The existing rules for [§157.122](https://texreg.sos.state.tx.us/public/readtac$ext.TacPage?sl=R&app=9&p_dir=&p_rloc=&p_tloc=&p_ploc=&pg=1&p_tac=&ti=25&pt=1&ch=157&rl=122) and [§157.133](https://texreg.sos.state.tx.us/public/readtac$ext.TacPage?sl=R&app=9&p_dir=&p_rloc=&p_tloc=&p_ploc=&pg=1&p_tac=&ti=25&pt=1&ch=157&rl=133), in Texas Administrative Code Title 25, Chapter 157, Subchapter G are being repealed entirely. This draft includes the new rules for §157.122 and §157.133.

TITLE 25 HEALTH SERVICES

PART 1 DEPARTMENT OF STATE HEALTH SERVICES

CHAPTER 157 EMERGENCY MEDICAL CARE

SUBCHAPTER G EMERGENCY MEDICAL SERVICES TRAUMA SYSTEMS

§157.122. Trauma Service Areas.

(a) Trauma service areas (TSAs) are established for effective coordination, oversight, system development and enhancements, and delivery of trauma, stroke, perinatal, acute care, disaster response, and emergency medical services in geographical regions consistent with national standards.

(b) Texas is geographically divided into defined TSAs. Each TSA shall:

(1) contain no fewer than three Texas counties;

(2) use county borders to geographically define the TSA boundaries; and

(3) have at least one designated trauma facility within its boundaries that has or exceeds the advanced Level III trauma facility designation requirements as defined in §157.125 of this title (relating to Requirements for Trauma Facility Designation).

(c) The department shall maintain the current list of counties included in each TSA and made available on the department’s website: dshs.texas.gov.

(d) The realignment of a county to a different TSA may be initiated by the department or at the request of the Regional Advisory Council (RAC), provided the transferring county is contiguous to the county in the receiving TSA.

(1) The requesting RAC shall submit a request to the Director of EMS/Trauma Systems Section specifying:

(A) reasons for realignment request such as a decrease in emergency medical services (EMS) transport time, access to higher levels of care, or access to additional resources;

(B) existing patient routing patterns used by both EMS providers and health care facilities, including distances and transport times involved in this patient routing;

(C) a list of all health care facilities and all first responder organizations, EMS providers, and county governments affected by the requested realignment; and

(D) documentation that the RAC of the receiving TSA agrees with the proposed re-alignment.

(2) The requesting RAC shall forward copies of the request to all impacted health care facilities’ chief executive officer, first responder organizations, EMS provider medical directors, and county governments.

(3) The department evaluates the re-alignment request based on the impact to patient care, including transport times, access to higher levels of care facilities, or resources.

§157.133. Requirements for Stroke Facility Designation.

(a) The department ensures that stroke facility designation promotes the goal, objective, and purpose of the stroke system.

(1) The goal of the stroke system is to reduce the morbidity and mortality of the stroke victim, subsequently referred to as a stroke patient.

(2) The objective of the stroke system is to improve the overall care of stroke patients by rapidly recognizing the signs of a stroke and transporting the potential stroke patient to the appropriate level of stroke facility, in the appropriate time, with the appropriate level of resources.

(b) The department determines requirements for the levels of stroke facility designation. Hospitals seeking stroke facility designation must demonstrate compliance to department-approved national stroke standard requirements and have the compliance validated by a department-approved survey organization. The hospital must submit:

(1) a completed application for the stroke facility designation;

(2) the site survey summary to include the medical record reviews;

(3) the certificate provided by the survey organization; and

(4) the fee.

(c) Minimum requirements for stroke designation.

(1) Health care facilities eligible for stroke designation include:

(A) a hospital in Texas, licensed or otherwise meeting the description in accordance with Chapter 133 of this title (relating to Hospital Licensing);

(B) a hospital owned and operated by the State of Texas; or

(C) a hospital owned and operated by the federal government in Texas.

(2) Each hospital shall demonstrate the capability to provide stabilization and transfer or treatment for an acute stroke patient.

(3) Each hospital operating on a single hospital license with multiple locations (multi-location license) may apply for stroke designation separately by physical location for each designation.

(A) Hospital departments or services within a hospital shall not be designated separately.

(B) Hospital departments located in a separate building, which is not contiguous with the designated facility, shall not be designated separately.

(C) Each emergency department of a hospital operating on a single hospital license must provide the same level of emergency stroke care for patients.

(D) Stroke designation is issued for the physical location and to the legal owner of the operations of the designated facility and is non-transferable.

(4) If applicable, the designated stroke facility shall include stroke patients received at the non-contiguous departments in the facility’s stroke database and stroke performance improvement process.

(d) The four levels of stroke designation and the requirements for each are:

(1) Comprehensive (Level I) stroke designation. The hospital must meet the department-approved national stroke standards of care for a Comprehensive Stroke Center, participate in the hospital’s Regional Advisory Council (RAC) and regional stroke plan, and submit data to the department as requested.

(2) Advanced (Level II) stroke designation. The hospital must meet the department-approved national stroke standards of care for a non-Comprehensive Thrombectomy Stroke Center, participate in the hospital’s RAC and regional stroke plan, and submit data to the department as requested.

(3) Primary (Level III) stroke designation. The hospital must meet the department-approved national stroke standards of care for a Primary Stroke Center, participate in the hospital’s RAC and regional stroke plan, and submit data to the department as requested.

(4) Acute Stroke-Ready (Level IV) stroke designation. The hospital must meet the department-approved national stroke standards of care for an Acute Stroke-Ready Center, participate in the hospital’s RAC and regional stroke plan, and submit data to the department as requested.

(e) Designation of a hospital as a stroke facility is valid for the length of the approved stroke survey organization’s stroke certification.

(f) A hospital seeking stroke facility designation must undergo an onsite or virtual survey as outlined in this section.

(1) The hospital is responsible for scheduling a stroke designation survey through a department-approved survey organization.

(2) The hospital notifies the department of the stroke designation survey date.

(3) The hospital is responsible for expenses associated with the stroke designation survey.

(4) The hospital does not accept surveyors with any conflict of interest. If a conflict of interest is present, the hospital must decline the assigned surveyor through the surveying organization. A conflict of interest exists when the surveyor has a current or past relationship with the hospital or key hospital staff members. The conflict of interest includes a previous working relationship, residency training, or participation in a consultation program for the hospital within the past five years.

(5) The department, at its discretion, may appoint an observer to accompany the survey team, with the observer costs borne by the department.

(6) The survey team evaluates the hospital’s compliance with the department-approved national stroke standards of care requirements and documents all noncompliance issues identified in the survey report and patient care reviews.

(7) The hospital shall provide the survey team access to records regarding Quality Assessment and Performance Improvement (QAPI) program to include peer review activities related to the stroke patient. Failure to provide access to these records will result in a determination by the department that the hospital seeking stroke facility designation is not in compliance with Texas Health and Safety Code, Chapter 733, and the rules in this chapter.

(g) A hospital seeking stroke facility designation must submit a completed application packet.

(1) The completed application packet includes:

(A) an accurate and complete stroke designation application for the requested level of designation;

(B) full payment of the non-refundable, non-transferrable designation fee;

(C) the documented stroke designation survey summary report that includes the requirement compliance findings and the medical record summaries, and the report is submitted to the department no later than 60 days after the stroke site survey date;

(D) the stroke certificate issued by the survey organization;

(E) if required by the department, a plan of correction (POC) that addresses all requirements with identified non-compliance findings in the survey report and the POC shall include:

(i) a statement of the cited non-compliant requirement;

(ii) a statement describing the corrective action by the facility seeking stroke facility designation to ensure compliance with the defined requirement;

(iii) the title of the individuals responsible for ensuring the corrective actions are implemented;

(iv) the date the corrective actions will be implemented;

(v) how the corrective actions will be monitored;

(vi) supporting documentation of the requirement reaching compliance; and

(vii) corrective actions will be implemented within 60 days from the date the facility seeking stroke facility designation received the official survey summary report;

(F) written evidence of participation in the applicable RACs; and

(G) any subsequent documents requested by the department.

(2) If a hospital seeking stroke facility designation fails to submit the required application documents and fee listed in paragraph (1)(A) – (G) of this subsection, the application will not be processed.

(3) The stroke facility designation renewal process, a request to change the level of designation, or a change in ownership requiring re-designation follows the same requirements outlined in paragraph (1)(A) – (G) of this subsection.

(A) The hospital will submit the required documents described in paragraph (1)(A) – (G) of this subsection, to the department no later than 90 days before the facility’s stroke designation expiration date.

(B) The hospital will submit the stroke designation fee in full payment with the required application documents.

(4) The hospital has the right to withdraw its application for stroke facility designation any time before being recommended for designation by the department.

(5) The hospital must seek renewal of its stroke facility designation 90 days before the expiration date of its facility’s stroke designation. The facility’s stroke designation will expire if the facility fails to provide a complete stroke designation application packet to the department by its current designation’s expiration date.

(6) The stroke designation application packet, in its entirety, must be written as an element of the facility's QAPI program and subject to confidentiality as described in Texas Health and Safety Code, §773.095.

(7) The department reviews the application packet to determine the stroke facility designation recommendation.

(8) The department defines the final stroke facility designation level awarded to the hospital and this designation level may be different than the level requested based on the stroke survey designation summary report.

(9) If the department determines the hospital meets the requirements for stroke facility designation, the department provides the hospital with a designation award letter and a designation certificate.

(A) The hospital shall display its stroke facility designation certificate in a public area of the licensed premises that is readily visible to patients, employees, and visitors.

(B) The hospital shall not alter the stroke facility designation certificate. Any alteration voids stroke designation for the remainder of that designation period.

(h) If a hospital disagrees with the department's decision regarding its designation status, the hospital has a right to a hearing, in accordance with Texas Government Code, Chapter 2001.

(i) Exceptions and Notifications

(1) A designated stroke facility must provide written notification of any temporary event or decision preventing the facility from complying with requirements of its current stroke designation level. This notification shall outline the stroke facility requirements that the facility is not able to maintain compliance and be provided to the following:

(A) all emergency medical services (EMS) providers that transfer stroke patients to or from the designated stroke facility;

(B) the health care facilities to which it customarily transfers-out or transfers-in stroke patients;

(C) applicable RACs; and

(D) the department.

(2) If the designated stroke facility is unable to comply with requirements to maintain its current designation status, it shall submit to the department a POC as described in subsection (g)(1)(E)(i) - (vii) of this section, and a request for a temporary exception to the requirements. Any request for an exception shall be submitted in writing from the chief executive officer of the facility and define the facility’s plan of correction with a timeline to become compliant with the stroke facility requirements. The department shall review the request and the POC, and either grant the exception, with a specific timeline based on the public interest, or deny the exception. If the facility is not granted an exception, or it is not compliant to the requirements at the end of the exception period, the department shall elect one of the following:

(A) re-designate the facility at the level appropriate to its revised capabilities; or

(B) accept the facility’s surrender of its stroke facility designation certificate and designation award letter.

(j) An application for a higher or lower level of stroke facility designation may be submitted to the department at any time.

(1) A designated stroke facility that is increasing its stroke capabilities may choose to apply for a higher level of designation at any time. The facility must follow the designation process as described in subsection (g)(1)(A) – (G) of this section to apply for the higher level.

(2) A designated stroke facility that is unable to maintain compliance with the facility’s current level of stroke designation may choose to apply for a lower level of designation at any time.

(k) Before relinquishing its stroke facility designation, the facility shall provide 30 days written, advance notice of the relinquishment to the department, the applicable RACs, EMS providers, and health care facilities in which customarily transfer-out or transfer-in stroke patients.

(l) A hospital shall not use the terms "stroke facility," "stroke hospital," "stroke center," "comprehensive stroke center," “advanced stroke center,” "primary stroke center," "acute stroke ready hospital,” acute stroke ready center," or similar terminology in its signs or advertisements or in the printed materials and information it provides to the public, unless the hospital is currently designated at that level of stroke facility.

(m) The department has the right to review, inspect, evaluate, and audit all stroke patient records, stroke multidisciplinary QAPI program documents, and peer review activities As well as, any other documents relevant to stroke care in a designated stroke facility or facility seeking stroke facility designation at any time to verify compliance with the Texas Health and Safety Code, Chapter 773 and this section.

(n) The department maintains confidentiality of such records to the extent authorized by Texas Government Code, Chapter 552.

(o) Stroke designation site review of the hospital applying for stroke facility designation will be scheduled in-person or virtually by the survey organization or by the department when deemed appropriate.

(p) The department may deny, suspend, or revoke the designation if a designated stroke facility ceases to provide services to meet or maintain compliance with the requirements of this section or if it violates the Chapter 133 of this title, concerning requirements resulting in enforcement action or an agreed order.