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Time Critical Diagnosis System Regulation Frequently Asked Questions and Answers May 2010

Time Critical Diagnosis System

- Missouri was the first state to comprehensively integrate common processes for the time critical conditions of trauma, stroke, and the potentially fatal form of heart attack known as STEMI. All of these conditions require quick assessment, diagnosis and treatment by a facility that can provide timely, definitive care to minimize risk for preventable complications and death.
- Missouri enacted laws (RSMo 190.200-190.245)¹ in 2008 that created the Time Critical Diagnosis (TCD) System to provide medical care for these patients requiring time critical diagnosis and treatment for trauma, stroke and STEMI.
- The Department of Health and Senior Services convened experts from the emergency medical care system to help draft the regulations below to implement this system. DHSS has actively sought input on the proposed rules over the past 18 months through 10 statewide meetings, six regional meetings, an on-line survey and more than 28 conference calls and webinars. These efforts have produced a wide range of suggestions and advice from experts in the field. The department also has had public discussion on the standards to obtain a full understanding of the implications of the proposed rules. More than 500 individuals from multiple hospitals and emergency medical services agencies have requested to be on the list-serve for these notices. The DHSS web pages that carry current versions of the draft proposed regulations receive more than 32,000 hits monthly.

Proposed Regulations are currently undergoing administrative and legal reviews prior to filing with the Secretary of State's office. Copies are available on the department Web site at http://www.dhss.mo.gov/TCD_System/WhatsNew.html

1. **Definitions and Abbreviations Relating to STEMI Centers**
2. **Standards for Level I, II, III, and IV STEMI Center Designation** – describes designation standards in the following sections: general (requirements for the STEMI program, e.g., medical director and team functions, policies and agreements for STEMI care); medical staffing; hospital resources and capabilities; hospital performance improvement, patient safety, outreach, public education and training programs; and research.
3. **Application process and application for STEMI Centers** – outlines requirements for applications and process department uses for approval.
4. **Definitions and Abbreviations Relating to Stroke Centers**
5. **Standards for Level I, II, III, and IV Stroke center designation** – describes designation standards for the following sections: general (requirements for the stroke program, e.g., medical director and team functions, policies and agreements for stroke care; medical staffing); hospital resources and capabilities; hospital performance improvement, patient safety, outreach, public education and training programs; and research.
6. **Application process and application for Stroke Centers**-- outlines requirements for applications and process Department uses for approval

7. **Triage/Transport Protocol for Stroke and STEMI Patients** – establishes protocols for transporting suspected STEMI and stroke patients according to severity and time of onset to the designated STEMI or stroke center where resources exist to provide appropriate care.

Draft Regulations, being discussed for finalization for administrative and legal review by August 2010.

Trauma regulations and documents undergoing review for future submission separate from proposed Stroke/STEMI regulations:

1. Trauma Center Designation
2. Level IV Trauma Center Designation
3. Pediatric Trauma Center Regulations
4. Trauma Triage/Transport Protocol with companion guidance documents

Triage/Transport Protocol for Trauma Patients Frequently Asked Questions

1. **Question: What is the purpose of the Transport Protocol for Trauma Patients?**

Answer: This protocol establishes a consistent approach throughout the state for transporting trauma patients according to injury severity to the trauma center where resources exist to provide the necessary care.

2. **Question: Why do these need to be published in regulation form instead of guidelines?**

Answer: The law (RSMo 190.243) states that “Severely injured patients shall be transported to a trauma center.” RSMo 190.185 requires the department to promulgate and enforce rules to further the accomplishment of the purpose of this law in promoting state-of-the-art emergency medical services in the interest of public health, safety and welfare.

The American College of Surgeons-Committee on Trauma² states that to achieve the best possible outcomes, the system must be designed so that the right patient is transported to the right facility at the right time. In order to assure this on a statewide basis, they further recommend mandatory systemwide prehospital triage criteria to ensure that trauma patients are transported to an appropriate facility based on their injuries.

3. **Question: What is the foundation for the state’s trauma triage/transport protocol?**

Answer: The state will use the American College of Surgeons/ Committee on Trauma and CDC field triage document published in the January 2009 MMWR as the floor. The Trauma Task Force, which has met since 2008, has added Missouri specific elements gathered from protocols around the state to the CDC protocol to create the draft protocol. The Task Force is currently discussing this draft protocol and options for what will be contained in the protocol and what will be included in companion guidance documents that do not go into regulation.

4. Question: How will the Department update these protocols?

Answer: Several options are under discussion. It is envisioned that the transport/triage protocol for trauma will be regularly updated either through recommendations from the State Advisory Committee for EMS/ Trauma Sub-Committee, or another ad hoc content expert advisory body for trauma as well as for STEMI and stroke, external to the department. These bodies would review regional processes, results of quality improvement activities and new national evidence. They would then make recommendations to the department for updates to the triage and transport protocol.

In addition, it is envisioned that EMS, trauma, stroke and STEMI centers, and the Regional Emergency Medical Services Committees would regularly track and evaluate the timeliness of access to care commensurate with both injury type and severity and disease. This review would be used to help define optimal system configuration and transport protocols' sensitivity and specificity for appropriately identifying and triaging/transporting trauma patients. The regional committees can compare their performance to available state and national rates of acceptable and system-defined rates of primary and secondary over triage and under triage.

5. Question: What is the status of the transport protocols?

Answer: The stroke and STEMI transport protocols have received considerable review and discussion. These protocols have been drafted for proposed regulations and are undergoing administrative and legal reviews prior to filing with the Secretary of State's office. Filing may occur by fall 2010.

Likewise, the trauma transport protocol has received considerable review and discussion. It is based on the national trauma field triage guidelines³ published by the Centers for Disease Control and Prevention in 2009. At this time, the trauma task force is reviewing the options for the transport protocol and plans to finalize it in August 2010. Comments are welcome and those interested in these protocols are encouraged to participate in the Trauma Task Force meetings. When the protocol discussion is finalized, the department will submit the proposed regulations for administrative and legal review prior to filing with the Secretary of State's office after that review process.

6. Question: When will the protocols go into effect?

Answer: It is estimated that the stroke and STEMI transport protocols will be filed with the Secretary of State's Office by fall 2010 and go into effect approximately nine months later.

It is estimated that the trauma transport protocols will be filed by the first of 2011 and go into effect by the end of that year.

Community-based or Regional Plan for Emergency Medical Services for Trauma, STEMI or Stroke Frequently Asked Questions

7. Question: What is the purpose of a community-based or regional plan for emergency medical services?

Answer: Regions or communities may have unique issues that require alternative approaches for transport of trauma, stroke or STEMI patients. The law requires that the Department establish procedures so these communities or regions can submit a plan that proposes an alternative approach for trauma, STEMI, or stroke for that respective area that differs from what is required by the regulations.

8. Question: Will every region or community need to compile one?

Answer: No. Only those regions that are pursuing an alternative approach from the regulations need to submit community or regional plans.

9. Question: How much detail will be expected in the community plan application?

Answer: In general, plans should succinctly describe:

- The region or community to be affected by the plan, which could be depicted showing a map with clear boundaries for the proposed area;
- Why the plan was needed. This would include a description of the unique factors within the community or region that warrants a different approach than what is required in the regulations. This should be based on an assessment of the community's or region's capacity or variables such as terrain or long distances to level I or II facilities, and how best practices will be managed differently but still in a manner that ensures appropriate outcomes;
- Relevant data and evidence being used to compile the plan;
- How the effect on medical outcomes will be evaluated.
- Those involved in compiling the plan, which can simply be a list noting the individual, their expertise and affiliation and
- The alternate plan.

10. Question: Who needs to be involved in compiling the plan?

Answer: State law requires these plans to be developed by or in consultation with the representatives of hospitals, physicians, and emergency medical services providers in the community or region.

11. Question: What does it mean when it says the plan shall be based on "clinical research and guidelines"?

Answer: The term "clinical research and guidelines" means relevant data or evidence about field triage, transport, diagnosis, prognosis, therapy and other clinical and health care issues. Relevant literature should be used to compile the alternative plan to provide a safe and effective process for triage and transport of patients that is in line with best practices.

For example, a community or region could point to recent data to support the use of a 4.5 hour window for group I in its plan rather than a three hour window for lytic therapy for stroke patients. Or a community or region could point to a change in American College of Surgeons/Committee on Trauma guidelines to support alternatives. This does not mean that communities or regions must generate original research, data and papers. But if a region or community did want to do so, that could also be used to support an alternative plan as well as be informative for the state.

12. Question: What steps are in the approval process?

Answer: The steps currently proposed are:

1. Completed plan is submitted to Regional EMS Committee and Medical Director.
2. After the Regional EMS Committee's approval or recommendations, the plan is forwarded to Missouri Department of Health and Senior Services.
3. The department shares with the Regional Medical Directors subcommittee of the State Advisory Council for their review and recommendations.
4. The department approves or disapproves based on its own review and the prior reviews and recommendations.

13. Question: Can I still submit comments on the proposed regulations?

Answer: Yes, the community plan regulations are still being drafted and comments are welcome. When the proposed regulations are filed with the Secretary of State's office there will be a formal comment period that will be publicized. However, the department welcomes comments and suggestions prior to the formal filing of the regulations.

References

1. Missouri State Statutes-Emergency Medical Services Chapter: <http://www.moga.mo.gov/statutes/c100-199/1900000200.htm>
2. Regional Trauma Systems: Optimal Elements, Integration, and Assessment, American College of Surgeons Committee on Trauma Systems Consultation Guide. 2008.
3. Centers for Disease Control and Prevention. [Guidelines for Field Triage of Injured Patients Recommendations of the National Expert Panel on Field Triage]. MMWR 2009; 58(No. RR-1): [1-35]. <http://www.cdc.gov/fieldtriage/>