Texas Hospital Association

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Via electronic submission to: DSHS.EMS-TRAUMA@dshs.texas.gov

PUBLIC COMMENT LETTER

Elizabeth Stevenson, RN
Designation Program Manager – CEFDT, Maternal, Neonatal, Stroke, and Trauma
Texas Department of State Health Services
1100 West 49th Street
Austin, Texas 78756-3199

Re: Texas Department of State Health Services' August 2019 Proposed Stroke Resource Document

Dear Ms. Stevenson:

On behalf of our more than 460 member hospitals and health systems, including rural, urban, children's, teaching and specialty hospitals, the Texas Hospital Association is pleased to submit the below comments on the Texas Department of State Health Services' August 2019 Proposed Stroke Resource Document. THA appreciates TDSHS's collaborative approach regarding the stroke facility designation process, including the opportunity to participate in the August 19 stroke stakeholder meeting. THA looks forward to participating in future stakeholder meetings.

Comments on the Resource Document

1. Section 157.133(a)(6), related to provider-based departments, adds the following new sentence: "If stroke patients are received by the facility, these patients must be included in the stroke registry and stroke performance improvement process." THA assumes that this sentence refers to patients received in the excluded noncontiguous provider-based department. If that is the case, THA requests clarification that those are the patients to which the new sentence is referencing. However, and more important, if that is the intent of the new sentence, THA questions why patients received in a place that may not be included in the hospital's license (in the case of an outpatient department) or the stroke designation would be included in either the registry or the performance improvement process. THA understands the importance of a comprehensive registry, but believes this requirement casts the net far too wide and would result in including information in the registry and in the performance improvement process that is not meaningful to the stroke designation process.

2. Section 157.133(a)(9)(A) of the Proposed Stroke Resource Document states that a Level I stroke facility must either meet the current Brain Attack Coalition recommendations or meet the newly added phrase "other recognized standards of practice of stroke care approved by the department." TDSHS should clarify the process of how TDSHS will approve other standards, what accrediting bodies are recognized by TDSHS and the criteria for how those crediting bodies are selected.

3. The Proposed Stroke Resource Document adds a new level of stroke designation between Level I and Level II, which would designate a facility as an "Enhanced Primary Stroke Center." This new proposed level of designation does not appear in other publications. If the goal is to designate stroke facilities as what the Joint Commission calls "Thrombectomy Capable Centers," THA would like to point TDSHS to clinical concerns about the risk of negatively impacting the state's quality of stroke care, particularly in urban areas. If TDSHS moves forward with this new level of designation, it should be utilized only in rural areas that are isolated from Comprehensive Stroke Centers. TDSHS should select the distance and travel time based on current published research and guidelines.

   In addition, with a fourth level of designation added under the TDSHS Proposed Stroke Resource Document, will the stroke designations be renumbered?

4. The Proposed Stroke Resource Document requires facilities to schedule a stroke designation survey and notify TDSHS of the survey date. Facilities are responsible for all expenses associated with the survey. TDSHS may appoint an observer to accompany the survey team, which mirrors the trauma designation process. THA wants to ensure that these expectations are clearly communicated to applicants, and therefore supports including this language in the rules.

5. The Proposed Stroke Resource Document requires new standards for surveyors related to preventing conflicts of interest. THA believes that these standards are positive changes to the process aimed at fundamental fairness. Proposed § 157.133(b)(5)(A) sets out two restrictions related to trauma facility employment. THA would like to inquire as to whether these proposed sections are meant to refer to stroke facilities.

6. There is typographical error in proposed § 157.133(c)(5). The word "an" should state "and".

7. The Proposed Stroke Resource Document strikes the $100 application fee for stroke facility designation. The explanation from the stroke resource document stakeholder meeting is that the $100 fee does not come close to covering the cost of designation. With facilities bearing the cost of surveys—in addition to the application fee—it is important that the amount of the fee is stated in the rule for clarity and to comport with rulemaking standards of notice and opportunity to comment.

8. The Proposed Stroke Resource Document shortens the length of time in which a facility must submit a copy of the stroke designation survey report from 180 days from the date of the survey to 120 days from the date of survey. THA's comment on this proposed requirement concerns timely completion of the survey report by the surveying entity. Because the facility's compliance with this deadline depends on timely receipt of the survey report from a third party, the stroke resource document should require surveying entities to complete a survey report within a specific deadline to ensure timely submission of the report by the facility applicant or tie the submission deadline to the receipt of the report by the facility, rather than the completion of the survey. A facility should not be penalized for late submission of a report if the facility does not receive the report from the surveying entity within the deadline.

9. THA believes the Proposed Stroke Resource Document's shift from a denial of initial stroke certification based on failure to meet the standards to a withdrawn application is appropriate and appreciates TDSHS's proposed change. THA has a non-substantive comment that some of the numbering appears to be off on this portion of the document.

10. The Proposed Stroke Resource Document clarifies the process for changes to lower or higher levels of designation. Requests for higher levels of designation require a new application and survey. Applications for lower levels of designation will be subject to a desk review by TDSHS to determine whether a new survey is necessary. THA appreciates the additional clarity regarding these requirements, which frequently create confusion for facilities.

11. If a facility relinquishes its designation, the Proposed Stroke Resource Document requires the facility to notify within 30 days RACs and transferring facilities, in addition to EMS providers. THA wants to ensure that these changes are communicated to facilities and RACs to promote compliance.

12. The Proposed Stroke Resource Document includes restrictions on advertising a stroke designation or using advertising terms that imply a particular level of stroke designation unless the facility is designated as such by TDSHS. THA believes these restrictions are appropriate.

13. The proposed resource document permits TDSHS to:

> review, inspect, evaluate, and audit all stroke patient records, stroke multidisciplinary quality assessment and performance improvement documents, and peer case review committee documents and other documents relevant to stroke care in any designated stroke facility or applicant facility at any time to verify compliance with the statute and this rule. The department shall maintain confidentiality of such records to the extent authorized by the Texas Public Information Act, Government Code, Chapter and consistent with current laws and regulations related to the Health Insurance Portability and Accountability Act of 1996 and/or any other relevant confidentiality law or regulation.

THA has serious concerns related to protecting the confidentiality of patient records and peer review records. Peer review documents are confidential and not subject to disclosure to the state or other regulatory entities. Permitting TDSHS to access peer review documents risks waiving the privilege of confidentiality that attaches to those records, which will have a chilling effect on peer review, undermining the intended goals of peer review to improve patient care and address instances of substandard practice. The rules should be clear that facilities are not expected to disclose records of peer reviews of individuals practicing within the facility. Without that clarity, disputes may arise during inspections as to the accessibility of those records. Further, in addition to the references to the Texas Public Information Act and to the Health Insurance Portability and Accountability Act, the resource document should reference Texas law related to privacy of medical records, which is located in Chapter 181 of the Health & Safety Code. The state should not in any case remove or maintain a patient's health information resulting in potential discovery by the public. This would be a breach of patient privacy protections.

14. The proposed resource document sets out a new list for general compliance with stroke designation, which includes, among other things, new requirements for facilities to:
    a. Appropriately utilize telemedicine to enhance stroke care and improve outcomes.
    b. Identify a stroke program sponsor who is a member of the executive leadership at the facility.
    c. Identify a Stroke Medical Director and credential that person to treat stroke patients (the credentialing element is new).
    d. Identify a Stroke Program Manager who is a registered nurse and credential that person (again, the credentialing element is new).
    e. Develop contingency plans for vacancies in the Stroke Medical Director and Stroke Program Manager positions.
    f. Require appropriate participation by the stroke leadership team in RACs. *THA has a question as to what the abbreviation "SR" refers to on page 11, paragraph 8*.
    g. Have a transfer plan for stroke patients who require a higher level of care or specialty services.
    h. Define an individual charged with community outreach and education.
    i. Provide education to, and consultations with, area physicians.
    j. Provide stroke continuing education for staff and community members as identified by the performance improvement program to clinical staff, pre-hospital personnel and other appropriate personnel involved in stroke care.
    k. Have a public education program to address stroke prevention, identification and appropriate care.
    l. Coordinate with RAC and community stroke education activities.
    m. Ensure two-way communication with all pre-hospital EMS vehicles.

    THA appreciates TDSHS's clear description of the baseline designation requirements. THA's understanding is that individual stroke level designation requirements will be outlined in separate documents provided by the department, as individual specialty capabilities are struck from this portion of the resource document (e.g., neurosurgery capabilities and anesthesiology).

Again, thank you for the opportunity to comment on the 2019 Proposed Stroke Resource Document. Please do not hesitate to contact me directly with any questions.

Respectfully submitted,

D. Cameron Duncan III
Associate General Counsel
Texas Hospital Association