.

COMMENT #14: Judy Aslin, with Southeast Health comments that, as drafted, the department is the designated body for stroke center designation and the proposed rule does not indicate it will recognize the Joint Commission Disease Specific Care Primary or Comprehensive Stroke Center status from applying hospital facilities. Ms. Aslin asks whether Joint Commission Primary or Comprehensive Stroke Certified Centers will be required to go through a separate department review in addition to the Joint Commission review. Ms. Aslin is concerned this proposed rule could potentially create an environment that would keep facilities from pursuing the Joint Commission or other national accreditations/certifications because it would not be accepted by the department. The Joint Commission launched its disease specific care certification program in 2002 and now has in excess of ten (10) years of experience evaluating stroke program management. Ms. Aslin also feels the department regulations are in excess of the standards expected of the Joint Commission for Primary Care Certified or Comprehensive Stroke Certified and this brings an unwarranted cost to the hospital facility designation, which is in conflict with value-based systems of care. Ms. Aslin recommends that the Joint Commission be the standard certification/designation used by the department. This will help accelerate implementation of the Time Critical Diagnosis stroke center level designation throughout the state by allowing the department to focus on hospitals new to the certification process. Ms. Aslin specifically requests the department recognize and accept the Joint Commission Comprehensive Stroke Center certification as a level I stroke center designation and the Joint Commission Primary Stroke Center certification as a level II stroke center designation.

RESPONSE AND EXPLANATION OF CHANGE: The department understands this concern. The department did not intend to accept Joint Commission stroke certification status from hospitals who apply to the department to become a stroke center. During these past several years the department met with many representatives from the healthcare community in Missouri to create this proposed rule and proposed rule 19 CSR 30-40.730 which sets forth the requirements for a stroke center. During these meetings, the healthcare representatives came to a consensus on the requirements for a stroke center. These requirements set forth in 19 CSR 30-40.730 are not identical to the Joint Commission's stroke certification process. For example, sections 190.200 and 190.241, RSMo, mandate the department to

promulgate rules to create stroke centers in Missouri and to create a transport protocol in order to route stroke patients in Missouri to these stroke centers. This system of routing patients in Missouri to appropriate stroke centers is not part of the Joint Commission's stroke center certification process. As such, the proposed rules integrate the stroke centers into the larger system of care that includes components that precede and follow hospital based care for these patients. Thus, the consensus of the healthcare representatives decided to create a proposed rule on the requirements of a stroke center instead of accepting Joint Commission's stroke certification process for the state stroke designation program. The department also felt that to accept the Joint Commission stroke certification status instead of creating state requirements would eliminate the smaller and more rural hospitals from being able to participate as stroke designated centers because these hospitals would most likely not qualify for Joint Commission stroke certification and the hospitals might not be able to afford such a certification. For example, the Joint Commission Advanced Certification for Comprehensive Stroke Centers would be similar to the department designated level I stroke center. The Advanced Certification for Primary Stroke Centers would be similar to the department's designated level II stroke center. There are no Joint Commission stroke certifications which would be similar to the department designated level III and IV stroke centers. The requirements created in 19 CSR 30-40.730 set up four (4) levels of stroke centers which can provide appropriate care to stroke patients and set requirements based on the evidence and resources and size of the facility. These differing levels of stroke centers allow smaller hospitals to be able to receive stroke center designation. The department also seriously considered whether to conduct a joint review with the Joint Commission for comprehensive and primary stroke centers. Currently, the department conducts joint reviews with the American College of Surgeons in the department's trauma designation system for those hospitals that wish to be a state designated trauma center and also accredited by the American College of Surgeons. There was no consensus reached between the Joint Commission and the department after the department contacted the Joint Commission about conducting joint reviews. Taking into account all of the reasons, the department agrees to amend 19 CSR 30-40.730 in that the department will only send out one (1) department staff liaison and may send out one (1) qualified contractor to conduct an initial review on a Joint Commission certified Comprehensive Stroke Center which applies to become a level I stroke center with the department. Similarly, the department will only send out one (1) department staff liaison and may also send one (1) qualified contractor to conduct an initial review on a Joint Commission certified Primary Stroke Center which applies to become a level II stroke center with the department. This change will save the Joint Commission stroke certified facilities money and time, since the department will not be sending out the maximum of four (4) qualified contractors plus the department's staff liaison as originally proposed. The department will not rely on Joint Commission stroke certifications status for validation reviews when the stroke centers apply for renewal of their stroke center designation because the department is not able to conduct a joint review with the Joint Commission stroke certified facilities to ensure that the department's requirements are met. The department has amended section (4) to reflect this change and the application for stroke centers.

COMMENT #15: Sharon Pulver, with SSM Neurosciences Institute comments that in subsection (2)(D) validation reviews shall occur no less than every four (4) years. Later, in the private and public fiscal notes, cost estimates are for a period of five (5) years and this includes salaries for a department staff liaison. Ms. Pulver questions whether these estimates are for the cost to the state for running the certification program. Ms. Pulver requests what are the actual fees expected from the facility for the application, review, and certification annually and over the four- (4-) year certification period and how is it paid—lump sum or annual amount.

RESPONSE: The department is required to not only give an estimated cost for the first years (period of time) but also an estimated cost for annually thereafter. This cost is just an estimate. It is similar to a budget in the future. The department used the trauma center program as a guide to estimate the costs. The department chose the five- (5-) year period as the period of time to estimate the costs for the first years because that will account for both the initial review and a validation review to renew the stroke center's designation and a potential focus review. The department thought this would give the public a better idea of costs than just using the four- (4-) year period where the costs would be for an initial review and possibly a focus review. In the public fiscal note there is a section that details the department's costs for the stroke center designation program. The rest of the costs set forth in the private and public fiscal notes are the costs to the hospital/stroke center. There is no cost to a facility to apply to become a stroke designated center with the department. For a level I or level II stroke center, as an example, the costs for the review and to receive stroke center designation would include five thousand, eight hundred dollars ($5,800) for honorariums plus one thousand, six hundred dollars ($1,600) for an estimate for airfare (this could instead be mileage costs instead of airfare which would be cheaper) plus lodging for an estimate of four hundred twenty dollars ($420) plus no more than two hundred fifty dollar ($250) for incidental expenses per review which would be an estimate of one thousand dollars ($1,000) at the most. This would equal eight thousand, eight hundred twenty dollars ($8,820) which again is only an estimate based on the figures in the fiscal notes. This eight thousand, eight hundred twenty dollars ($8,820) is an estimate for a level I stroke center for the initial review and validation reviews. It is to be paid prior to the review to the reviewers and/or directly to the vendor (e.g., hotel, airline). This money is not paid to the department. During the first four (4) year period, a level I or level II stroke center would have to pay this cost for the initial review. There is always a potential that there might be issues with the stroke center that would require a focus review prior to the four- (4-) year validation review. Depending on what issues are involved in a focus review, the cost of the focus review should cost no more than the cost of the initial review if you take into account changes in the price of airfare and lodging. There is no cost to the hospitals/stroke centers on an annual basis. The costs to the hospitals/stroke centers during the reviews by the department and its qualified contractors are only to pay for the qualified contractors for reviews. No changes have been made to this rule as a result of this comment.

COMMENT #16: Nancy Jackson, with SSM DePaul Health Center asks if the costs to hospitals outlined in section (6) and the private cost estimate for the initial five- (5-) year period means that the cost to a private hospital will be in the neighborhood of nine thousand dollars ($9,000) for a level I certification. Ms. Jackson comments that the private costs states that the proposed rule will cost state agencies or political subdivisions three hundred eighty seven thousand, seven hundred forty dollars ($387,740) for the initial five- (5-) year period. Ms. Jackson finds this confusing and cost prohibitive and requests clarification of the costs to the entity.

RESPONSE: The department is required to not only give an estimated cost for the first years (period of time) but also an estimated cost for annually thereafter. This cost is just an estimate. It is similar to a budget in the future. The department used the trauma center program as a guide to estimate the costs. The department chose the five- (5-) year period as the period of time to estimate the costs for the first years because that will account for both the initial review and a validation review to renew the stroke center's designation and a potential focus review. The department thought this would give the public a better idea of costs than just using a four- (4-) year period where the costs would be for an initial review and possibly a focused review. The costs look so high because the department had to multiply the costs by the five (5) years and by the number of estimated hospitals which will be stroke centers. The estimated cost to a level

I private hospital for an initial review would be five thousand, eight hundred dollars ($5,800) for honorariums plus one thousand, six hundred dollars ($1,600) for an estimate for airfare (this could instead be mileage costs instead of airfare which would be cheaper) plus lodging for an estimate of one thousand dollars ($1,000) at the most. This would equal eight thousand, eight hundred twenty dollars ($8,820) which again is only an estimate based on the figures in the fiscal notes for a level I stroke center initial review. This money is to be paid prior to the review to the reviewers and/or directly to the vendor (e.g., hotel, airline). This money is not paid to the department. No changes have been made to this rule as a result of this comment.

19 CSR 30-40.720 Stroke Center Designation Application and Review

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

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

SECTION A

In accordance with the requirements of the Chapter 190 RSMo and the applicable regulations, this application is hereby submitted for review and designation as a stroke center. Please complete all information applicable to the requested designation level.	Designation Level Requested ☐ I ☐ II ☐ III ☐ IV
Joint Commission Certification ☐ Primary Stroke Center ☐ Comprehensive Stroke Center	

HOSPITAL INFORMATION

Name Of Hospital (Name To Appear On Designation Certificate)	Telephone Number	
Address (Street And Number)	City	Zip Code

PROFESSIONAL INFORMATION

Chief Executive Officer	Chairman/President Of Board Of Trustees
Stroke Medical Director	Stroke Program Manager
Medical Director of Emergency Medicine	Medical Director of Intensive Care Unit

RESOURCE INFORMATION

Stroke Caseload	Stroke Team Activations	CT Scan Capability ☐ FULL ☐ PARTIAL ☐ NONE	MRI Capability ☐ FULL ☐ PARTIAL ☐ NONE
Neurosurgical Capability or Transfer Plan	ICU or NICU Beds	Stroke Unit Beds	Stroke Rehab ☐ INPATIENT ☐ OUTPATIENT
Neurologists	Neurosurgeons	Neuro-Interventionalists	Emergency Department (ED) Physicians
Anesthesiologists/ CRNAs & AAs	Angiography Suites	Avg number of patients who received neuro-intervention (not required for initial review)	Avg number of patients who received thrombolytics in the past 24 months (not required for initial review)

CERTIFICATION

We, the undersigned, hereby certify that the information provided in this application for stroke center review and designation is true and accurate; and give assurance of the intent and ability of the hospital to comply with regulations promulgated under the Chapter 190, RSMo.

We further certify that the hospital will comply with all recommendations for improvement contained in the stroke center site review reports prepared by the Missouri Department of Health and Senior Services.

Date of application_____

Signed_____
Chairman/President of Board of Trustees,
Owner, or one Partner of Partnership

Signed_____
Hospital Chief Executive Officer

Signed_____
Stroke Medical Director

Signed_____
Director of Emergency Medicine

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

SECTION B

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

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

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

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

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

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

[1] Include data for the last two (2) years of hospital data. Indicate time frame in months if it is other than January to December.
[2] Include all stroke patients, independent of hospital admission or hospital transfer status. To include walk-ins, transfers, EMS transports, admitted patients, and patients that die. Include all stroke patients that have ICD-9-principal diagnosis code of 433.01, 433.10, 433.11, 433.21, 433.31, 433.81, 433.91, 434.00, 434.01, 434.11, 434.91, 436.00, 430.00 and 431.00
[3] Provide number of all stroke patients transferred to this hospital from another hospital.
[4] Provide number of stroke patients eligible for neuro-intervention (NI).
[5] Provide number of stroke patients that received neuro-intervention (NI).
[6] Provide number of stroke patients that are eligible for thrombolytics.
[7] Provide number of stroke patients that received thrombolytics.
[8] Include all deaths, ED and inpatient, independent of hospital admission or hospital transfer status.

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

ORDER OF RULEMAKING

By the authority vested in the Missouri Department of Health and Senior Services under section 192.006, RSMo 2000, and sections 190.185 and 190.241, RSMo Supp. 2012, the department adopts a rule as follows:

19 CSR 30-40.730 Standards for Stroke Center Designation **is adopted**.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on December 17, 2012 (37 MoReg 1907–2072). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The Department of Health and Senior Services received twenty-six (26) comments.

COMMENT #1: Shane Lockard, with the Johnson County Ambulance District commented about his concern with the fiscal impact of the time critical diagnosis (TCD) regulations on the many hospitals that are interested in seeking formal designation as a stroke center. Mr. Lockard commented that the federal Medicare program is seeking to cut funding to healthcare, the Affordable Care Act has cut several billion dollars from the funding stream for hospitals, and the Missouri Medicaid program inadequately funds healthcare services. Mr. Lockard is concerned that some hospitals will be unable to seek designation due to the high cost to participate combined with other unrelated funding cuts creating fiscal challenges for hospitals. Finally, Mr. Lockard encourages the department to evaluate the fiscal impact of the proposed regulations on the hospitals which could seek designation in order to balance the various factors needed to assure an adequate number of facilities in the TCD system.
RESPONSE: The department understands this concern. The option as to whether or not a hospital chooses to apply to the department to become a designated stroke center is voluntary. In addition, the department has tiered the requirements of each level of stroke center based on the level of resources it is able to provide for the care of the stroke patient. For example, a level IV stroke center which is typically a smaller hospital in a rural area will not be required to have the healthcare staff and resources compared to a level I stroke center. Further, many representatives from hospitals throughout Missouri met with the department to create these regulations and during these meetings the costs to the hospitals were considered as well as what resources the hospitals already had for a stroke program (e.g., emergency department, helipad, etc.). No changes have been made to this rule as a result of this comment.

COMMENT #2: Dr. David Gustafson, with the Kansas City Regional Emergency Medical Services (EMS) Committee and Ben Chlapek, with the Mid-America Regional Council Emergency Rescue Committee (MARCER) commented that they are concerned with the fiscal impact of the TCD regulations on the many hospitals they believe are interested in seeking formal designation as a stroke center. Dr. Gustafson and Mr. Chlapek are aware that many hospitals have indicated concern regarding the fiscal note related to designation. Dr. Gustafson and Mr. Chlapek are concerned that some hospitals that were seriously considering seeking designation will decide to not seek designation due to the high cost to participate. Finally, Mr. Gustafson and Mr. Chlapek believe the department should evaluate the fiscal impact of the proposed regulations on the hospitals that could seek designation in order to balance the various factors needed to assure an adequate number of facilities in the TCD system.
RESPONSE: The department understands this concern. The option as to whether or not a hospital chooses to apply to the department to become a designated stroke center is voluntary. In addition, the department has tiered the requirements of each level of stroke center based on the level of resources it is able to provide for the care of the stroke patient. For example, a level IV stroke center which is typically a smaller hospital in a rural area will not be required to have the healthcare staff and resources compared to a level I stroke center. Further, many representatives from hospitals throughout Missouri met with the department to create these regulations and during these meetings the costs to the hospitals were considered as well as what resources the hospitals already had for a stroke program (e.g., emergency department, helipad, etc.). No changes have been made to this rule as a result of this comment.

COMMENT #3: Ken Koch, with the Missouri Emergency Medical Services Association (MEMSA) and Art Maxwell, with the Missouri Ambulance Association commented that they particularly appreciate the regulatory language requiring emergency medical services (EMS) personnel be included in the "core team" established at each hospital designated as a stroke center. This will help assure that EMS personnel are party to the continual program improvement which will occur through these conversations. Mr. Koch and Mr. Maxwell also support the effort to assure that there is some sort of feedback loop to provide outcome information regarding stroke patients back to EMS personnel to further professional development.
RESPONSE: No changes have been made to this rule as a result of this comment.

COMMENT #4: Thomas L. Holloway, with the Missouri State Medical Association comments that subsection (1)(E) "recommends" certain minimum interventions at a level I STEMI center. Mr. Holloway worries that a mere recommendation is somewhat loose for an emergency medical regulation, which might technically give a rogue facility free reign to completely ignore the recommended minimums. Mr. Holloway suggests that if these are considered minimum standards, then perhaps they should be required, even if there is an allowance for flexibility in unforeseen circumstances. Mr. Holloway notes that the term "recommends" shows up in other places in these proposed regulations, as well.
RESPONSE: The department understands this concern and is aware of the word "recommends" in the proposed rule. The department used the word "recommends" in order to be inclusive. The department is trying to build the stroke center designation program in order to have a sufficient number of hospitals in Missouri to become designated stroke centers where the transport routing system of patients could work most effectively. Although the department will not be able to enforce the volume requirements with the proposed rule, once the stroke center designation program has matured and there are sufficient numbers of designated stroke centers throughout Missouri then the department can have discussions with hospitals to determine if the "recommended" language should become mandatory. No changes have been made to this rule as a result of this comment.

COMMENT #5: Judy Aslin, with Southeast Health comments that in paragraph (1)(Q)1. the department cites to a document entitled "Time Critical Diagnosis Stroke Center Registry Data Elements" dated March 1, 2012, which is incorporated by reference as the data that the stroke designated center is required to enter into its stroke registry. Ms. Aslin recommends the regulation incorporate language that accepts the Quality Assurance committee as the body that sets the standards for the elements measured based on currently accepted evidence/clinical practice guidelines/best practice.
RESPONSE: The department understands this suggestion. However, the Quality Assurance committee was an ad hoc committee created to

develop the elements and measures related to the stroke center data registry. This committee is not created by statute, specifically Chapter 190, RSMo. This committee consisted of healthcare professionals and experts in the field who volunteered their time to develop these elements and measures. If this document entitled "Time Critical Diagnosis Stroke Center Registry Data Elements" were to be amended in the future then the department intends to seek input from the healthcare community and experts in the field as it has to date. However, the department cannot require this ad hoc committee to be the body to set such standards when this body is not created by statute, specifically Chapter 190, RSMo. No changes have been made to this rule as a result of this comment.

Due to the similarity in the following three (3) comments, one (1) response that addresses these comments is presented after the three (3) comments.

COMMENT #6: Judy Aslin, with Southeast Health comments that in paragraph (1)(Q)1. the department cites to a document entitled "Time Critical Diagnosis Stroke Center Registry Data Elements" dated March 1, 2012, which is incorporated by reference. Ms. Aslin comments that she is concerned with the posted date of March 1, 2012, of the document entitled "Time Critical Diagnosis Stroke Center Registry Data Elements" in this paragraph because if the data elements are revised or updated in response to evidence based practice/clinical practice guideline changes, then updating the data elements collected would have to go through the legal process to be changed. Ms. Aslin suggests not including the date of the document in this section and recommends removing the language "this rule does not incorporate any subsequent amendments or additions."

COMMENT #7: Susan Law, with Midwest Health Systems comments that when citing in the proposed regulation to the document entitled "Time Critical Diagnosis Stroke Center Registry Data Elements" dated March 1, 2012, and the exclusion of any subsequent amendments or additions the facilities will be limited in their ability to implement evidence based practice improvements/recommendations because of the stated document in the rules.

COMMENT #8: Jace Smith, with the American Heart Association, Midwest Affiliate; Rebekah Terrell; Natalie Mills; Todd Sampson; Sascha Haley; Cammie Johnson; Sharon Spero; John Paul Pe; Ronnie Gibbs; Pat Kueny; Rona Frey; Vickie Brown; Cynthia Rasdall; Ashlea Serri; Sheila Beck; Mary Jane Beck; Deborah Gieselman; Sandra Pelletier; Justin Blomquist; Kelly Minnis; Rita Phillips; Shelly Wright; April Dimas; Dianna Smith; Frank Scharsch; Annette Long; Jeffrey Hasty; Jill Snider; Jessica Powell; Jacob Roach; Hillis Doyel; Linda Duncan; Amber Boes; Kathy Fidler; Corrine Everson; Becky Madonia; Brian Marriott; Mary Murphy; Juli Christopher; Michael Dieker; Grace Sumption; Greg Simpson; Tina York; Kathryn Hedges; Carla Di Maggio; Brandi King; Connie Horne; Tracy Thellman; Janet Frye; Tina Johnson; Cie Cascone; Hannah Earhart; Rebecca Froese; Debra Smith; Sandra Shipman; Gina Gregg; Rachelle Mellor; Doris Owens; Patricia Doyel; Shawn Kegley; John Young; Deborah Popp; Kevin Johnson; Wayne Arndt; Elizabeth Martin; Greg Carson; Deanna Bailey; Cheryl Allen; Randal Moberg; Heath King; Jackie De Souza; Larry Todd; and Michele Kueny ask what the reasoning is behind including a document entitled "Time Critical Diagnosis Stroke Center Registry Data Elements" dated March 1, 2012. They are concerned that as science improves, and best practices/recommendations change, there will be difficulty implementing those changes because of the dated document in the rules. This document includes some data elements and some measures. The data elements used to collect measures may change, be revised, or updated as needed on an ongoing basis. They are concerned that the language related to this document limits these changes/revisions.

RESPONSE: This document entitled "Time Critical Diagnosis Stroke Center Registry Data Elements" dated March 1, 2012, is a listing of all of the data elements that the stroke centers are required to enter into the stroke data registry. This document was created and incorporated by reference into the proposed rule because it would be more efficient to amend this document in the future. Section 536.031, RSMo, requires the department to date such document and to state that the referenced document does not include any later amendments or additions. Whether or not the department listed the required data elements into the body of the proposed rule or into the document entitled "Time Critical Diagnosis Stroke Center Registry Data Elements" dated March 1, 2012, the department is required to go through the formal rulemaking process when it changes the data elements that a stroke center is required to enter into the stroke database. No changes have been made to this rule as a result of this comment.

COMMENT #9: Susan Law, with Midwest Health Systems; Jace Smith, with the American Heart Association, Midwest Affiliate; Rebekah Terrell; Natalie Mills; Todd Sampson; Sascha Haley; Cammie Johnson; Sharon Spero; John Paul Pe; Ronnie Gibbs; Pat Kueny; Rona Frey; Vickie Brown; Cynthia Rasdall; Ashlea Serri; Sheila Beck; Mary Jane Beck; Deborah Gieselman; Sandra Pelletier; Justin Blomquist; Kelly Minnis; Rita Phillips; Shelly Wright; April Dimas; Dianna Smith; Frank Scharsch; Annette Long; Jeffrey Hasty; Jill Snider; Jessica Powell; Jacob Roach; Hillis Doyel; Linda Duncan; Amber Boes; Kathy Fidler; Corrine Everson; Becky Madonia; Brian Marriott; Mary Murphy; Juli Christopher; Michael Dieker; Grace Sumption; Greg Simpson; Tina York; Kathryn Hedges; Carla Di Maggio; Brandi King; Connie Horne; Tracy Thellman; Janet Frye; Tina Johnson; Cie Cascone; Hannah Earhart; Rebecca Froese; Debra Smith; Sandra Shipman; Gina Gregg; Rachelle Mellor; Doris Owens; Patricia Doyel; Shawn Kegley; John Young; Deborah Popp; Kevin Johnson; Wayne Arndt; Elizabeth Martin; Greg Carson; Deanna Bailey; Cheryl Allen; Randal Moberg; Heath King; Jackie De Souza; Larry Todd; and Michele Kueny comment that in the document entitled "Time Critical Diagnosis Stroke Center Registry Data Elements" dated March 1, 2012, cited to in proposed rule 19 CSR 30-40.730, the word "elements" should be changed to "measures."

RESPONSE: All of the terms listed in the document entitled "Time Critical Diagnosis Stroke Center Registry Data Elements" dated March 1, 2012, are the actual elements (data fields) that the stroke centers will be entering directly into the stroke registry. The measures are then calculated from the data elements entered into the stroke registry. These measures will be beneficial to the stroke centers in their performance improvement process. No changes have been made to this rule as a result of this comment.

COMMENT #10: Jace Smith, with the American Heart Association, Midwest Affiliate; Rebekah Terrell; Natalie Mills; Todd Sampson; Sascha Haley; Cammie Johnson; Sharon Spero; John Paul Pe; Ronnie Gibbs; Pat Kueny; Rona Frey; Vickie Brown; Cynthia Rasdall; Ashlea Serri; Sheila Beck; Mary Jane Beck; Deborah Gieselman; Sandra Pelletier; Justin Blomquist; Kelly Minnis; Rita Phillips; Shelly Wright; April Dimas; Dianna Smith; Frank Scharsch; Annette Long; Jeffrey Hasty; Jill Snider; Jessica Powell; Jacob Roach; Hillis Doyel; Linda Duncan; Amber Boes; Kathy Fidler; Corrine Everson; Becky Madonia; Brian Marriott; Mary Murphy; Juli Christopher; Michael Dieker; Grace Sumption; Greg Simpson; Tina York; Kathryn Hedges; Carla Di Maggio; Brandi King; Connie Horne; Tracy Thellman; Janet Frye; Tina Johnson; Cie Cascone; Hannah Earhart; Rebecca Froese; Debra Smith; Sandra Shipman; Gina Gregg; Rachelle Mellor; Doris Owens; Patricia Doyel; Shawn Kegley; John Young; Deborah Popp; Kevin Johnson; Wayne Arndt; Elizabeth Martin; Greg Carson; Deanna Bailey; Cheryl Allen; Randal Moberg; Heath King; Jackie De Souza; Larry Todd; and Michele Kueny ask what the reasoning is behind the date listed in the recommendation that a level I stroke center meet the volume for stroke patient cases that is required for eligibility by the Joint Commission in its Advanced Certification of Comprehensive Stroke Centers as posted on January 31, 2012, which is incorporated by reference in the rule. They are concerned that if the Joint

Commission changes or improves upon their Advanced Certification process in the future, stroke centers will be held to the original requirements posted on January 31, 2012, in which the stroke centers would not be able to improve upon standards.
RESPONSE: This document/posting on January 31, 2012, by the Joint Commission on the volumes for stroke patient cases that is required for eligibility in the Joint Commission's Advanced Certification of Comprehensive Stroke Centers was not included in the text of the rule. Section 536.031, RSMo, allows the department to incorporate by reference standards and guidelines of a nationally recognized organization without publishing the material in full. However, the reference in the rules must include a date, publisher's name, address, and state that the referenced material does not include any later amendments or additions. Currently, the volumes in the rule are recommendations based on the current science and are not requirements to which the stroke centers are held. The department is required to go through the formal rulemaking process when it changes these recommended volumes in the rule. No changes have been made to this rule as a result of this comment.

COMMENT #11: Jace Smith, with the American Heart Association, Midwest Affiliate; Rebekah Terrell; Natalie Mills; Todd Sampson; Sascha Haley; Cammie Johnson; Sharon Spero; John Paul Pe; Ronnie Gibbs; Pat Kueny; Rona Frey; Vickie Brown; Cynthia Rasdall; Ashlea Serri; Sheila Beck; Mary Jane Beck; Deborah Gieselman; Sandra Pelletier; Justin Blomquist; Kelly Minnis; Rita Phillips; Shelly Wright; April Dimas; Dianna Smith; Frank Scharsch; Annette Long; Jeffrey Hasty; Jill Snider; Jessica Powell; Jacob Roach; Hillis Doyel; Linda Duncan; Amber Boes; Kathy Fidler; Corrine Everson; Becky Madonia; Brian Marriott; Mary Murphy; Juli Christopher; Michael Dieker; Grace Sumption; Greg Simpson; Tina York; Kathryn Hedges; Carla Di Maggio; Brandi King; Connie Horne; Tracy Thellman; Janet Frye; Tina Johnson; Cie Cascone; Hannah Earhart; Rebecca Froese; Debra Smith; Sandra Shipman; Gina Gregg; Rachelle Mellor; Doris Owens; Patricia Doyel; Shawn Kegley; John Young; Deborah Popp; Kevin Johnson; Wayne Arndt; Elizabeth Martin; Greg Carson; Deanna Bailey; Cheryl Allen; Randal Moberg; Heath King; Jackie De Souza; Larry Todd; and Michele Kueny comment that they would like for the Quality Assurance Committee to be listed into the rules as setting the standards for the measures listed in the document entitled "Time Critical Diagnosis Stroke Center Registry Data Elements" dated March 1, 2012.
RESPONSE: The department understands this suggestion. However, the Quality Assurance committee was an ad hoc committee created to develop the elements and measures related to the stroke center data registry. This committee is not created by statute, specifically Chapter 190, RSMo. This committee consisted of health care professionals and experts in the field who volunteered their time to develop these elements and measures. If this document entitled as "Time Critical Diagnosis Stroke Center Registry Data Elements" were to be amended in the future then the department intends to seek input from the health care community and experts in the field as it has to date. However, the department cannot require this ad hoc committee to be the body to set such standards when this body is not created by statute, specifically Chapter 190, RSMo. No changes have been made to this rule as a result of this comment.

COMMENT #12: Ben Chlapek, with the Mid-America Regional Council Emergency Rescue Committee (MARCER) commented that he particularly appreciates the regulatory language requiring emergency medical services (EMS) personnel be included in the "core team" established at each hospital designated as a stroke center. He also supports the effort to assure that there is some sort of feedback loop to provide outcome information regarding stoke patients back to EMS personnel to further professional development.
RESPONSE: No changes have been made to this rule as a result of this comment.

COMMENT #13: Daniel Landon, with the Missouri Hospital Association comments that subsection (1)(Q) states that stroke centers shall electronically enter data into the Missouri stoke registry as defined by the March 1, 2012 "Time Critical Diagnosis Stroke Center Registry Data Elements" document. Mr. Landon comments that while many hospitals providing stoke care collect this type of data on stroke patients, not all centers collect every one of the measures detailed in the document. Additionally, the department's website does not detail the mechanism for electronic reporting and the data requirements to appropriately match the fields required. This lack of interface information makes it impossible for hospitals to effectively evaluate the resources needed to electronically transmit this data to the department. Mr. Landon recommends that this section be removed. In the alternative Mr. Landon recommends that this section be revised to include a mechanism that allows the department to enforce this requirement after successfully demonstrating its ability to accept this data from multiple information systems without manual intervention. Mr. Landon is willing to serve on a committee to define the criteria used to successfully demonstrate ability by the state to receive this data electronically.
RESPONSE: The department understands this concern. The stroke registry created by the department will be free for the stroke centers to utilize. There are some hospitals that already have their own registry because they have been utilizing a database from a national sponsor (e.g., the American Heart Association). For those hospitals that are already utilizing a database from a national sponsor, the department's vendor has been developing an interface with the assistance from vendors of those databases that hospitals may be currently using (e.g., the American Heart Association) to facilitate the flow of data to the department's registry from the hospitals. The department has been working on this issue in order to avoid redundant data entry and to make the data entry process as efficient and cost effective as possible. No changes have been made to this rule as a result of this comment.

COMMENT #14: Susan Law, with Midwest Health Systems Missouri Hospitals comments that the requirement to provide data to another database on top of the multiple nationally recognized databases currently being submitted to meet existing certification/designation programs will require additional time, money, and resources and it is unclear how the state required data will be used to impact quality. A current example is that the state trauma program requires data entry but does not drive local trauma quality initiatives.
RESPONSE: The department understands this concern. The stroke registry created by the department will be free for the stroke centers to utilize. There are some hospitals that already have their own registry because they have been utilizing a database from a national sponsor (e.g., the American Heart Association). For those hospitals that are already utilizing a database from a national sponsor, the department's vendor has been developing an interface with the assistance from vendors of those databases that hospitals may be currently using (e.g., the American Heart Association) to facilitate the flow of data to the department's registry from the hospitals. The department has been working on this issue in order to avoid redundant data entry and to make the data entry process as efficient and cost effective as possible. In the future, the department's stroke registry will allow the stroke centers to provide systems level surveillance on the local and regional level for their performance improvement process and enable participation at the state level performance improvement process. The department anticipates this will assist the stroke centers in integrating into the larger local, regional, and state system of care and in targeting programming and prevention efforts in their facilities, referral patterns, and catchment areas. No changes have been made to this rule as a result of this comment.

COMMENT #15: Susan Law, with Midwest Health Systems Missouri Hospitals comments that the regulations specifically list the equipment that you must have available to care for the patients versus relying on

the medical leadership outcomes research to drive this request (for example, it lists extra cranial ultrasound and defines how quickly the tech must respond).
RESPONSE: The department does list specific equipment that must be available to care for the stoke patients in the proposed rule. Pursuant to section 190.200, RSMo, the department was required to use peer-reviewed and evidence-based research, guidelines, and assessment to promulgate the rules. Based on the department's review of this information in addition to the input from many people in the medical community over the past several years, the department created the requirements for the stroke centers which include, among other things, equipment. No changes have been made to this rule as a result of this comment.

COMMENT #16: Ken Koch, with the Missouri Emergency Medical Services Association (MEMSA); Dr. Gustafson, with the Kansas City Regional EMS Committee; Ben Chlapek, with the Mid-America Regional Council Emergency Rescue Committee (MARCER); and Art Maxwell, with the Missouri Ambulance Association commented that they support the proposed regulations which will establish the critical hospital based system.
RESPONSE: No changes have been made to this rule as a result of this comment.

COMMENT #17: Dr. David Gustafson, with the Kansas City Regional EMS Committee comments that he particularly appreciates the regulatory language which requires the EMS personnel to be included in the "core team" established at each hospital designated as a stroke center as well as the effort to assure that there is some sort of feedback loop to provide outcome information regarding stroke patients back to EMS personnel to further professional development.
RESPONSE: No changes have been made to this rule as a result of this comment.

COMMENT #18: Judy Aslin, with Southeast Health comments that she has concern regarding including the posted date of January 31, 2012, of the Advanced Certification Comprehensive Stroke Centers standards in proposed rule 19 CSR 30-40.730(1)(E) in that if the Joint Commission revises their standards, then this original date will be the standard to which Missouri level I stroke centers are evaluated and any revisions would have to go through the legal process to be changed. Ms. Aslin recommends that this statement be edited as not to be held to a dated document in a regulation by removing the posted date of January 31, 2012.
RESPONSE: This document/posting on January 31, 2012, by the Joint Commission on the volumes for stroke patient cases that is required for eligibility in the Joint Commission's Advanced Certification of Comprehensive Stroke Centers was not included in the text of the rule. Section 536.031, RSMo, allows the department to incorporate by reference standards and guidelines of a nationally recognized organization without publishing the material in full. However, the reference in the rules must include a date, publisher's name, and address, and state that the referenced document does not include any later amendments or additions. Currently, the volumes in the rule are recommendations based on the current science and are not requirements to which the stroke centers are held. The department is required to go through the formal rulemaking process when it changes these recommended volumes. No changes have been made to this rule as a result of this comment.

COMMENT #19: Sharon Pulver, with SSM Neurosciences Institute asked if a telephone response is acceptable to meet the requirement in paragraph (2)(B)1. for a Level I Stroke Center to have a neurologist available for consultation within fifteen (15) minutes of patient notification.
RESPONSE: A telephone response is acceptable to meet this requirement. No changes have been made to this rule as a result of this comment.

COMMENT #20: Sharon Pulver, with SSM Neurosciences Institute comments that paragraph (3)(C)1. does not define whether or not the designated medical director of the stroke unit can also be the stroke medical director. Ms. Pulver suggests that this could be cost prohibitive.
RESPONSE: The designated medical director of the stroke unit may also be the stroke medical director. No changes have been made to the rule as a result of this comment.

COMMENT #21: Sharon Pulver, with SSM Neurosciences Institute comments that the time window in subsection (5)(E) for providing feedback to emergency medical services providers is very short. Some patients will not have a disposition within this time frame.
RESPONSE: The department understands this concern. However, subsection (5)(E) only recommends that feedback on the patient to EMS provider be provided within seventy-two (72) hours. Also, the department points out that this disposition is only intended to be disposition of the patient at that time, not disposition of the patient from the hospital. The department understands that some patients will not have a disposition from the hospital within seventy-two (72) hours. No changes have been made to this rule as a result of this comment.

COMMENT #22: Nancy Jackson, with SSM DePaul Health Center expressed concerns regarding subparagraph (1)(C)3.D. Ms. Jackson states that her peer review process is part of a professional practice evaluation. It is confidential, protected information limited to the committee member, the Vice President of Medical Affairs, and the involved physician. This then becomes part of that physician's professional practice evaluation. Ms. Jackson comments that she is not able to include the stroke call roster members in this meeting. Ms. Jackson asks if the department perhaps means attendance in the performance improvement plans at the stroke team meeting. Finally, Ms. Jackson states that attendance by all stroke roster members is impossible, yet dissemination of the meeting findings could meet this measure.
RESPONSE: In subparagraph (1)(C)3.D., the department is requiring the core team and members of the stroke call roster to participate in ongoing stroke program peer review system meetings for the performance improvement process of the stroke center. These ongoing stroke program peer review system meetings are not intended to be the peer review meetings for the hospital. No changes have been made to this rule as a result of this comment.

COMMENT #23: Susan Law, with Midwest Health Systems comments that the volume requirement for levels places greater emphasis on volume vs. quality. Ms. Law explains that a facility can receive awards from nationally recognized stroke organizations such as the Joint Commission, the American Heart Association, and the American Stroke Association for quality and outcomes and still not be considered to be a level I designated center.
RESPONSE: The volumes listed in 19 CSR 30-40.730(1) are recommended and are not required. No changes have been made to this rule as a result of this comment.

COMMENT #24: Susan Law, with Midwest Health Systems comments that driving all volume of stroke patients to the highest level facilities will create a situation where it will become nearly impossible for a level II or level I stroke center to increase their volume to move to the next higher level. The unfair leveling of facilities based on volume may have an unintended negative consequence.
RESPONSE: The department understands this concern. The explanation provided by Ms. Law is the primary reason that the department decided to make the volumes listed in section (1) as recommended volumes instead of required volumes. No changes have been made to this rule as a result of this comment.

COMMENT #25: Susan Law, with Midwest Health Systems comments that when citing in the proposed regulation to the dated Joint

Commission rule in 19 CSR 30-40.730(1)(E) and the exclusion of any subsequent amendments or additions, the facilities will potentially be unable to maintain their state designation if they pursue the improvements/changes required to maintain Joint Commission accreditation status. Ms. Law states that given that evidence-based practice is improving standards of care in almost a continuous basis, this proposed rule seems to lock facilities into outdated practices and requirements. Ms. Law suggests that the Joint Commission Advanced Certification of Comprehensive Stroke Centers document be a living resource with allowance for centers to meet those changes on an ongoing basis within a defined time period post publication.
RESPONSE: This document/posting on January 31, 2012, by the Joint Commission on the volumes for stroke patient cases that is required for eligibility in the Joint Commission's Advanced Certification of Comprehensive Stroke Centers was not included in the text of the rule. Section 536.031, RSMo, allows the department to incorporate by reference standards and guidelines of a nationally recognized organization without publishing the material in full. However, the reference in the rules must include a date, publisher's name and address, and state that the referenced document does not include any later amendments or additions. The department is required to go through the formal rulemaking process when it changes these recommended volumes. Finally, with the volumes being only recommended then a stroke center that is also certified by the Joint Commission will not be penalized by the department for its volume numbers. This allows the stroke center that is also certified by the Joint Commission to continue meeting the Joint Commission's required volumes. No changes have been made to this rule as a result of this comment.

COMMENT #26: Jace Smith, with the American Heart Association, Midwest Affiliate, provided the department with one document that compared the department's proposed rule 19 CSR 30-40.730 with the Joint Commission Primary Stroke Center Advanced Certification requirements.
RESPONSE: No changes have been made to this rule as a result of this comment.

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

ORDER OF RULEMAKING

By the authority vested in the Missouri Department of Health and Senior Services under section 192.006, RSMo 2000, and sections 190.185 and 190.241, RSMo Supp. 2012, the department adopts a rule as follows:

19 CSR 30-40.740 is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on December 17, 2012 (37 MoReg 2073–2075). Changes have been made in the text of the proposed rule, so it is reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The Department of Health and Senior Services received three (3) comments.

COMMENT #1: Robert C. Scanlon, II, D.O., with the Missouri Association of Osteopathic Physicians & Surgeons commented that the definition of "board-certified" under subsection (1)(D) that currently reads "the Bureau of Osteopathic Specialties" should actually read "American Osteopathic Association Board of Osteopathic Specialists."
RESPONSE AND EXPLANATION OF CHANGE: The department agrees and has amended subsections (1)(C) and (1)(D).

COMMENT #2: Thomas L. Holloway, with the Missouri State Medical Association suggests that additional language be added to subsection (1)(J), which defines a certified registered nurse anesthetist (CRNA), in order to specify that a CRNA must be licensed pursuant to Chapter 335, RSMo.
RESPONSE AND EXPLANATION OF CHANGE: The department agrees and has amended the proposed rule.

COMMENT #3: Thomas L. Holloway, with the Missouri State Medical Association comments that proposed rule 19 CSR 30-40.750(4) refers to cardiologist(s) and interventional cardiologist(s) but there is no definition for these terms. Mr. Holloway recommends that the rule specify that a cardiologist and interventional cardiologist are licensed physicians with the appropriate specialty training.
RESPONSE AND EXPLANATION OF CHANGE: The department agrees and has added new subsections (1)(H) defining "cardiologist" and (1)(FF) defining "interventional cardiologist" and renumbered the remaining subsections in section (1).

19 CSR 30-40.740 Definitions and Abbreviations Relating to ST-Segment Elevation Myocardial Infarction (STEMI) Centers

(1) For the purposes of 19 CSR 30-40.750 and 19 CSR 30-40.760 the following terms shall mean:

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

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

(H) Cardiologist—a licensed physician with appropriate specialty training;

(I) Cardiology Service—an organizational component of the hospital specializing in the care of patients who have had STEMIs or some other cardiovascular condition or disorder;

(J) Catchment area—the surrounding area served by the institution (the STEMI center);

(K) Certified registered nurse anesthetist (CRNA)—a registered nurse who—

1. Has graduated from a school of nurse anesthesia accredited by the Council on Accreditation of Educational Programs of Nurse Anesthesia or its predecessor;

2. Has been certified as a nurse anesthetist by the Council on Certification of Nurse Anesthetists; and

3. Has been licensed in Missouri pursuant to Chapter 335, RSMo;

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

(M) Clinical team—a team of health care professionals involved in the care of the STEMI patient and may include, but not be limited to, cardiologists, interventional cardiologists, cardiovascular surgeons, anesthesiologists, emergency medicine, and other STEMI center clinical staff. The clinical team is part of the hospital's STEMI team;

(N) Contiguous leads—the electrical cables that attach the electrodes on the patient to the electrocardiograph recorder and which are

next to one another. They view the same general area of the heart;

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

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

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

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

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

(T) Door-to-balloon-time—the time from arrival at the hospital door to percutaneous coronary intervention balloon inflation for the purpose of restoring blood flow in an obstructed coronary artery in the cardiac catheterization lab. This term is commonly abbreviated as D2B;

(U) Door-to-device-time—the time from patient arrival at the hospital to the time the device is in the affected cardiac blood vessel;

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

(W) Electrocardiogram (ECG/EKG)—a recorded tracing of the electrical activity of the heart. The heart rate, heartbeat regularity, size and chamber position, presence of any prior heart attack, current injury, and the effects of drugs or devices (i.e., pacemaker can be determined). An abnormal ECG pattern is seen during a heart attack because damaged areas of the heart muscle do not conduct electricity properly;

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

(Y) First medical contact—a patient's initial contact with a health-care provider either pre-hospital, which could be contact with emergency medical service personnel or another medical provider, or in the hospital;

(Z) First medical contact to balloon or device time—the time from a patient's first medical contact with a health-care provider to the time when the balloon is inflated or the device is in the affected cardiac blood vessel;

(AA) First medical contact to hospital door time—the time from a patient's first medical contact with a health-care provider to the time when the patient arrives at the hospital door;

(BB) Hospital—an establishment as defined by section 197.020.2, RSMo, or a hospital operated by the state;

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

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

(EE) Intermediate care unit—the functional division or facility of the hospital that provides care for STEMI patients admitted to the STEMI center;

(FF) Interventional cardiologist—a licensed cardiologist with the appropriate specialty training;

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

(HH) Mentoring relationship—a relationship in which a high volume percutaneous coronary interventions operator, often described as performing one hundred fifty (150) or more procedures per year, serves as a mentor for an operator who performs less than eleven (11) primary percutaneous coronary interventions per year;

(II) Missouri STEMI registry—a statewide data collection system comprised of key data elements as identified by the Department of Health and Senior Services used to compile and trend statistics of STEMI patients both pre-hospital and hospital, using a coordinated electronic reporting method provided by the Missouri Department of Health and Senior Services;

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

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

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

(MM) Percutaneous coronary intervention (PCI)—is a procedure used to open or widen narrowed or blocked blood vessels to restore blood flow supplying the heart. A primary percutaneous coronary intervention is one that is generally done on an emergency basis for a ST-elevation myocardial infarction (STEMI). Treatment occurs while the blood clot is still forming—usually within twenty-four (24) hours of onset, but ideally within two (2) hours of symptoms onset. An elective percutaneous coronary intervention is one that is done on a non-urgent basis to reduce signs and symptoms of angina;

(NN) Percutaneous coronary intervention window—the time frame in which percutaneous coronary intervention is most advantageous and recommended;

(OO) Phase I cardiac rehabilitation—an inpatient program that provides an individualized exercise and education plan for patients with cardiac illnesses;

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

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

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

(SS) Qualified individual—a physician, registered nurse, advanced practice registered nurse, and/or physician assistant that demonstrates administrative ability and shows evidence of educational preparation and clinical experience in the care of STEMI patients and is licensed by the state of Missouri;

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

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

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

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

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

(YY) ST-elevation myocardial infarction (STEMI)—a myocardial infarction for which the electrocardiogram shows ST-segment elevation, usually in association with an acutely blocked coronary artery.

A STEMI is one type of heart attack that is a potentially lethal condition for which specific therapies, administered rapidly, reduce mortality and disability. The more time that passes before blood flow is restored, the more damage that is done to the heart muscle;

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

(AAA) STEMI care—education, prevention, emergency transport, triage, acute care, and rehabilitative services for STEMI that requires immediate medical or surgical intervention or treatment;

(BBB) STEMI center—a hospital that is currently designated as such by the department to care for patients with ST-segment elevation myocardial infarctions.

1. A level I STEMI center is a receiving center staffed and equipped to provide total care for every aspect of STEMI care, including care for those patients with complications. It functions as a resource center for the hospitals within that region and conducts research.

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

3. A level III STEMI center is primarily a referral center that provides prompt assessment, indicated resuscitation, and appropriate emergency intervention for STEMI patients to stabilize and arrange timely transfer to a Level I or II STEMI center, as needed.

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

(CCC) STEMI identification—a diagnosis is made on a basis of symptoms, clinical examination, and electrocardiogram changes, specifically ST-segment elevation;

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

(EEE) STEMI program—an organizational component of the hospital specializing in the care of STEMI patients;

(FFF) STEMI program manager—a qualified individual designated by the hospital with responsibility for monitoring and evaluating the care of STEMI patients and the coordination of performance improvement and patient safety programs for the STEMI center in conjunction with the physician in charge of STEMI care;

(GGG) STEMI team—a component of the hospital STEMI program which consists of the core team and the clinical team;

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

(III) 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

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

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

ORDER OF RULEMAKING

By the authority vested in the Missouri Department of Health and Senior Services under section 192.006, RSMo 2000, and sections 190.185 and 190.241, RSMo Supp. 2012, the department adopts a rule as follows:

19 CSR 30-40.750 ST-Segment Elevation Myocardial Infarction (STEMI) Center Designation Application and Review **is adopted**.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on December 17, 2012 (37 MoReg 2075–2090). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The Department of Health and Senior Services received twelve (12) comments.

COMMENT #1: Shane Lockard, with the Johnson County Ambulance District commented about his concern with the fiscal impact of the time critical diagnosis (TCD) regulations on the many hospitals that are interested in seeking formal designation as a STEMI center. Mr. Lockard commented that the federal Medicare program is seeking to cut funding to healthcare, the Affordable Care Act has cut several billion dollars from the funding stream for hospitals, and the Missouri Medicaid program inadequately funds health care services. Mr. Lockard is concerned that some hospitals will be unable to seek designation due to the high cost to participate combined with other unrelated funding cuts creating fiscal challenges for hospitals. Finally, Mr. Lockard encourages the department to evaluate the fiscal impact of the proposed regulations on the hospitals which could seek designation in order to balance the various factors needed to assure an adequate number of facilities in the TCD system.

RESPONSE: The department understands this concern. The option as to whether or not a hospital chooses to apply to the department to become a designated STEMI center is voluntary. In addition, the department has tiered the requirements of each level of STEMI center based on the level of resources it is able to provide for the care of the STEMI patient. For example, a level IV STEMI center which is typically a smaller hospital in a rural area will not be required to have the healthcare staff and resources compared to a level I STEMI center. Finally, many representatives from hospitals throughout Missouri met with the department to create these regulations and during these meetings the costs to the hospitals were considered as well as what resources the hospitals already had for a STEMI program (e.g., emergency department, helipad, etc.). No changes have been made to this rule as a result of this comment.

COMMENT #2: Dr. David Gustafson, with the Kansas City Regional Emergency Medical Services (EMS) Committee and Ben Chlapek, with the Mid-America Regional Council Emergency Rescue Committee (MARCER) commented that they are concerned with the fiscal impact of the TCD regulations on the many hospitals they believe are interested in seeking formal designation as a STEMI center. Dr. Gustafson and Mr. Chlapek are aware that many hospitals have indicated concern regarding the fiscal note related to designation. Dr. Gustafson and Mr. Chlapek are concerned that some hospitals that were seriously considering seeking designation will decide to not seek designation due to the high cost to participate. Finally, Dr. Gustafson and Mr. Chlapek believe the department should evaluate the fiscal impact of the proposed regulations on the hospitals that could seek designation in order to balance the various factors needed to assure an adequate number of facilities in the system.

RESPONSE: The department understands this concern. The option as to whether or not a hospital chooses to apply to the department to become a designated STEMI center is voluntary. In addition, the department has tiered the requirements of each level of STEMI center based on the level of resources it is able to provide for the care of

the STEMI patient. For example, a level IV STEMI center which is typically a smaller hospital in a rural area will not be required to have the healthcare staff and resources compared to a level I STEMI center. Finally, many representatives from hospitals throughout Missouri met with the department to create these regulations and during these meetings the costs to the hospitals were considered as well as what resources the hospitals already had for a STEMI program (e.g., emergency department, helipad, etc.). No changes have been made to this rule as a result of this comment.

COMMENT #3: Thomas L. Holloway, with the Missouri State Medical Association commented that section (4) refers to "cardiologist(s)" and "interventional cardiologist(s)" but those terms appear to not be defined in the proposed rules. Mr. Holloway suggests that the department define these terms as a licensed physician with the appropriate specialty training.

RESPONSE: The department agrees and has added these definitions to 19 CSR 30-40.740 Definitions and Abbreviations Relating to ST-Segment Elevation Myocardial Infarction (STEMI) Centers. No changes have been made to this rule as a result of this comment.

COMMENT #4: Daniel Landon, with the Missouri Hospital Association (MHA) commented that section (3) states that the STEMI designation shall be valid for a period of three (3) years from the date the STEMI center/hospital is designated. This proposed designation period is inconsistent with the current trauma center designation period of five (5) years as detailed in 19 CSR 30-40.420(4)(A). The proposed three- (3-) year period is also inconsistent with the four- (4-) year time period as proposed in 19 CSR 30-40.720(3). The department does not specify the rationale for the differing length of designation. The disparate timing of revalidation activities may create undue burden on both the hospital and the department as they try to manage the appropriate cycles for revalidation of hospitals that participate in more than one center across all designated centers and correspond with the existing standard of five (5) years as detailed in the trauma center regulations.

RESPONSE: The department understands this concern. The department and representatives of the healthcare community felt that a five- (5-) year designation period was too long of a period. The department with a consensus from the healthcare community decided to designate STEMI centers for a period of three (3) years to correlate with the American College of Surgeons three- (3-) year accreditation cycle, a vetted national standard for trauma centers which by design STEMI centers closely resemble. This three- (3-) year designation period has also been raised in trauma system discussions with trauma care professionals in Missouri for consensus driven changes to the department's trauma designation program in order for the designation time to more closely align with the American College of Surgeons three- (3-) year accreditation cycle. The department decided to designate stroke centers for a period of four (4) years in order to correlate with the Joint Commission's stroke certification process which is every two (2) years. The department felt that two (2) years was too short of a designation time period, but the four- (4-) year time frame allows the department to accommodate a hospital's request to conduct a stroke center designation review during a similar time frame that the Joint Commission will visit a hospital that is also a Joint Commission stroke certified center. No changes have been made to this rule as a result of this comment.

COMMENT #5: Judy Aslin, with Southeast Health comments that the assumptive statements in both the private and public fiscal notes should be clarified because it is unclear if the assumptions of how many hospitals will apply to become a designated STEMI center are stating the maximum capacity the department can review each year. Ms. Aslin suggests these assumptive statements be clarified to clearly state the number of annual reviews for which the department has capacity.

RESPONSE: The assumptive statements in the fiscal note are estimates of how many hospitals might apply to become a designated STEMI center during the time frames discussed in the fiscal notes. This estimate is not based on the maximum capacity the department can review to become designated STEMI centers during the time frames discussed in the fiscal notes. No changes have been made to this rule as a result of this comment.

COMMENT #6: Judy Aslin, with Southeast Health recommends that the assumptive statements in the private and public fiscal notes clearly state the process planned for releasing level designations to the public.

RESPONSE: A process planned for releasing level designations to the public would not go into fiscal notes. No changes have been made to this rule as a result of this comment.

COMMENT #7: Judy Aslin, with Southeast Health comments that it is unclear in the assumptive statements for the fiscal note if a STEMI center would be recognized as a designated STEMI center by the state after the end of the on-site review, at the end of each year or at the end of the first five- (5-) year period. Ms. Aslin requests clarification of this process.

RESPONSE: As outlined in the proposed rule, after a hospital applies to become a STEMI center then a review by a department staff member and qualified contractors will occur. Following the review, the qualified contractors will submit a report of their findings to the department. The department will then give a copy of this report to the hospital. This report indicates whether a hospital has met the criteria to be designated as a STEMI center, or in the case of renewal of STEMI center designation, whether the hospital will be redesignated as a STEMI center. If a hospital has met the requirements to be designated by the department as a STEMI center, then it will be designated as a STEMI center for a period of three (3) years from the date that it was designated or redesignated following the issuance of the report confirming that the hospital has met the criteria to be designated as a STEMI center. No changes have been made to this rule as a result of this comment.

COMMENT #8: Jace Smith, with the American Heart Association, Midwest Affiliate; Rebekah Terrell; Natalie Mills; Todd Sampson; Sascha Haley; Cammie Johnson; Sharon Spero; John Paul Pe; Ronnie Gibbs; Pat Kueny; Rona Frey; Vickie Brown; Cynthia Rasdall; Ashlea Serri; Sheila Beck; Mary Jane Beck; Deborah Gieselman; Sandra Pelletier; Justin Blomquist; Kelly Minnis; Rita Phillips; Shelly Wright; April Dimas; Dianna Smith; Frank Scharsch; Annette Long; Jeffrey Hasty; Jill Snider; Jessica Powell; Jacob Roach; Hillis Doyel; Linda Duncan; Amber Boes; Kathy Fidler; Corrine Everson; Becky Madonia; Brian Marriott; Mary Murphy; Juli Christopher; Michael Dieker; Grace Sumption; Greg Simpson; Tina York; Kathryn Hedges; Carla Di Maggio; Brandi King; Connie Horne; Tracy Thellman; Janet Frye; Tina Johnson; Cie Cascone; Hannah Earhart; Rebecca Froese; Debra Smith; Sandra Shipman; Gina Gregg; Rachelle Mellor; Doris Owens; Patricia Doyel; Shawn Kegley; John Young; Deborah Popp; Kevin Johnson; Wayne Arndt; Elizabeth Martin; Greg Carson; Deanna Bailey; Cheryl Allen; Randal Moberg; Heath King; Jackie De Souza; Larry Todd; and Michele Kueny, question whether, as drafted in the proposed rules, the department is going to be the accrediting body and will not be relying or accepting Society of Cardiovascular Patient Care (SCPC) STEMI status for participating hospital facilities. If that is so, then this will mean that if a hospital wants to be certified as a STEMI receiving facility, then it will need to go through a separate department accreditation process in addition to the SCPC process. As drafted it appears the rules could potentially create an environment that would keep facilities from ever pursuing SCPC or other national accreditation because it would not "count" toward state accreditation. They also feel that is an unwarranted cost to the state, since the standards for STEMI care in Missouri have already been

set. Finally, they recommend that the SCPC be the standard accreditation the department uses.

RESPONSE: The department understands this concern. The department will not be relying on or accepting Chest Pain Accreditation with the Society of Cardiovascular Patient Care. During these past several years the department met with many representatives from the healthcare community in Missouri to create this proposed rule and proposed rule 19 CSR 30-40.760 which sets forth the requirements for a STEMI center. During these meetings, the healthcare representatives came to a consensus on the requirements for a STEMI center. The requirements set forth in 19 CSR 30-40.760 are vastly different compared to the Society of Cardiovascular Patient Care's Chest Pain Accreditation program. For example, the Society of Cardiovascular Patient Care's Chest Pain Accreditation program is a process improvement experience and differs from the department's designation process which sets specifications and then measures compliance, such as what is required in proposed rule 19 CSR 30-40.760. Additionally, the Society of Cardiovascular Patient Care's Chest Pain Accreditation program has three (3) phases that a Chest Pain Accredited center must go through which do not correlate with any of the four (4) levels of STEMI centers set forth and detailed in proposed rule 19 CSR 30-40.760. It also focuses on acute coronary syndrome while the department's authority to create a designated center is specific to STEMI and not acute coronary syndrome. Finally, sections 190.200 and 190.241, RSMo, mandate the department to promulgate rules to create STEMI centers in Missouri and to create a transport protocol in order to route STEMI patients in Missouri to these STEMI centers. This system of routing patients in Missouri to appropriate STEMI centers is not part of the Society of Cardiovascular Patient Care's Chest Pain Accreditation program. As such, the proposed rules integrate the STEMI centers into the larger system of care that includes components that precede and follow hospital based care for these patients. Thus, the consensus of healthcare representatives decided to create a proposed rule on the requirements of a STEMI center instead of accepting or relying on the Society of Cardiovascular Patient Care's Chest Pain Accreditation program for the state STEMI designation program. The department also felt that to accept the Society of Cardiovascular Patient Care's Chest Pain Accreditation program instead of creating state requirements would eliminate the smaller and more rural hospitals from being able to participate as STEMI designated centers because these hospitals would most likely not qualify for Society of Cardiovascular Patient Care's Chest Pain Accreditation and the hospitals might not be able to afford such accreditation. The requirements created in 19 CSR 30-40.760 set up four (4) levels of STEMI centers which can provide appropriate care to STEMI patients and set requirements based on the evidence and resources and size of the facility. These differing levels of STEMI centers allow smaller hospitals to be able to receive STEMI center designation. Further, the department seriously considered whether to conduct a joint review with the Society of Cardiovascular Patient Care's Chest Pain Accreditation program. Currently, the department conducts joint reviews with the American College of Surgeons in the department's trauma designation system for those hospitals that wish to be a state designated trauma center and also accredited by the American College of Surgeons. After the department reviewed the Society of Cardiovascular Patient Care's Chest Paint Accreditation program with proposed rule 19 CSR 30-40.760 there were too many differences in requirements in addition to fundamental theory differences to be able to accommodate such a joint review with the Society of Cardiovascular Patient Care. The department felt that it would be more efficient and less burdensome on the hospitals to simply conduct separate reviews because of the many differences. No changes have been made to this rule as a result of this comment.

COMMENT #9: Judy Aslin, with Southeast Health recommends both STEMI center and stroke center designations be valid for a period of four (4) years from the date the center/hospital is designated. Ms. Aslin points out that STEMI centers are designated by the department for three (3) years and stroke centers are designated by the department for four (4) years. These designation periods are asynchronous. The proposed rule does not state the rationale for the different designation periods. Ms. Aslin believes facilities with dedicated internal resources for this work could create efficiencies if both center reviews had the same designation period.

RESPONSE: The department understands this concern. The department and representatives of the healthcare community felt that a five- (5-) year designation period was too long of a period. The department with a consensus from the healthcare community decided to designate STEMI centers for a period of three (3) years to correlate with the American College of Surgeons three- (3-) year accreditation cycle, a vetted national standard for trauma centers which by design STEMI centers closely resemble. This three- (3-) year designation period has also been raised in trauma system discussions with trauma care professionals in Missouri for consensus driven changes to the department's trauma designation program in order for the designation time to more closely align with the American College of Surgeons three- (3-) year accreditation cycle. The department decided to designate stroke centers for a period of four (4) years in order to correlate with the Joint Commission's stroke certification process which is every two (2) years. The department felt that two (2) years was too short of a designation time period, but the four- (4-) year time frame allows the department to accommodate a hospital's request to conduct a stroke center designation review during a similar time frame that the Joint Commission will visit a hospital that is also a Joint Commission stroke certified center. No changes have been made to this rule as a result of this comment.

COMMENT #10: Susan Law, with Midwest Health Systems comments that many Missouri healthcare facilities have pursued and maintained the Joint Commission Society of Chest Pain Center (SCPC) STEMI certification. Much work has been done on achieving Joint Commission certification and the on-going requirements are rigorous. Ms. Law states that the current proposed rules state the department is going to be the accrediting body for STEMI certification and that the state will not be accepting Joint Commission STEMI certification status as the basis for Missouri state designation. Ms. Law comments that this will mean that if a hospital wants to be certified as a STEMI receiving facility, then it will need to go through a separate department accreditation process in addition to the Joint Commission process. Ms. Law believes that this could potentially create an environment that could place facilities in the position of choosing state designation instead of Joint Commission or other national accreditation because the state will not recognize the vast amount of work that is required to achieve and maintain Joint Commission certification. The Joint Commission STEMI certification program is nationally recognized as the gold standard. Ms. Law recommends that the Joint Commission SCPC STEMI certification program be the accreditation standard used by the department.

RESPONSE: The department understands this concern. The department will not be relying on or accepting Chest Pain Accreditation with the Society of Cardiovascular Patient Care. This chest pain accreditation is not conducted by the Joint Commission. Instead, it is conducted by the Society of Cardiovascular Patient Care. During these past several years the department met with many representatives from the healthcare community in Missouri to create this proposed rule and proposed rule 19 CSR 30-40.760 which sets forth the requirements for a STEMI center. During these meetings, the healthcare representatives came to a consensus on the requirements for a STEMI center. The requirements set forth in 19 CSR 30-40.760 are vastly different compared to the Society of Cardiovascular Patient Care's Chest Pain Accreditation program. For example, the Society of Cardiovascular Patient Care's Chest Pain Accreditation program is a process improvement experience and differs from the department's designation process which sets specifications and then measures compliance such as what is required in proposed rule 19 CSR 30-40.760. Additionally, the Society of Cardiovascular Patient Care's

Chest Pain Accreditation program has three (3) phases that a Chest Pain Accredited center must go through which do not correlate with any of the four (4) levels of STEMI centers set forth and detailed in proposed rule 19 CSR 30-40.760. It also focuses on acute coronary syndrome while the department's authority to create a designated center is specific to STEMI and not acute coronary syndrome. Finally, sections 190.200 and 190.241, RSMo, mandated the department to promulgate rules to create STEMI centers in Missouri and to create a transport protocol in order to route STEMI patients in Missouri to these STEMI centers. This system of routing patients in Missouri to appropriate STEMI centers is not part of the Society of Cardiovascular Patient Care's Chest Pain Accreditation program. As such, the proposed rules integrate the STEMI centers into the larger system of care that includes components that precede and follow hospital based care for these patients. Thus, the consensus of healthcare representatives decided to create a proposed rule on the requirements of a STEMI center instead of accepting or relying on the Society of Cardiovascular Patient Care's Chest Pain Accreditation program for the state STEMI designation program. The department also felt that to accept the Society of Cardiovascular Patient Care's Chest Pain Accreditation program instead of creating state requirements would eliminate the smaller and more rural hospitals from being able to participate as STEMI designated centers because these hospitals would most likely not qualify for Society of Cardiovascular Patient Care's Chest Pain Accreditation and the hospitals might not be able to afford such accreditation. The requirements created in 19 CSR 30-40.760 set up four (4) levels of STEMI centers which can provide appropriate care to STEMI patients and set requirements based on the evidence and resources and size of the facility. These differing levels of STEMI centers allow smaller hospitals to be able to receive STEMI center designation. Further, the department seriously considered whether to conduct a joint review with the Society of Cardiovascular Patient Care's Chest Pain Accreditation program. Currently, the department conducts joint reviews with the American College of Surgeons in the department's trauma designation system for those hospitals that wish to be a state designated trauma center and also accredited by the American College of Surgeons. After the department reviewed the Society of Cardiovascular Patient Care's Chest Pain Accreditation program with proposed rule 19 CSR 30-40.760 there were too many differences in requirements in addition to fundamental theory differences to be able to accommodate such a joint review with the Society of Cardiovascular Patient Care. The department felt that it would be more efficient and less burdensome on the hospitals to simply conduct separate reviews because of the many differences. No changes have been made to this rule as a result of this comment.

COMMENT #11: Susan Law, with Midwest Health Systems comments that instituting a state designation program will create duplication of survey processes competing directly with the Joint Commission, the American Heart Association, and the American Stroke Association surveys in which many facilities already participate.

RESPONSE: The Missouri STEMI designation program is voluntary. No hospital is required to go through the designation process. Sections 190.200 and 190.241, RSMo, mandated that the department promulgate rules to create STEMI centers in Missouri and to create transport protocols in order to route STEMI patients in Missouri to these STEMI centers. The department created these rules as mandated by sections 190.200 and 190.241, RSMo. No changes have been made to this rule as a result of this comment.

COMMENT #12: Dr. David Gustafson, with the Kansas City Regional Emergency Medical Services (EMS) Committee; Ken Koch, with the Missouri Emergency Medical Services Association (MEMSA); Art Maxwell, with the Missouri Ambulance Association; and Ben Chlapek, with Mid-America Regional Council Emergency Rescue Committee (MARCER) comment that they support the proposed regulations which will establish the critical hospital based system.

RESPONSE: No changes have been made to this rule as a result of this comment.

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

ORDER OF RULEMAKING

By the authority vested in the Missouri Department of Health and Senior Services under sections 190.185 and 190.241, RSMo Supp. 2012, the department adopts a rule as follows:

19 CSR 30-40.760 Standards for ST-Segment Elevation Myocardial Infarction (STEMI) Center Designation **is adopted**.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on December 17, 2012 (37 MoReg 2097–2283). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The Department of Health and Senior Services received eighteen (18) comments.

COMMENT #1: Shane Lockard, with the Johnson County Ambulance District commented about his concern with the fiscal impact of the time critical diagnosis (TCD) regulations on the many hospitals that are interested in seeking formal designation as a STEMI center. Mr. Lockard commented that the federal Medicare program is seeking to cut funding to healthcare, the Affordable Care Act has cut several billion dollars from the funding stream for hospitals, and the Missouri Medicaid program inadequately funds healthcare services. Mr. Lockard is concerned that some hospitals will be unable to seek designation due to the high cost to participate combined with other unrelated funding cuts creating fiscal challenges for hospitals. Finally, Mr. Lockard encourages the department to evaluate the fiscal impact of the proposed regulations on the hospitals which could seek designation in order to balance the various factors needed to assure an adequate number of facilities in the TCD system.

RESPONSE: The department understands this concern. The option as to whether or not a hospital chooses to apply to the department to become a designated STEMI center is voluntary. In addition, the department has tiered the requirements of each level of STEMI center based on the level of resources it is able to provide for the care of the STEMI patient. For example, a level IV STEMI center which is typically a smaller hospital in a rural area will not be required to have the healthcare staff and resources compared to a level I STEMI center. Further, many representatives from hospitals throughout Missouri met with the department to create these regulations and during these meetings the costs to the hospitals were considered as well as what resources the hospitals already had for a STEMI program (e.g., emergency department, helipad, etc.). No changes have been made to this rule as a result of this comment.

COMMENT #2: Dr. David Gustafson, with the Kansas City Regional Emergency Medical Services (EMS) Committee and Ben Chlapek, with the Mid-America Regional Council Emergency Rescue Committee (MARCER) commented that they are concerned with the fiscal impact of the TCD regulations on the many hospitals they believe are interested in seeking formal designation as a STEMI center. Dr. Gustafson and Mr. Chlapek are aware that many hospitals have

indicated concern regarding the fiscal note related to designation. Dr. Gustafson and Mr. Chlapek are concerned that some hospitals that were seriously considering seeking designation will decide to not seek designation due to the high cost to participate. Finally, Mr. Gustafson and Mr. Chlapek believe the department should evaluate the fiscal impact of the proposed regulations on the hospitals that could seek designation in order to balance the various factors needed to assure an adequate number of facilities in the TCD system.

RESPONSE: The department understands this concern. The option as to whether or not a hospital chooses to apply to the department to become a designated STEMI center is voluntary. In addition, the department has tiered the requirements of each level of STEMI center based on the level of resources it is able to provide for the STEMI patient. For example, a level IV STEMI center, which is typically a smaller hospital in a rural area, will not be required to have the healthcare staff and resources compared to a level I STEMI center. Further, many representatives from hospitals throughout Missouri met with the department to create these regulations and during these meetings the costs to the hospitals were considered as well as what resources the hospitals already had for a STEMI program (e.g., emergency department, helipad, etc.). No changes have been made to this rule as a result of this comment.

COMMENT #3: Ken Koch, with the Missouri Emergency Medical Services Association (MEMSA) and Art Maxwell, with the Missouri Ambulance Association commented that they particularly appreciate the regulatory language requiring emergency medical services (EMS) personnel be included in the "core team" established at each hospital designated as a STEMI center. This will help assure that EMS personnel are party to the continual program improvement which will occur through these conversations. Mr. Koch and Mr. Maxwell also support the effort to assure that there is some sort of feedback loop to provide outcome information regarding STEMI patients back to EMS personnel to further professional development.

RESPONSE: No changes have been made to this rule as a result of this comment.

COMMENT #4: Thomas L. Holloway, with the Missouri State Medical Association comments that subsection (1)(E) "recommends" certain minimum interventions at a level I STEMI center. Mr. Holloway worries that a mere recommendation is somewhat loose for an emergency medical regulation, which might technically give a rogue facility free reign to completely ignore the recommended minimums. Mr. Holloway suggests that if these are considered minimum standards, then perhaps they should be required, even if there is an allowance for flexibility in unforeseen circumstances. Mr. Holloway notes that the term "recommends" shows up in other places in these proposed regulations, as well.

RESPONSE: The department understands this concern and is aware of the word "recommends" in the proposed rule. The department used the word "recommends" in regard to volumes in order to be inclusive. The department is trying to build the STEMI center designation program in order to have a sufficient number of hospitals in Missouri to become designated STEMI centers where the transport routing system of patients could work most effectively. Further, although the department will not be able to enforce the volume requirements with the proposed rule, once the STEMI center designation program has matured and there are sufficient numbers of designated STEMI centers throughout Missouri, then the department can have discussions with hospitals to determine if the volume criteria should become mandatory. Finally, section 190.200, RSMo, required the department to use a variety of evidence based research in order to develop this proposed rule. The evidence based research on volumes showed outcomes for the volumes that the department included in this proposed rule as the "recommended" volumes. If the department sets the volumes lower than the volumes found to be acceptable in the research, then the department would have no evidence based research to support such outcomes. No changes have been made to this rule as a result of this comment.

COMMENT #5: Judy Aslin, with Southeast Health comments that in paragraph (1)(T)1. the department cites to a document entitled "Time Critical Diagnosis ST-Segment Elevation Myocardial Infarction (STEMI) Center Registry Data Elements" dated March 1, 2012, which is incorporated by reference as the data that the STEMI designated center is required to enter into its STEMI registry. Ms. Aslin suggests that the Quality Assurance Committee be the body that sets the standards for the elements measured based on currently accepted evidence/clinical practice guidelines/best practice.

RESPONSE: The department understands this suggestion. However, the Quality Assurance Committee was an ad hoc committee created to develop the elements and measures related to the STEMI center data registry. This committee is not created by statute, specifically Chapter 190, RSMo. This committee consisted of health care professionals who volunteered their time to develop these elements and measures. If this document entitled "Time Critical Diagnosis ST-Segment Elevation Myocardial Infarction (STEMI) Center Registry Data Elements" were to be amended in the future then the department intends to seek input from the healthcare community as it has to date. However, the department does not want to require this ad hoc committee to be the body to set such standards when this body is not created by statute, specifically Chapter 190, RSMo. The assembly of this committee is contingent on people volunteering their time to review such evidence/clinical practice guidelines/best practice to create such elements and measures. No changes have been made to this rule as a result of this comment.

Due to the similarity in the following three (3) comments, one (1) response that addresses these comments is presented after the three (3) comments.

COMMENT #6: Judy Aslin, with Southeast Health comments that in paragraph (1)(T)1. the department cites to a document entitled "Time Critical Diagnosis ST-Segment Elevation Myocardial Infarction (STEMI) Center Registry Data Elements" dated March 1, 2012, which is incorporated by reference as the data that the STEMI designated center is required to enter into its STEMI registry. Ms. Aslin suggests that the regulatory language of "This rule does not incorporate any subsequent amendments or additions" be removed. Ms. Aslin recommends deleting the date for the document in this section so that the data elements would not have to go through the legal process to be changed.

COMMENT #7: Susan Law, with Midwest Health Systems comments that when citing in the proposed regulation to the document "Time Critical Diagnosis ST-Segment Elevation Myocardial Infarction (STEMI) Center Registry Data Elements" dated March 1, 2012, and the exclusion of any subsequent amendments or additions the facilities will be limited in their ability to implement evidence based practice improvements/recommendations because of the stated document in the rules.

COMMENT #8: Jace Smith, with the American Heart Association, Midwest Affiliate; Rebekah Terrell; Natalie Mills; Todd Sampson; Sascha Haley; Cammie Johnson; Sharon Spero; John Paul Pe; Ronnie Gibbs; Pat Kueny; Rona Frey; Vickie Brown; Cynthia Rasdall; Ashlea Serri; Sheila Beck; Mary Jane Beck; Deborah Gieselman; Sandra Pelletier; Justin Blomquist; Kelly Minnis; Rita Phillips; Shelly Wright; April Dimas; Dianna Smith; Frank Scharsch; Annette Long; Jeffrey Hasty; Jill Snider; Jessica Powell; Jacob Roach; Hillis Doyel; Linda Duncan; Amber Boes; Kathy Fidler; Corrine Everson; Becky Madonia; Brian Marriott; Mary Murphy; Juli Christopher; Michael Dieker; Grace Sumption; Greg Simpson; Tina York; Kathryn Hedges; Carla Di Maggio; Brandi King; Connie Horne; Tracy Thellman; Janet Frye; Tina Johnson; Cie Cascone; Hannah Earhart; Rebecca Froese; Debra Smith; Sandra Shipman; Gina Gregg; Rachelle Mellor; Doris Owens; Patricia Doyel; Shawn Kegley; John Young; Deborah Popp; Kevin Johnson; Wayne Arndt; Elizabeth Martin; Greg Carson; Deanna Bailey; Cheryl Allen; Randal Moberg; Heath King; Jackie De Souza; Larry Todd; and Michele Kueny ask what the reasoning is behind including a document entitled "Time Critical Diagnosis ST-Segment

Elevation Myocardial Infarction (STEMI) Center Registry Data Elements" dated March 1, 2012. They are concerned that as science improves, and best practices/recommendations change, there will be difficulty implementing those changes because of the stated document in the rules.

RESPONSE: This document entitled "Time Critical Diagnosis ST-Segment Elevation Myocardial Infarction (STEMI) Center Registry Data Elements" dated March 1, 2012, is a listing of all of the data elements that the STEMI centers are required to enter into the STEMI data registry. This document was created and incorporated by reference into the proposed rule because it would be more efficient to amend this document in the future. Section 536.031, RSMo, requires the department to date such document and to state that the referenced document does not include any later amendments or additions. Whether or not the department listed the required data elements into the body of the proposed rule or into the document entitled "Time Critical Diagnosis ST-Segment Elevation Myocardial Infarction (STEMI) Center Registry Data Elements" dated March 1, 2012, the department is required to go through the formal rulemaking process when it changes the data elements that a STEMI center is required to enter into the STEMI database. No changes have been made to this rule as a result of this comment.

COMMENT #9: Susan Law, with Midwest Health Systems; Jace Smith, with the American Heart Association, Midwest Affiliate; Rebekah Terrell; Natalie Mills; Todd Sampson; Sascha Haley; Cammie Johnson; Sharon Spero; John Paul Pe; Ronnie Gibbs; Pat Kueny; Rona Frey; Vickie Brown; Cynthia Rasdall; Ashlea Serri; Sheila Beck; Mary Jane Beck; Deborah Gieselman; Sandra Pelletier; Justin Blomquist; Kelly Minnis; Rita Phillips; Shelly Wright; April Dimas; Dianna Smith; Frank Scharsch; Annette Long; Jeffrey Hasty; Jill Snider; Jessica Powell; Jacob Roach; Hillis Doyel; Linda Duncan; Amber Boes; Kathy Fidler; Corrine Everson; Becky Madonia; Brian Marriott; Mary Murphy; Juli Christopher; Michael Dieker; Grace Sumption; Greg Simpson; Tina York; Kathryn Hedges; Carla Di Maggio; Brandi King; Connie Horne; Tracy Thellman; Janet Frye; Tina Johnson; Cie Cascone; Hannah Earhart; Rebecca Froese; Debra Smith; Sandra Shipman; Gina Gregg; Rachelle Mellor; Doris Owens; Patricia Doyel; Shawn Kegley; John Young; Deborah Popp; Kevin Johnson; Wayne Arndt; Elizabeth Martin; Greg Carson; Deanna Bailey; Cheryl Allen; Randal Moberg; Heath King; Jackie De Souza; Larry Todd; and Michele Kueny comment that in the document entitled "Time Critical Diagnosis ST-Segment Elevation Myocardial Infarction (STEMI) Center Registry Data Elements" dated March 1, 2012, cited to in the proposed rule, the word elements should be changed to measures.

RESPONSE: All of the terms listed in the document entitled "Time Critical Diagnosis ST-Segment Elevation Myocardial Infarction (STEMI) Center Registry Data Elements" dated March 1, 2012, are the actual elements (data fields) that the STEMI centers will be entering directly into the STEMI registry. The measures are then calculated from the data elements entered into the STEMI registry. These measures will be beneficial to the STEMI centers in their performance improvement process. No changes have been made to this rule as a result of this comment.

COMMENT #10: Jace Smith, with the American Heart Association, Midwest Affiliate; Rebekah Terrell; Natalie Mills; Todd Sampson; Sascha Haley; Cammie Johnson; Sharon Spero; John Paul Pe; Ronnie Gibbs; Pat Kueny; Rona Frey; Vickie Brown; Cynthia Rasdall; Ashlea Serri; Sheila Beck; Mary Jane Beck; Deborah Gieselman; Sandra Pelletier; Justin Blomquist; Kelly Minnis; Rita Phillips; Shelly Wright; April Dimas; Dianna Smith; Frank Scharsch; Annette Long; Jeffrey Hasty; Jill Snider; Jessica Powell; Jacob Roach; Hillis Doyel; Linda Duncan; Amber Boes; Kathy Fidler; Corrine Everson; Becky Madonia; Brian Marriott; Mary Murphy; Juli Christopher; Michael Dieker; Grace Sumption; Greg Simpson; Tina York; Kathryn Hedges; Carla Di Maggio; Brandi King; Connie Horne; Tracy Thellman; Janet Frye; Tina Johnson; Cie Cascone; Hannah Earhart; Rebecca Froese; Debra Smith; Sandra Shipman; Gina Gregg; Rachelle Mellor; Doris Owens; Patricia Doyel; Shawn Kegley; John Young; Deborah Popp; Kevin Johnson; Wayne Arndt; Elizabeth Martin; Greg Carson; Deanna Bailey; Cheryl Allen; Randal Moberg; Heath King; Jackie De Souza; Larry Todd; and Michele Kueny comment that they would like for the Quality Assurance Committee to be listed into the rules as setting the standards for the measures listed in the document entitled "Time Critical Diagnosis ST-Segment Elevation Myocardial Infarction (STEMI) Center Registry Data Elements" dated March 1, 2012.

RESPONSE: The department understands this suggestion. However, the Quality Assurance Committee was an ad hoc committee created to develop the elements and measures related to the STEMI center data registry. This committee is not created by statute, specifically Chapter 190, RSMo. This committee consisted of healthcare professionals and experts in the field who volunteered their time to develop these elements and measures. If this document entitled "Time Critical Diagnosis ST-Segment Elevation Myocardial Infarction (STEMI) Center Registry Data Elements" were to be amended in the future then the department intends to seek input from the healthcare community and experts in the field as it has to date. However, the department cannot require this ad hoc committee to be the body to set such standards when this body is not created by statute, specifically Chapter 190, RSMo. No changes have been made to this rule as a result of this comment.

COMMENT #11: Ben Chlapek, with the Mid-America Regional Council Emergency Rescue Committee (MARCER) and Dr. Gustafson, with the Kansas City Regional EMS Committee commented that they particularly appreciate the regulatory language which requires that emergency medical services (EMS) personnel be included in the "core team" established at each hospital designated as a STEMI center. Mr. Chlapek and Dr. Gustafson also support the effort to assure that there is some sort of feedback loop to provide outcome information regarding STEMI patients back to EMS personnel to further professional development.

RESPONSE: No changes have been made to this rule as a result of this comment.

COMMENT #12: Daniel Landon, with the Missouri Hospital Association (MHA) comments that subsection (1)(T) states that STEMI centers shall electronically enter data into the Missouri STEMI registry as defined by the March 1, 2012, "Time Critical Diagnosis ST-Segment Elevation Myocardial Infarction (STEMI) Center Registry Data Elements" document. Mr. Landon comments that while many hospitals providing STEMI care collect this type of data on STEMI patients, not all centers collect every one of the measures detailed in the document. Additionally, the department's website does not detail the mechanism for electronic reporting and the data requirements to appropriately match the fields required. This lack of interface information makes it impossible for hospitals to effectively evaluate the resources needed to electronically transmit this data to the department. Mr. Landon recommends that this section be removed. In the alternative, Mr. Landon recommends that this section be revised to include a mechanism that allows the department to enforce this requirement after successfully demonstrating its ability to accept this data from multiple information systems without manual intervention. Mr. Landon is willing to serve on a committee to define the criteria used to successfully demonstrate ability by the state to receive this data electronically.

RESPONSE: The department understands this concern. The STEMI registry created by the department will be free for the STEMI centers to utilize. There are some hospitals that already have their own registry because they have been utilizing a database from a national sponsor (e.g., the American Heart Association). For those hospitals that are already utilizing a database from a national sponsor, the department's vendor has been developing an interface with the assistance

from vendors of those databases that hospitals may be currently using (e.g., the American Heart Association) to facilitate the flow of data to the department's registry from the hospitals. The department has been working on this issue in order to avoid redundant data entry and to make the data entry process as efficient and cost effective as possible. No changes have been made to this rule as a result of this comment.

COMMENT #13: Susan Law, with Midwest Health Systems Missouri Hospitals comments that the requirement to provide data to another database on top of the multiple nationally recognized databases currently being submitted to meet existing certification/designation programs will require additional time, money, and resources and it is unclear how the state required data will be used to impact quality. A current example is that the state trauma program requires data entry but does not drive local trauma quality initiatives.
RESPONSE: The department understands this concern. The STEMI registry created by the department will be free for the STEMI centers to utilize. There are some hospitals that already have their own registry because they have been utilizing a database from a national sponsor (e.g., the American Heart Association). For those hospitals that are already utilizing a database from a national sponsor, the department's vendor has been developing an interface with the assistance from vendors of those databases that hospitals may be currently using (e.g., the American Heart Association) to facilitate the flow of data to the department's registry from the hospitals. The department has been working on this issue in order to avoid redundant data entry and to make the data entry process as efficient and cost effective as possible. In the future, the department's STEMI registry will allow the STEMI centers to provide systems level surveillance on the local and regional level for their performance improvement process and enable participation at the state level performance improvement process. The department anticipates this will assist the STEMI centers in integrating into the larger local, regional, and state system of care and in targeting programming and prevention efforts in their facilities, referral patterns, and catchment areas. No changes have been made to this rule as a result of this comment.

COMMENT #14: Susan Law, with Midwest Health Systems Missouri Hospitals comments that the regulations specifically list the equipment that you must have available to care for the patients versus relying on the medical leadership outcomes research to drive this request (for example, it lists extra cranial ultrasound and defines how quickly the tech must respond).
RESPONSE: The department does list specific equipment that must be available to care for the STEMI patients in the proposed rule. Pursuant to section 190.200, RSMo, the department was required to use peer-reviewed and evidence-based research, guidelines and assessment to promulgate the rules. Based on the department's review of this information in addition to the input from many people in the medical community over the past several years, the department created the requirements for the STEMI centers which includes, among other things, equipment. No changes have been made to this rule as a result of this comment.

COMMENT #15: Ken Koch, with the Missouri Emergency Medical Services Association (MEMSA); Dr. Gustafson, with the Kansas City Regional EMS Committee; Ben Chlapek, with Mid-America Regional Council Emergency Rescue Committee (MARCER); and Art Maxwell, with the Missouri Ambulance Association commented that they support the proposed regulations which will establish the critical hospital based system.
RESPONSE: No changes have been made to this rule as a result of this comment.

COMMENT #16: Susan Law, with Midwest Health Systems comments that the volume requirement for levels places greater emphasis on volume versus quality. Ms. Law explains a facility can receive awards from nationally recognized STEMI organizations such as the Joint Commission, the American Heart Association and the American Stroke Association for quality and outcomes and still not be considered a level I designated center.
RESPONSE: The volumes listed in section (1) are recommended and are not required. No changes have been made to this rule as a result of this comment.

COMMENT #17: Susan Law, with Midwest Health Systems comment that driving all volume of STEMI patients to the highest level facilities will create a situation where it will become nearly impossible for a level II or level I STEMI center to increase their volume to move to the next higher level. The unfair leveling of facilities based on volume may have an unintended negative consequence.
RESPONSE: The department understands this concern. The explanation provided by Ms. Law is the primary reason that the department decided to make the volume requirements listed in section (1) as recommended volumes instead of required volumes. No changes have been made to this rule as a result of this comment.

COMMENT #18: Jace Smith, with the American Heart Association, Midwest Affiliate, provided the department with two (2) documents that compared the department's proposed system of care for STEMI centers with the American Heart Association's current recommendations for all levels of STEMI centers.
RESPONSE: No changes have been made to this rule as a result of this comment.

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

ORDER OF RULEMAKING

By the authority vested in the Missouri Department of Health and Senior Services under section 192.006, RSMo 2000, and sections 190.185 and 190.241, RSMo Supp. 2012, the department adopts a rule as follows:

19 CSR 30-40.770 is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on December 17, 2012 (37 MoReg 2284). Changes have been made in the text of the proposed rule, so it is reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The Department of Health and Senior Services received two (2) comments.

COMMENT #1: Shane Lockard, with the Johnson County Ambulance District; Dr. David Gustafson, with the Kansas City Regional EMS Committee; and Ben Chlapek, with Mid-America Regional Council Emergency Rescue Committee (MARCER) commented that presently the process to appeal a decision made to deny approval of a proposed community or regional time critical diagnosis (TCD) plan would end with the Director of the Department of Health and Senior Services. Mr. Lockard, Dr. Gustafson, and Mr. Chlapek suggest that the appeals process in the proposed rule follow the same appeal process as proposed for decisions rendered regarding hospital designation as STEMI or stroke centers using the administrative hearing commission under Chapter 621, RSMo.

RESPONSE AND EXPLANATION OF CHANGE: The department understands this concern. However, the procedure, venue, and ability to appeal a denial are created by statute and not regulation. The department cannot create the appeals process for community-based and regional plans in this proposed rule. After careful consideration the department agrees to add a sentence to section (5) explaining that if a community-based or regional plan is denied by the Director of the Department of Health and Senior Services, then the department will include the right of appeal in the denial letter to the plan's designee.

COMMENT #2: Ken Koch, with the Missouri Emergency Medical Services Association (MEMSA) and Art Maxwell, with the Missouri Ambulance Association commented that these associations endorse the regulations regarding community and regional emergency medical services (EMS) TCD plans. MEMSA and the Missouri Ambulance Association believe these are a welcome option for EMS agencies to consider in their areas.
RESPONSE: No changes have been made to this rule as a result of this comment.

19 CSR 30-40.770 Community-based or Regional Plan for Emergency Medical Services for Trauma, ST-Segment Elevation Myocardial Infarction (STEMI), or Stroke

(5) Following recommendation of a community-based or regional plan, the committee shall forward the plan to the Director of the Department of Health and Senior Services (director) for approval. The director shall have thirty (30) days to review the plan for its compliance with section 190.200.3, RSMo. At the conclusion of the review, the director shall approve or disapprove the plan. If the director disapproves the plan, the reason(s) for disapproval shall be provided in writing to the plan's designee along with the right to appeal the director's decision. The director's decision shall be the final agency action. A community or region whose plan is not approved by the director may modify its plan according to the director's reason(s) for disapproval and resubmit the plan within thirty (30) days directly to the committee and follow the approval process as outlined herein.

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

ORDER OF RULEMAKING

By the authority vested in the Missouri Department of Health and Senior Services under sections 190.185 and 190.241, RSMo Supp. 2012, the department adopts a rule as follows:

19 CSR 30-40.780 Definitions and Abbreviations Relating to the Transport Protocol for Stroke and the Transport Protocol for ST-Segment Elevation Myocardial Infarction (STEMI) Patients **is adopted**.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on December 17, 2012 (37 MoReg 2284–2285). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

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

ORDER OF RULEMAKING

By the authority vested in the Missouri Department of Health and Senior Services under sections 190.185 and 190.241, RSMo Supp. 2012, the department adopts a rule as follows:

19 CSR 30-40.790 Transport Protocol for Stroke and ST-Segment Elevation Myocardial Infarction (STEMI) Patients **is adopted**.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on December 17, 2012 (37 MoReg 2285–2286). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The Department of Health and Senior Services received two (2) comments.

COMMENT #1: Shane Lockard, with the Johnson County Ambulance District; Dr. David Gustafson, with the Kansas City Regional EMS Committee; and Ben Chlapek, with Mid-America Regional Council Emergency Rescue Committee (MARCER) commented that clinical responsibility and cost factors will substantially increase on emergency medical services (EMS) if an inadequate number of hospitals seek designation. The system must have an adequate number of designated hospitals spread throughout the state for the vision of the 2008 time critical diagnosis (TCD) law to be reasonably accomplished. The TCD law and proposed regulations establish a formal responsibility on EMS regarding the treatment and transportation of patients. If an inadequate number of hospitals participate, ambulance services will be transporting patients greater distances, paramedics will be managing critical patients for longer periods of time and EMS managers will be dealing with the cost of service area coverage associated with units transporting to more distant hospitals.
RESPONSE: The creation of proposed rules 19 CSR 30-40.730 and 19 CSR 30-40.760 which lists the requirements for hospitals to be designated as stroke and STEMI centers by the department involved many representatives from the hospital community. As stated in the fiscal notes for 19 CSR 30-40.730 and 19 CSR 30-40.760 many hospitals already have the resources needed to be designated as a stroke and STEMI center. Based on discussions with hospital representatives, the department anticipates many hospitals in Missouri will apply to become stroke and STEMI centers designated by the department throughout Missouri. No changes have been made to the rule as a result of this comment.

COMMENT #2: Susan Law, representing Midwest Health Systems Missouri Hospitals commented that the draft version of the emergency medical services (EMS) routing criteria redirects most critical patients from lower levels to the highest levels, at times bypassing current processes of "nearest capable facility" without any demonstration of how this routing will enhance patient care when time is one of the key factors.
RESPONSE: Section 190.243.3, RSMo, requires the transport of STEMI and stroke patients to be governed by principles of timely and medically appropriate care. The department worked with representatives from hospitals and emergency medical services communities over a period of several years in order to draft a rule that ensures STEMI and stroke patients are routed to the level of stroke or STEMI center which will provide them with both timely and medically appropriate care. Further, the transport protocol was based on data

and evidence-based research of patients' needs. The proposed rule takes into account that there are times when a patient should be stabilized at the nearest appropriate facility. This rule does not prohibit emergency medical services providers from using judgment as to the routing of the patient. No changes have been made to the rule as a result of this comment.

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2245—Real Estate Appraisers
Chapter 3—Applications for Certification and Licensure

ORDER OF RULEMAKING

By the authority vested in the Missouri Real Estate Appraisers Commission under sections 339.509, 339.511, and 339.515, RSMo Supp. 2012, and section 339.544, RSMo 2000, the commission adopts a rule as follows:

20 CSR 2245-3.001 Implementation of 2015 AQB Criteria **is adopted**.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on December 17, 2012 (37 MoReg 2299–2300). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2245—Real Estate Appraisers
Chapter 3—Applications for Certification and Licensure

ORDER OF RULEMAKING

By the authority vested in the Missouri Real Estate Appraisers Commission under section 339.509(8), RSMo Supp. 2012, the commission amends a rule as follows:

20 CSR 2245-3.005 is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 17, 2012 (37 MoReg 2300–2303). Those sections with changes are reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The commission received two (2) comments and noted one (1) error on the proposed amendment.

COMMENT #1: Joseph F. Rose, with the Missouri Appraisers Advisory Council, discovered that subsection (6)(H) incorrectly references Chapter 333, RSMo, rather than Chapter 339, RSMo.
RESPONSE AND EXPLANATION OF CHANGE: The commission concurs that the reference should be to Chapter 339, RSMo. The commission thanks Mr. Rose for his comment and has made the correction as suggested.

COMMENT #2: Joseph F. Rose, with the Missouri Appraisers Advisory Council, noted that subsection (7)(D) refers to the requirement that fifty percent (50%) of all experience hours must be completed in the state of Missouri found in 20 CSR 2245-3.010(5) which has been removed.
RESPONSE AND EXPLANATION OF CHANGE: The commission concurs that the reference should be removed from this rule to prevent confusion. The commission thanks Mr. Rose for his comment and has made the correction as suggested.

COMMENT #3: Upon review of the published rules in the *Missouri Register*, the commission discovered that a reference is made to a different profession in the fiscal note.
RESPONSE AND EXPLANATION OF CHANGE: The commission has corrected the fiscal note to refer to the correct profession.

20 CSR 2245-3.005 Trainee Real Estate Appraiser Registration

(6) Training.

(H) A certified appraiser may not serve as the supervising appraiser for an individual trainee for more than five (5) years, unless otherwise approved by the commission for good cause. The "trainee real estate appraiser" registration is not intended as a long-term method of performing appraisal services in the absence of progress toward licensure or certification as an appraiser. A supervising appraiser shall not serve as supervising appraiser for any trainee if the supervisor has knowledge that the trainee does not intend to progress toward licensure or certification or with the intent to evade the appraiser licensing or certification requirements of Chapter 339, RSMo.

(7) A person may register as a trainee under a supervising appraiser certified in another state if—

(D) Upon application for certification, trainees that are supervised by an appraiser certified in another state shall be required to comply with all certification requirements established by Missouri law. Trainees are also reminded that pursuant to 20 CSR 2245-3.010, applicants for a general certification must have accumulated a total of three thousand (3,000) hours of appraisal experience of which at least fifty percent (50%) (one thousand five hundred (1,500) hours) shall be in nonresidential appraisal work and under the supervision of a Missouri certified general real estate appraiser or a certified general appraiser certified in another state and who is authorized to perform the same scope of appraisal services as a Missouri-certified general appraiser.

PRIVATE COST: This proposed amendment will cost private entities approximately two thousand, six hundred ten dollars ($2,610) annually for the life of the rule. The cost for the proposed amendment has not changed, however, the name of the commission identified on the fiscal note has been corrected.

PRIVATE FISCAL NOTE

I. RULE NUMBER

Title 20 - Department of Insurance, Financial Institutions and Professional Registration
Division 2245 - Missouri Real Estate Appraisers Commission
Chapter 3 - Applications for Certification and Licensure
Proposed Amendment - 20 CSR 2245-3.005 Trainee Real Estate Appraiser Registration
Prepared January 17, 2013 by the Division of Professional Registration

II. SUMMARY OF FISCAL IMPACT

First Year of Implementation of Rule

Estimate the number of entities by class which would likely be affected by the adoption of the proposed rule:	Classification by type of the business entities which would likely be affected:	Estimated cost of compliance with the rule by affected entities:
50	Applicants for Licensure as a Real Estate Appraiser Trainee (Background check @ $49.45)	$2,610.00
	Estimated Annual Cost of Compliance for the Life of the Rule	**$2,610.00**

III. WORKSHEET

See Table Above

IV. ASSUMPTION

1. Based on FY2012 actual number of trainees registered with the commission, the commission estimates that approximately 50 additional trainees will register with the commission each year.
2. The estimated fingerprinting fee is a pass through fee determined by the Federal Bureau of Investigation and the Missouri State Highway Patrol. The commission does not establish or receive fingerprint fees.
3. It is anticipated that the total costs will recur for the life of the rule, may vary with inflation and is expected to increase at the rate projected by the Legislative Oversight Committee.

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2245—Real Estate Appraisers
Chapter 3—Applications for Certification and Licensure

ORDER OF RULEMAKING

By the authority vested in the Missouri Real Estate Appraisers Commission under sections 339.509, 339.515, and 339.517, RSMo Supp. 2012, the commission amends a rule as follows:

20 CSR 2245-3.010 Applications for Certification and Licensure **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 17, 2012 (37 MoReg 2304). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2245—Real Estate Appraisers
Chapter 4—Certificates and Licenses

ORDER OF RULEMAKING

By the authority vested in the Missouri Real Estate Appraisers Commission under sections 339.509 and 339.521, RSMo Supp. 2012, and section 339.523, RSMo 2000, the commission amends a rule as follows:

20 CSR 2245-4.050 Nonresident Certification or Licensure; Reciprocity **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 17, 2012 (37 MoReg 2305). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2245—Real Estate Appraisers
Chapter 6—Educational Requirements

ORDER OF RULEMAKING

By the authority vested in the Missouri Real Estate Appraisers Commission under sections 339.509, 339.511, and 339.515, RSMo Supp. 2012, and section 339.544, RSMo 2000, the commission adopts a rule as follows:

20 CSR 2245-6.016 Examinations and Education **is adopted**.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on December 17, 2012 (37 MoReg 2313–2315). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.