DRAFT

Requirements for Texas Stroke Center Designations

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

Level I: 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 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 Attached to this document for reference). 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. *Is the concept that ALL of these services be present and/or available? There are absolutely no hospitals in our TSA with this level of physician specialty/expertise.*
    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.
    e. Supporting infrastructure such as 24/7 operating room support, specialized critical care support, 24/7 interventional neuroradiology/endovascular support, and stroke registry
    f. Educational and research programs

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:

All these criterion are good/needed, but generally too vague to assess.

a. 24 hour stroke team
b. Written care protocols
c. EMS agreements and services
d. Trained ED personnel *– what specifically?*
e. Dedicated stroke unit *– to include what, who?*
f. Neurosurgical , Neurological, and Medical Support Services
g. Stroke Center Director that is a physician *– any physician?*
h. Neuroimaging services available 24 hours a day *– CT? MRI?, Angio?*
i. Lab services available 24 hours a day
j. Outcomes and quality improvement plan
k. Annual stroke CE requirement
l. Public education program

3) Level 3[1]: 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:
   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 to accept their stroke patients where they lack the capacity to provide stroke treatment.
   c. Identify in the plan the Level 1 or Level 2 center that has agreed to collaborate with and accept their stroke patients for stroke treatment therapies the SSF are not capable of providing
   d. Obtain a written agreement between the Level 1 or Level 2 Stroke Center with their facility specifying the collaboration and interactions.
   e. 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.
   f. Obtain an EMS/RAC agreement that:
      1. clearly specifies transport protocols to the SSF, including a protocol for identifying and specifying any

[1] 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.

times or circumstances in which the center cannot provide stroke treatment; and,

2. specifies alternate transport agreements that comply with GETAC EMS Transport protocols.

g. Document ED personnel training in stroke.
h. Designate a stroke director (this may be an ED physician or non-Neurologist physician)
i. Employ the NIHSS for the evaluation of acute stroke patients administered by personnel holding current certification
j. Clearly designate and specify the availability of neurosurgical and interventional neuroradiology/endovascular services.
k. Document access and transport plan for any unavailable neurosurgical services within 90 minutes of identified need with collaborating Level 1 or 2 Stroke Center.

(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. *As the criteria are written, there is too much latitude for interpretation by the CEO to determine compliance to A STANDARD of CARE.*

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.

2.) Each center or hospital shall submit annual proof *– to who? -* of continued compliance by submission of a signed affidavit by the CEO of the organization.

(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 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. *There must be some form of survey process to validate a facilities capabilities and compliance to the standard of care. How can a facility hold a similar designation without having gone through the same validation process as the JCAHO or other state-recognized certified center?*

(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.

The DETRAC is totally in support of creating a designation process for stroke care and centers. A uniform standard of care and criterion should be developed at the State level. The criterion for each level facility should be clearly defined and objectively measurable. And all facilities should routinely go through a survey/validation process by an outside reviewer to obtain/maintain their designation as a stroke center.