

§157.133. Requirements for Stroke Facility Designation.

- (a) ~~General Provisions. The goal of the A-strong-stroke system for stroke survival is needed in the state's communities in order to reduce the morbidity and mortality of the stroke patient. The objective of the stroke system is to treat stroke patients in a timely manner and to improve the overall treatment and survival of stroke patients. The state stroke system will improve the overall care of stroke patients by rapidquick~~ identification, ~~timely triage~~, transport to and treatment in an appropriate ~~designated~~ stroke ~~treatment~~ facility. The purpose of this section is to set forth the requirements for a healthcare facility to become a designated stroke facility.

- (1) The Department of State Health Services (department) shall determine the designation level for each ~~facility by physical~~ location, based on, but not limited to, the location's own resources and levels of care capabilities; ~~Trauma Service Area (TSA) capabilities~~; and compliance with the ~~essential criteria and standard~~ requirements outlined in this section. ~~The final determination of the level(s) of designation may not be the level(s) requested by the facility.~~

- (2) The ~~Office of~~ Emergency Medical Services (EMS)/Trauma Systems ~~Section Coordination (office)~~ shall recommend to the Commissioner of the Department of State Health Services (commissioner) the stroke designation of a facility at the level ~~the office~~ it deems appropriate.

- (3) Facilities eligible for stroke designation include:

- (A) ~~a~~A hospital in the State of Texas, licensed or otherwise meeting the description in accordance with Texas Administrative Code (TAC) Chapter 133 Hospital Licensing; or
- (B) a hospital owned and operated by the State of Texas; or
- (C) a hospital owned and operated by the federal government, ~~and~~

- (4) Each facility shall ~~demonstrate~~have the capability to provide stabilization and transfer or treatment for the acute stroke patient.

(54) Each facility operating on a single hospital license with multiple locations (multi-location license) shall be considered separately by physical location for designation.

(65) Designation does not include provider-based departments of the designated facility, which are not contiguous with the designated facility. If stroke patients are received by the facility, these patients must be included in the stroke registry and stroke performance improvement process.

(76) Departments or services within a facility shall not be separately designated.

(87) A stroke facility designation is issued for the physical location and to the legal owner of the operations of the facility. If a designated facility has a change of ownership or a change of the physical location of the facility, the designation shall not be transferred or assigned.

(98) The four levels of stroke designation and the requirements for each are as follows:

(A) Comprehensive (Level I). Stroke Facility designation, Level I—The facility shall meet the current Brain Attack Coalition recommendations or other recognized standards of practice of stroke care approved by the department for a Comprehensive Stroke Center; actively participates in the appropriate Regional Advisory Council (RAC); and submits data to the department as requested.

(B) Enhanced Primary (Level ??). The facility shall meet the current Brain Attack Coalition recommendations or other recognized standards of practice of stroke care approved by the department for an Enhanced Primary Stroke Center; actively participates in the appropriate RAC; and submits data to the department as requested.

(C) Primary Stroke Facility designation, (Level II).—The facility shall meet the current Brain Attack Coalition recommendations or other recognized standards of practice of stroke care approved by the department for a Primary Stroke Center; actively participates in the appropriate RAC; and submits data to the department as requested.

(D) Acute Stroke-Ready Facility designation, (Level III). The facility shall meet the current Brain Attack Coalition recommendations or other recognized standards of practice of stroke care approved by the department for Acute Stroke-Ready Centers~~Hospitals~~; actively

participates in the appropriate RAC; and submits data to the department as requested.

~~(109) Facilities seeking Comprehensive, Enhanced Primary, Primary or Acute Stroke Ready facility designation shall be surveyed through an organization approved by the office to verify that the facility is meeting relevant stroke facility standards.~~

~~(110) Facilities seeking Comprehensive, Enhanced Primary, Primary or Acute Stroke Ready facility designation shall be currently certified by a survey organization approved by the office for the applicable level of care for the designation level applied.~~

~~(1021) A designated stroke facility shall must:~~

~~(A) comply with the provisions within this rule, all current state and regional stroke system standards as described in this chapter, and all policies, guidelines, protocols, and procedures as set forth in the state stroke system plan; and~~

~~(B) — (B) continue to provide the resources, personnel, equipment, and responses for stroke care throughout the designation cycle as required by the its designation level.~~

~~(1012)~~ Designation of a ~~healthcare~~ facility as a stroke ~~center facility~~ is valid for three years.

~~(b) Survey Process.~~ A facility seeking designation shall undergo an onsite survey as outlined in this section.

~~(1) The facility shall be responsible for scheduling a stroke designation survey through an organization approved by the department office.~~

~~(2) The facility shall notify the department office of the survey date.~~

~~(3) The facility shall be responsible for any expenses associated with the survey.~~

~~(4) The department, at its discretion, may appoint an observer to accompany the survey team. In this event, the cost for the observer shall be borne by the department.~~

(5) The survey team shall evaluate the facility's compliance with Brain Attack Coalition recommendations or other recognized standards of practice of stroke care approved by the department and document any noncompliance in the survey report and/or patient case reviews. Each member of the survey teams described above shall:

(A) be currently employed at a designated trauma facility that is greater than 100 miles from the requesting facility;

(B) not be employed in the same TSA as the designating facility;

(C) not be a current or former employee of the facility that is the subject of the survey or of an affiliated facility;

(D) not be employed at a facility that is a primary transfer facility with the facility being surveyed;

(E) not survey the facility program and physical location on consecutive designation cycles;

(F) participate as members of the same Board;

(G) not have been requested by the facility; and

(H) not possess other potential conflict of interest between the surveyor or the surveyor's place of employment and the facility being surveyed.

~~(c)~~ Designation Process.

~~(1)~~ A facility seeking designation, shall submit a completed application packet ~~to include.~~

(1) The completed application packet will include:-

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

(B)

~~(B)~~ full payment of the non-refundable, non-transferrable ~~(\$100)~~ designation fee;

(C)

~~(C)~~—documentation copy of the stroke disease specific certification issued by the survey organization for the applicable level of requested designation;

(D)

~~(D)~~—a completed stroke designation survey report, including patient care reviews if required by the department, submitted ~~within no later than 120~~ days ~~from~~ the date of the survey;

~~(E)~~ If deficiencies, findings of not met, are identified on the survey report and patient care reviews, the facility shall develop and implement a plan of correction (POC). The POC shall include;

- (i) a statement of the cited deficiency;
- (ii) a statement describing the corrective action by the facility to ensure compliance with the requirement;
- (iii) the title of the individual(s) responsible for ensuring the corrective action(s) is implemented;
- (iv) the date by which the corrective action will be implemented, ~~within not to exceed~~ 90 days from the date the facility received the official survey report; and
- (v) how the corrective action(s) will be monitored.

(2) ~~(F)~~—Evidence of participation in the applicable RAC(s); and

(3) ~~(G)~~—any subsequent documents submitted to the department office by the date requested, ~~by the office~~.

~~(4)~~ Initial Designation. Initial designation includes facilities that are designating for the first time, those designating following a hiatus from the system, following a change of ownership, or a change in the physical location.

(A) The facility shall submit the documents described in subsection (b)(1)(A) – (G) above, to the department office within 120 days from the date of the survey;

(B3) If a ~~healthcare~~ facility seeking initial designation fails to meet the requirements in subsection (b)(1)(A) – (G) of this section, the application shall be ~~denied~~ considered withdrawn by the facility.

~~(5342) -Renewal of Designation- Renewal of designation occurs every three years an includes facilities designating at the same level and location.~~

- (A) ~~(A)~~ The facility applicant shall submit the documents described in subsection (b)(1)(A) – (G) above, to the department office within 90 days prior to the designation expiration date.

~~(B5A)~~ If a facility seeking renewal of designation fails to meet the requirements in subsection (b)(1)(A) – (G) of this section, the application shall be denied ~~considered withdrawn by the facility~~ and the original designation will expire on theits expiration date.

~~(6463) (e)~~ The facility shall have the right to withdraw its application at any time prior to being recommended for stroke facility designation by the department office.

~~(757)~~ It shall be necessary to repeat the stroke designation process as described in this section prior to expiration of a facility's designation or the designation expires.

~~(c) Survey Process. A facility seeking designation shall undergo an onsite survey as outlined in this section.~~

~~(1) The facility shall be responsible for scheduling a certification or stroke designation survey through an organization approved by the office.~~

~~(2) The facility shall notify the office of the date of the planned survey.~~

~~(3) The facility shall be responsible for any expenses associated with the survey.~~

~~(4) The office, at its discretion, may appoint an observer to accompany the survey team. In this event, the cost for the observer shall be borne by the office.~~

~~(865)~~ The stroke designation application packet, survey report and patient care reviews, in its entirety shall be part of a facility's Quality Assessment and Performance Improvement (QAPI) program and subject to confidentiality as articulated in the Health and Safety Code, §773.095.

~~(97d).~~ ~~Approval Process.~~

~~(A)~~ The ~~department~~office will review the entire application ~~and~~ the findings of the survey report ~~and patient case reviews~~ to determine the designation recommendation.

~~(10)~~ ~~(B2)~~ A recommendation for designation will be made to the commissioner if the facility meets the requirements for designation found in this section.

~~(11)~~ ~~(C3)~~ If the commissioner concurs with the recommendation to designate, the facility shall receive a letter of designation valid for ~~three~~3 years and a certificate of designation.

- (A) ~~(iA) Display:~~ The facility shall ~~prominently and conspicuously~~ display the stroke designation certificate and the current letter awarding designation from the Commissioner, in a public area of the licensed premises that is readily visible to patients, employees, and visitors.
- (B) ~~(iiB)~~ The stroke designation certificate shall be valid only when displayed with the current letter awarding designation.
- (C) ~~(iiiC)~~ If the facility closes or is ~~not longer~~ stroke designated, the certificate shall be returned to the ~~department~~office.
- (D) ~~(ivD) Alteration:~~ ~~T~~he stroke designation certificate and the award letter shall not be altered. Any alteration to either document voids stroke designation for the remainder of that designation cycle.

~~(e) The facility shall have the right to withdraw its application at any time prior to being recommended for stroke facility designation by the office.~~

~~(def)~~ ~~The~~ ~~department~~office shall post the current designation status of each facility on the ~~department~~office website.

(e) If a facility disagrees with the ~~department~~office's decision regarding its designation status, the facility has a right to a hearing, in accordance with the department's rules for contested cases, and Government Code, Chapter 2001.

(f) Exceptions and Notifications

(1) Written notification of an event or decision impacting the ability of a stroke facility to comply with designation ~~requirements~~criteria to maintain the current designation status, or to increase the stroke facility's capabilities that affect the region, shall be provided to the following:

(A) the emergency medical services (EMS) providers within 24 hours;

(B) the healthcare facilities to which it customarily transfers-out and/or transfers-in stroke patients within 24 hours;

(C) applicable RAC(s) within 24 hours; and

(D) the ~~department~~office within 5 days.

(2) If the facility is unable to comply with requirements to maintain the current designation status, it shall submit to the ~~department~~office a POC as described in (E)(i) - (v) of this section, and a request for a temporary exception to the ~~requirement(s)~~criteria. Any request for an exception shall be submitted in writing from an executive officer of the facility. The ~~department~~office shall review the request and the POC, and either grant or deny the exception. If the facility has not come into compliance at the end of the exception period, the ~~department~~office may at its discretion elect one of the following:

(A) allow the facility to request designation at the level appropriate to its revised capabilities;

(B) redesignate the facility at the level appropriate to its revised capabilities; or

(C) the facility may relinquish designation status.

~~(g) Upgrade or Downgrade of designation levels.~~

~~(1)~~ An application for a higher or lower level of designation may be submitted to the ~~department~~office at any time.

(12) A designated stroke facility that is increasing its stroke capabilities may choose to apply for a higher level of ~~stroke~~ designation at any time. It shall be necessary to repeat the designation process for the higher level.

(2) ~~(3)~~ A designated stroke facility that is unable to maintain compliance with the level of the current designation may choose to apply for a lower level of ~~stroke~~ designation at any time. It shall be necessary to repeat the designation process for the lower level. There shall be a desk review by the ~~department~~ office to determine if and when a full survey shall be required.

(h) ~~Relinquishment of designation.~~ If the facility chooses to relinquish its stroke designation, it shall provide ~~at least a 30-day~~ notice to the ~~department~~ office, the applicable RAC(s), the ~~EMS~~ emergency medical services providers, and facilities to which it customarily transfers out and/or transfers in stroke patients if it no longer provides stroke services ~~within 30 days~~.

(i) A ~~healthcare~~ facility may not use the terms "stroke facility," "stroke hospital," "stroke center," "comprehensive stroke center," ~~"enhanced primary stroke center," "primary stroke center," "acute stroke ready hospital,"~~ ~~acute support~~ stroke ready facility," or similar terminology in its signs or advertisements or in the printed materials and information it provides to the public unless the ~~healthcare~~ facility is currently designated ~~ass~~ that level of stroke facility according to the process described in this section.

(j) The department shall have the right to review, inspect, evaluate, and audit all stroke patient records, stroke multidisciplinary quality assessment and performance improvement ~~documents~~, and peer case review committee ~~documents~~ minutes 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 552, 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. Such inspections shall be scheduled by the ~~department~~ office when deemed appropriate. The department shall provide a survey report with results, for surveys conducted by or contracted for the department, to the facility.

~~(g) Designated stroke facilities failing to meet and/or maintain critical services outlined in this subsection, must provide notification about such failings~~

immediately to ~~emergency medical services(EMS) providers, the healthcare facilities from which it receives and to which it transfers stroke patients, its RAC and all other affected RACs;~~ and provide notification to the office within five days:

~~(1) neurosurgery capabilities (Level I);~~

~~(2) neurointerventional surgery capabilities (Level I);~~

~~(3) 24 hours a day procedural capabilities (Level I)~~

~~(4) neuro-critical care services (Level I, II)~~

~~(5) neurology capabilities (Level I, II);~~

~~(6) anesthesiology (Levels I);~~

~~(7) emergency physicians (all levels);~~

~~(8) stroke medical director (all levels);~~

~~(9) stroke program manager per individual facility (all levels); and~~

~~(10) stroke registry (all levels).~~

~~_(gh) If the facility chooses to apply for a lower level of stroke designation, it may do so at any time; however, it may be necessary to repeat the designation process. There shall be a deskpaper review by the office to determine if and when a full survey shall be required. The office may waive the survey process.~~

~~_(hi) If the facility chooses to relinquish or change its stroke designation, it must provide not less than 30 days notice to the RAC and the office.~~

~~(kj) _If a designated stroke facility ceases to provide services temporarily or intermittently to meet and/or maintain compliance with the requirements of this section or if it violates the TAC Chapter 133 Hospital Licensing requirements resulting in enforcement action or under an agreed order, the department may deny, suspend or revoke the designation.~~

~~_(l) _~~

A designated stroke facility shall:

(1) comply with all requirements within this rule;

- (2) maintain resources, personnel, equipment, and responses for stroke care throughout the designation cycle as required by the designation level;
- (3) utilize telemedicine appropriately to enhance stroke care and improve outcomes;
- (4) identify a program sponsor who is a member of the executive leadership at the facility;
- (5) identify a Stroke Medical Director who is responsible for the provision of stroke care and credentialed by the facility for the treatment of stroke patients;
- (6) identify Stroke Program Manager who is a Registered Nurse responsible for monitoring stroke patient care throughout the continuum of care and through discharge, and is credentialed by the facility;
- (7) have contingency plans to ensure the immediate continuation of an active stroke program in the event the Stroke Medical Director or the Stroke Program Manager position becomes vacant;
- (8) have provisions for consistent participation by the SMD, SPM, SR, or other members of the stroke program in the appropriate RAC(s);
- (9) have a transfer plan to expedite the transfer of stroke patients requiring a higher level of care or specialty services to include written triage, stabilization and transfer guidelines for the stroke patient that include consultation and transport services;
- (10) a defined individual to coordinate the facility's community outreach and education programs for the public and professionals is evident;
- (11) provide education to and consultations with physicians of the community and outlying areas; and
- (12) provide training programs in stroke continuing education provided by facility for staff and community members involved in stroke care based on needs identified from the PI program for:

- (i) staff physicians;
- (ii) nurses;
- (iii) Advanced Practice clinicians including Physician Assistants, Advanced Nurse Practitioners and Certified Registered Nurse Anesthetists;
- (iv) allied health personnel;
- (v) specialty and community physicians;
- (vi) pre-hospital personnel; and
- (vii) other appropriate personnel involved in stroke care.

(13) A public education program to address stroke prevention, identification and appropriate care identified within the facility's service area; and

(14) Coordination and/or participation in community and/or RAC stroke education activities.

(15) ensure two-way communication with all pre-hospital emergency medical services vehicles.

Email Comments To:

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