

DRAFT

In SB330 enacted by our legislature in 2005, a strong system to treat stroke victims in a timely manner and to improve the overall treatment of stroke victims was ordered. The Governor's EMS and Trauma Advisory Council (GETAC) Stroke Committee makes the following recommendations to meet that goal.

[Public comment made and accepted by majority of committee that the term "stroke victims" be replaced with "persons affected by stroke".](#)

### **Texas Stroke Center Designations**

(A.) The Governor's EMS and Trauma Advisory Council (GETAC) Stroke Committee of the Department of State Health Services (DSHS) recommend the designation of three levels of state recognized stroke centers/facilities as follows:

Level 1: Comprehensive Stroke Centers

Level 2: Primary Stroke Centers

Level 3: Support Stroke Facilities

(B) Each center applying for state Stroke Center/Facility level designation shall meet the following criteria:

1) Level 1: Comprehensive Centers ("CSCs") will meet the requirements of a Primary Stroke Center and those specified in the Consensus Statement of Stroke on Comprehensive Stroke Centers. (Recommendations for comprehensive Stroke centers: a consensus statement from the Brain Attack Coalition. Stroke, 2005; 36(7):1597-616.) These include, but are not limited by, the following specifications:

- a. A 24/7 stroke team capability as defined herein plus all of the requirements specified for a Primary Stroke Center
- b. Personnel with expertise to include vascular neurology, neurosurgery, neuroradiology, interventional neuroradiology/endovascular physicians, critical care specialists, advanced practice nurses, rehabilitation specialists with staff to include physical, occupational, speech, and swallowing therapists, and social workers.

[Public comment made that case managers be included. After discussion by committee, this addition was rejected in order to keep language in accord with BAC guidelines.](#)

c. Advanced diagnostic imaging techniques such as magnetic resonance imaging (MRI), computerized tomography angiography (CTA), digital cerebral angiography and transesophageal echocardiography.

d. Capability to perform surgical and interventional therapies such as stenting and angioplasty of intracranial vessels, carotid endarterectomy, aneurysm clipping and coiling, endovascular ablation of AVM's and intra-arterial reperfusion.

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e. Supporting infrastructure such as 24/7 operating room support, specialized critical care support, 24/7 interventional neuroradiology/endovascular support, and stroke registry

Discussion was held regarding whether the requirement for stroke registry entailed utilization of a centralized registry such as the state trauma/EMS registry that resides within DSHS. Decision was that ideal registry was a 3<sup>rd</sup> party database with capability to merge with a state-wide system. No specific requirements made.

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f. Educational and research programs

Discussion was held regarding change of this requirement to read "educational and/or research programs". After a vote the decision was to leave as written.

\*Comment made that it will be approximately 2 years before a formal certification for comprehensive stroke centers will be available through agencies such as JCAHO or TETAF.

2) Level 2: Primary Stroke Centers ("PSCs") will meet the requirements specified in "Recommendations for the Establishment of Primary Stroke Centers, JAMA 2000 June 21; 283 (23):3125-6." They will be able to deliver stroke treatment 24/7. These include, but are not limited by, the following specifications:

- a. 24 hour stroke team
- b. Written care protocols
- c. EMS agreements and services
- d. Trained ED personnel
- e. Dedicated stroke unit
- f. Neurosurgical , Neurological, and Medical Support Services
- g. Stroke Center Director that is a physician
- h. Neuroimaging services available 24 hours a day
- i. Lab services available 24 hours a day
- j. Outcomes and quality improvement plan. At a minimum this plan will incorporate the following 13 items for tracking, performance, and reporting :
  - i. Deep Vein Thrombosis prophylaxis given
  - ii. Discharged on antiplatelet/antithrombotics
  - iii. Patients with atrial fibrillation receiving anticoagulation therapy
  - iv. Tissue Plasminogen Activator (tPA) considered
  - v. Antithrombotic medication within 48 hours of hospitalization
  - vi. Lipid profile ordered during hospitalization
  - vii. Screen for dysphagia performed
  - viii. Stroke education provided

- ix. A smoking cessation program provided or discussed
- x. A plan for rehabilitation was considered
- xi. The number of EMS stroke patients transported to the facility
- xii. The number of EMS stroke patients admitted to the hospital

Discussion was held regarding xi. and xii. to determine if the intent was to identify the number of EMS transported patients admitted to the hospital or the total number of stroke patients presenting through the ED admitted to the hospital. The decision was made for this clarification to be made within rules.

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- xiii. The number of stroke cases treated with intravenous (IV) or intraarterial (IA) tPA

Proposal made to change xiii. to "the percentage of stroke cases treated with IV or IA tPA". This was voted and accepted by the committee. Additionally the proposal was made that if a center falls below the national average for IV tPA treatment rates then an automatic site review is triggered.

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Lengthy discussion held regarding additional performance measures on acute stroke treatments and prevention to ensure that centers are appropriately treating acute patients. No additional measures were added. Decision was made to maintain compliance with JCAHO recognized measures.

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- k. Annual stroke CE requirement

Discussion was held regarding the specifics of the CE requirement. The proposal was made and accepted to add "as defined by the Medical Director in accordance with JCAHO guidelines.

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- l. Public education program

3) Level 3<sup>1</sup>: Support Stroke Facilities ("SSFs") provide timely access to stroke care but may not be able to meet all the criteria specified in the Level 1 (CSCs) and Level 2 (PSCs) guidelines. They are required to:

<sup>1</sup> The designation of a Level 3 Center is defined to allow timely access to acute stroke care that would not otherwise be available such as in rural situations where transportation and access are

limited and is intended to recognize those models that deliver standard of care in a quality approach utilizing methods commonly known as “drip and ship” and telemedicine approaches.

- a. Develop a plan specifying the elements of operation they do meet.
- b. Have a Level 1 or Level 2 center that agrees to collaborate with their facility and provide the supplemental resources needed to meet the criteria outlined in the Level 2 requirements that they lack.
- c. The collaboration will provide 24/7 access to a qualified health care individual.
- d. Identify in the plan where the Level 1 or Level 2 center has agreed to collaborate with and accept their stroke patients for stroke treatment therapies the SSF are not capable of providing
- e. Obtain a written agreement between the Level 1 or Level 2 Stroke Center with their facility specifying the collaboration and interactions.
- f. Develop written treatment protocols which will include at a minimum:
  1. Transport or communication criteria with the collaborating/accepting Level 1 or Level 2 center.
  2. Protocols for administering thrombolytics and other approved acute stroke treatment therapies.
- g. Obtain an EMS/RAC agreement that:
  1. clearly specifies transport protocols to the SSF, including a protocol for identifying and specifying any times or circumstances in which the center cannot provide stroke treatment; and,
  2. specifies alternate transport agreements that comply with GETAC EMS Transport protocols.
- h. Document ED personnel training in stroke.
- i. Designate a stroke director (this may be an ED physician or non-Neurologist physician)
- j. Employ the NIHSS for the evaluation of acute stroke patients administered by personnel holding current certification
- k. Clearly designate and specify the availability of neurosurgical and interventional neuroradiology/endovascular services.
- l. Document access and transport plan for any unavailable neurosurgical services within 90 minutes of identified need with collaborating Level 1 or 2 Stroke Center.
- m. Be a licensed DSHS general hospital

4) Any center applying for or receiving a state Stroke Center/Facility level designation must maintain active participation [by a stroke healthcare professional \(as defined in RAC bylaws\)](#) in their designated RAC. [Discussion held regarding the level of participation within the RAC required. The above addition was agreed upon.](#)

(C) Centers or hospitals requesting Level 1, Level 2, or Level 3 state-approved Stroke Center/Facility designation will submit a signed affidavit by the CEO of the organization to the DSHS detailing compliance with the requirements designated in this Rule.

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There was lengthy discussion regarding whether or not a CEO affidavit was sufficient to ensure compliance with the aforementioned criteria. There was a motion made, and seconded, to delete the CEO affidavit as a method of certification. Discussion was held regarding alternative methods of certification. Clarification was made that this affidavit required accompanying support documentation including Performance Measure data/Performance Improvement Plan. After this clarification, the motion was rescinded. Verbage to include the requirement for submission of supportive documentation.

1.) Centers or hospitals seeking Level 1 CSC or Level 2 PSC state-approved Stroke Center designation who submit a copy of that level of certification by state-recognized organizations such as JCAHO shall be assumed to meet the requirements pursuant to this Rule.

Additionally, a requirement for a letter of affirmation detailing participation and good standing within the individual RAC will be added.

2.) Each center or hospital shall submit annual proof of continued compliance by submission of a signed affidavit by the CEO of the organization along with detailed compliance support documentation.

3.) The DSHS may review sites as needed to verify compliance.

Examples of situations triggering site review to include centers with significant data outliers and centers with concerns raised by their local RAC.

(D) DSHS will publish a list on its website of hospitals or centers meeting state approved criteria and their Stroke Center/Facility designation. This list will also be made available to the state RAC's for their EMS transportation plans.

1.) Centers holding JCAHO or other state-recognized certification will be specified with an additional qualifier and will be listed prior to listing centers holding similar level designation without formal certification.

Discussion was held whether triage will be based upon whether or not a site is JCAHO certified. The decision was no.

There was discussion as to whether JCAHO certified centers had to undergo a separate state certification. The decision was no, JCAHO certified centers automatically receive state certification at no additional cost. The comment was made by Steve Janda that there are 2 separate processes for trauma certification including a separate state fee via DSHS.

(E) If a hospital or center fails to meet the criteria for a state Stroke Center/Facility level designation for more than 6 weeks or if a hospital or center no longer chooses to maintain state Stroke Center/Facility level designation, the

hospital shall immediately notify, by certified mail return receipt requesting, the DSHS, local EMS, and governing RAC.

(F) If a hospital is in good standing and on the approved state Stroke Center list, the hospital may advertise to the public its state-approved status and state level designation. A Texas Level 1 (CSC) may use the words, "Texas-approved Level 1 Stroke Center" or "Texas-approved Comprehensive Stroke Center". A Level 2 center may use the words, "Texas-approved Level 2 Stroke Center" or "Texas-approved Primary Stroke Center". A Level 3 Stroke Facility approved by the state may use the words "Texas-approved Level 3 Support Stroke Facility" or "Texas-approved Support Stroke Facility". If the hospital or center is removed from state-approved level Stroke Center/Facility designation, no further public advertising is allowed and existing advertising must, where feasible, be removed from public distribution within 60 days from the date of removal. To the extent that removal of advertisement is infeasible, for example advertisement previously distributed in magazines, newspapers or on the internet, any automatic renewal of such advertisement shall be cancelled upon removal, and no further advertisement in said media shall be pursued.

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## Early Treatment Protocols for Rapid Transport

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The Governor's EMS and Trauma Advisory Council (GETAC) Stroke Committee of the Department of State Health Services (DSHS) recommend that the initial stroke transport plan have 3 components that each RAC should implement:

1. Appointment of a "stroke committee" to develop and oversee a region-specific stroke transport plan.
2. The regional plan will conform to the following general principles:

- a. A written plan is developed for regional triage of stroke patients to hospitals best able to care for them.

- b. Immediate transportation and emergent transfer to nearest appropriate facility of patients out to 8 hours from symptom onset. This time window can be altered as new therapies become available.

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Discussion held regarding transport of patients 3-8 hours from onset only to comprehensive stroke centers regardless of delay caused by diversion since theoretically only these centers can intervene with IA therapies. The committee rejected this proposal.

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Additionally discussion was held regarding emergency traffic management and the requirement for "lights and sirens" for transport of stroke patients (weighing risk of traffic accidents/EMS personnel safety and benefit of rapid transport). The decision was for local RACs to determine the detailed transport protocol with emphasis on minimizing time spent on the scene.

- c. Instruct paramedics to take patients to the highest level state designated Stroke Center if available within the region (or adjacent region, if a higher level Stroke Center in the adjacent region is closer than a lower level Stroke Center in the region). In making this determination, distance and time parameters should be considered. There should be no more than a 15 minute delay caused by taking a patient to the next highest level of stroke care. Where the available stroke care level and Stroke Centers/Facilities are comparable, a scheme should be developed to ensure a fair distribution of patients among qualified Stroke Centers/Facilities.

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The communication plan between EMS and hospital to determine the most appropriate facility was determined to be a RAC level protocol.

3. Create and maintain a registry of the number and destination of stroke patients transported and submit yearly to the DSHS.

[There was public comment made regarding the requirement for a helipad. Decision was made to follow requirements for trauma center defining a helipad or other acceptable predefined landing zone.](#)

### **Emergency Medical Services Training**

The Governor's EMS and Trauma Advisory Council (GETAC) Stroke Committee of the Department of State Health Services (DSHS) is cognizant that training and oversight of EMS personnel can be time and resource intensive, and so recommends the following minimal additions be added to Emergency Medical Service Provider's licensure detailed in the Texas Administrative Code.

- 1) That all EMS [personnel](#) be trained and use the "Cincinnati Stroke Scale" in the assessment of possible stroke victims.
- 2) That all certified EMS [personnel](#) receive training in the recognition and emergency care of stroke, equivalent to training received in the current "ACLS Case 10 stroke scenarios".
- 3) That EMS [licensed personnel](#) have documented familiarity with the Stroke Center Certification and the Emergency Transport Protocol in their RAC.
- 4) That recognition and documentation of stroke training be overseen by the Medical Director supervising the EMS personnel [on an annual basis](#).
- 5) That current [successful](#) ACLS [course completion](#) be recognized as documentation of that training or that alternatively the supervising Medical Director be responsible for the oversight, documentation and attestation of equivalent training on a yearly basis.

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[Discussion to replace "EMS providers" with "EMS personnel" so that training requirements also apply to Emergency Medical Dispatch in order to increase awareness of stroke symptoms over the phone and properly prioritize these patients.](#)

### **Coordination and Community Education of Stroke Plan**

The GETAC Stroke Committee is cognizant that such programs can be time and resource intensive, and recommends the Department of State Health Services (DSHS) and the Texas Council on Cardiovascular Disease and Stroke perform the following:

- Develop an effective and resource-efficient plan educating cities and RACs of the new GETAC rules on stroke facilities and emergency transport plan,
- conduct health education, public awareness, and community outreach on the emergent care of stroke and its prevention,
- coordinate its activities among other agencies within the state,
- develop a database of treatment and care of stroke,
- develop a web site and information on state stroke centers and facilities,

- collect and analyze information related to stroke and the state stroke plan, and
- include stroke care as a criteria in it's Recognition Programs.

