MHA INSIDE Track

*News for Health Care Professionals*

## REGULATORY COMPLIANCE — TCD UPDATE

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Information included in this briefing has been reviewed by MHA as a preliminary notice of changes to the state time critical diagnosis requirements resulting from the 2016 legislative session. Senate Bills 732, 635 and 988 go into effect Aug. 28. Some information is subject to change as the Department of Health and Senior Services promulgates new rules and clarifies existing regulations. Current standards and definitions surrounding designations can be found here.

**What are the key changes to the TCD Programs?**
It changes the process by which facilities can be designated as stroke centers in the state. For stroke, instead of applying for stroke center designation with the state, a hospital that has been certified as a stroke center by The Joint Commission, or any other certifying organization designated by DHSS when such certification is in accordance with American Heart Association/American Stroke Association guidelines, can be a designated stroke center by the state according to the level determined by either legislation or regulatory guidance. This means there is more than one way to be designated as a stroke center by the state.

If your center currently is dually designated, (state and TJC, et.al) the state shall designate your hospital as follows.

| State Designation | TJC Designation** |
|---|---|
| Level I | Comprehensive Stroke Center |
| Level II | Primary Stroke Center |
| Level III | Acute Stroke-Ready |

***The state will need to define state level comparisons, if in the future, there are other certifying organizations.*

**What if we currently are a primary stroke center with TJC but a Level I with the state?**
There are only three Level I centers in the state that are comprehensive stroke centers with TJC. A stroke center has the following choices.

1. Secure comprehensive stroke center designation with TJC and apply to the state to be designated as a Level I.
2. Keep primary stroke center designation by TJC and apply to the state for a Level II state designation. Your current designation will remain in place until the state develops the required application.
3. Maintain both TJC and state designation as currently is done.

**If I maintain both state and certified designation, will I still have to use the state registry for stroke?**
No. The regulation requires hospitals designated as a ST-Segment elevation myocardial infarction and/or stroke center by DHSS, including through a certification route, to submit data to meet the data submission requirements specified by rules promulgated by DHSS by one of the following methods.

1. Entering data directly into the state registry by direct data entry (current process).
2. Downloading hospital data from a nationally recognized registry or data bank, and importing the data files into the state registry. While this is the current process, not all fields will map and therefore the center will need to complete both registries for accuracy.
3. Authorizing a nationally recognized registry or data bank to disclose or grant access to the DHSS facility-specific data held by the registry or bank. To our knowledge, the American Hospitals Association's *Get With The Guidelines* is the only national registry meeting AHA specifications.

A hospital submitting by either 2 or 3 above will not be required to collect and submit any additional STEMI or stroke data elements.

**What about prehospitalization data?**
The biggest difference between the state registry and GWTG is the prehospital data that exists in the state registry, but does not exist in GWTG. This will be addressed at a different time. In the future, if you submit data using the state registry those data elements will still exist and need to be reported.

**Can we still submit data through the state registry if wanted?**
Yes. Another section of the law requires DHSS to generate and submit quarterly trauma, stroke and STEMI outcome data to designated centers, the state advisory council on EMS, and regional EMS committees for performance improvement and patient safety. The best way to look at statewide data would be 100 percent utilization of one registry. We currently have 11 centers that **only** submit stroke data to the state registry out of more than 50 programs.

**When does this reporting requirement change take effect?**
The law goes into effect Aug. 28. The current data reporting schedule to the state is as follows.

| Stroke Registry Due Dates for 2016 Per 19 CSR 30-40.730 | | | | |
|---|---|---|---|---|
| **Quarter** | **Month** | **Start of Quarter** | **End of Quarter** | **Due Date (90 days after quarter ends) Non-Compliant Letter Issued** |
| 1st | January to March | 1/1/2106 | 3/31/2016 | 6/30/2016 |
| 2nd | April to June | 4/1/2016 | 6/30/2016 | 9/30/2016 |
| 3rd | July to September | 7/1/2016 | 9/30/2016 | 12/31/2016 |
| 4th | October to December | 10/1/2016 | 12/31/2016 | 3/30/2017 |

To avoid confusion for everyone involved, we would suggest continuing to report in both systems through Sept. 30. Whatever you have used in the past as your cutoff or selection criteria, should be the same information you use to determine how you finish with in the state registry. Then, on Oct. 1, you will transition to the registry you designate with the state to collect, track and report using one system. This means the hospital will need to grant access to the state through Quintiles (company administering GWTG), or another approved registry as outlined by the state, as soon as possible or no later than Jan. 1, 2017.

**How do we grant access to the state?**
An addendum to your Quintiles contract (or process per other registry approved by the state) will need to be made to grant the state user access.

While some of the information in the addendum would be straightforward, it is important to identify early on what programs are necessary for accessing/reviewing data and at what level of data this initiative needs accessibility. Typically, initiatives try to match program options with the hospital base they are recruiting to participate in the initiatives. The registry should be able to assist with this process. AHA is aware of this communication.

If your legal team has questions surrounding access, completion of required forms, etc., they may contact Ted Wedel, MHA's Vice President of Policy Development at twedel@mhanet.com or 573/893-3700, ext. 1394.

**What if we want to maintain our Level I with the state and not become a comprehensive center?**
The legislation ensures that if you are a comprehensive stroke center you will be designated as Level I as long as you communicate and submit the required application, information, forms, etc. If you are a primary stroke center, you are assured as Level II. In this case, currently you would need to maintain both surveys, standards, etc. You still only have to report data using one mechanism as described above.

**What about data elements the state requires that are not required by a national registry?**
We recognize that Missouri's time critical diagnosis model of care is a leading model looking at the entire patient experience, including transport, the EMS community, etc. Our hospitals do not have to report any additional data elements other than those included in the national registry they are using as approved by the state. Prehospitalization data will be lost. Currently, the state is evaluating the creation of a Missouri-specific tab in GWTG or potential future registries that would include prehospital information and be required for future entry.

**Are physicians practicing in the emergency room of a designated trauma, stroke or STEMI center required to complete education in these areas?**
Yes. Legislation mandates the Missouri Board of Healing Arts to set the criteria and hours. However, any center certified by a certifying agency has education requirements that supersede this law. Additionally, the BOHA will look to national guidelines to establish requirements.

**Who is my main contact at the state?**
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**What's Next?**
The purpose of this letter is to notify the state of your hospital's current certification status and intent to report through the state registry or GWTG moving forward as of Oct. 1. Please keep a copy of the letter for your records.

**Will my designation with the state change on Aug. 28?**
No. Your existing designation with the state will not change Aug. 28. Currently, the state is working on the required application form and process. They will notify you when that is complete. At that time, you should follow the process outlined and submit the required information if your facility plans to be designated by the state by a certifying agency. If something occurs in your program that could change your designation with the state, certifying agency, etc., you should immediately notify your state contact.

**If our facility is designated as a stroke center by a certifying agency and submits the application to the state, will the state still complete initial and ongoing surveys?**
No. The only time the state would come in would be upon complaint investigation, validation survey, etc., as they do now during the normal course of business. If the complaint is specific to the stroke program and does not entail any other facet of operation, the state likely will turn the entire complaint process over to the certifying agency per our discussions. The state and MHA's interpretation of the legislation on this topic differs at this time. This may be subject to change. We believe they still will be investigating complaints even within the stroke program designated through application using a certifying route. Legislation mandates that the state report to the certifying agency all complaints related to designation and provide the complainant the name and contact information to the certifying agency.

**What if our facility is certified in trauma and STEMI by a certifying agency who is nationally**

**recognized?**
The state still surveys and designates trauma and STEMI centers in Missouri. However, if your hospital is submitting data through a nationally recognized registry or data bank for trauma, stroke, or STEMI, the data collection system shall be capable of accepting file transfers of data entered into any nationally recognized trauma, stroke or STEMI registry or data bank to fulfill certification reporting requirements. There likely will be more information to come on this front.

**If the stroke center is designated through a certifying organization, what should be submitted to the state and what ongoing requirements can our facility can expect?**
With this initial transition there will be a form forthcoming to stroke program directors and CEOs that should immediately be completed and returned to the state. It is only an informational communication. This initial form is not the application to be designated as a stroke center by a certifying agency. We need to work through who will be using a registry other than the state, who intends to be designated through the application route per a certifying agency, and that your facility received information about these changes, etc. We are helping the state draft this initial communication. After submitting to the state, we ask that you email a copy of the completed form to ptaylor@mhanet.com.

Currently, the state is developing the required forms and processes needed to meet the intent of the law. As stated earlier, the state will notify centers when they can apply for designation through a certifying agency. We believe the processes and forms developed will support the approved legislation as follows.

The hospital shall:

- Annually, and within 30 days of any changes, submit to the department proof of stroke certification and the names and contact information of the medical director and program manager of the stroke center.
- Submit a copy of the certifying organization's final stroke certification survey results within 30 days of receiving results.
- Every four years, submit an application, on a form prescribed by the department, for stroke center review and designation.
- Participate in the emergency medical services regional system of stroke care as already defined in regulation by DHSS.
- Participate in local and regional EMS systems by reviewing and sharing outcome data, and providing training and clinical education resources as already defined.

**Under what circumstance would a formal agreement with a Level I or II stroke center for physician consultation for evaluation of stroke patients for thrombolytic and the care of the patient post-thrombolytic therapy be required?** Upon review and approval of the certifying agencies findings and application, any hospital receiving Level III certification as an acute stroke-ready hospital by a certifying organization and designated by the state.

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