§157.133. Requirements for Stroke Facility Designation.

(a) General Provisions. A strong system for stroke survival is needed in the state's communities in order to treat stroke victims in a timely manner and to improve the overall treatment of stroke victims. The state stroke system will improve the overall care of stroke victims by quick identification, transport to and treatment in an appropriate stroke treatment facility. The purpose of this section is to set forth the requirements for a health care facility to become a designated stroke facility.

(1) The Department of State Health Services (department) shall determine the designation level for each 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.

(2) The Office of Emergency Medical Services (EMS)/Trauma Systems 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 deems appropriate.

(3) Facilities eligible for stroke designation include:

(A) A General Hospital, licensed or otherwise meeting the description (in accordance with Texas Administrative Code (TAC) Hospital Licensing Section 133.21).

(i) Each facility operating on a single general hospital license with multiple locations (multi-location license) shall be considered separately for designation. Designation does not include provider-based departments of the designated facility, which are not contiguous with the designated facility. Departments or services within a facility shall not be separately designated,

(ii) A general hospital owned and operated by the state of Texas, or

(iii) A general hospital owned and operated by the federal government.

(B) 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.

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

(i) Comprehensive Stroke Facility designation, Level I--The facility, including a stand-alone children's facility, meets the current Brain Attack Coalition recommendations; actively participates in the appropriate Regional Advisory Council (RAC); and submits data to the department as requested.

(ii) Primary Stroke Facility designation, Level II--The facility, including a stand-alone children's facility, meets the current Brain Attack Coalition recommendations; actively participates in the appropriate RAC; and submits data to the department as requested.

(iii) Support Stroke Facility designation, Level III--The facility, including a stand-alone children's facility, meets the Support Stroke Facility Designation Criteria for an accredited support stroke facility; actively participates in the appropriate RAC; and submits data to the department as requested.

(4) Facilities seeking Comprehensive, Primary or Support Stroke facility designation shall be surveyed through The Joint Commission's stroke certification program or other organization approved by the office to verify that the facility is meeting office-approved relevant stroke facility standards.

(5) A designated stroke facility 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, protocols, and procedures as set forth in the state stroke system plan; and

(B) continue to provide the resources, personnel, equipment, and response throughout the designation cycle as required by its designation level.

(6) Designation of a healthcare facility as a stroke facility is valid for three years.

(b) Designation Process.

(1) Designation Application submittal. The applicant shall submitthe following documents to the Office of EMS/Trauma systems corrdination (office):

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

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

(C) a completedstroke designation survey report, including patient care reviews, if required by the department, submitted not later than 180 days of the date of the survey;

(D) 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 person responsible for ensuring the correction(s) is implemented; and
(iv) The date by which the corrective action will be implemented, not to exceed 90 days from the date the facility received the official survey report.

(E) Evidence of participation in the applicable Regional Advisory Council; and

(F) any subsequent documents submitted by the date requested by the office;

(G) If a healthcare facility seeking initial designation fails to meet the requirements in subsection (f)(1)(A) – (F) of this section, the application shall be denied.

(2) Renewal of Designation. The applicant shall submit the documents described in subsection (f)(1)(A) – (F) above not less than 90 days prior to the designation expiration date.

(A) If a healthcare facility seeking renewal of designation fails to meet the requirements in subsection (f)(1)(A) – (F) of this section, the original designation will expire on its expiration date.

(3) It shall be necessary to repeat the stroke designation process as described in this section prior to expiration of a faciilty'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 designation survey through The Joint Commission's stroke certification program or other office approved organization.

(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.

(5) Level III facilities surveyed by an office approved agency shall have a surveyor that meets the following requirements:

(A) a registered nurse;

(B) currently employed at a designated stroke facility that is greater than 100 miles from the requesting facility;

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

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

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

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

(G) not have been requested by the facility;

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

(I) have at least 5 years of experience in the care of stroke patients;

(J) be currently employed in the management of or providing direct care services to stroke patients;

(K) have direct experience in the preparation for and successful completion of stroke facility designation for no fewer than 2 successful designation cycles;

(M) have current NIHSS certification;

(L) have successfully completed a DSHS-approved stroke facility site surveyor course and be successfully re-credentialed every 4 years; and

(N) have successfully completed a stroke designation surveyor internship.

(6) The surveyor(s) shall provide the facility with a written, signed survey report documenting their evaluation of the facility's compliance and the noncompliance with this section 157.133 by:

(A) reviewing documents, including a minimum of 10 closed medical records per surveyor;

(B) tour of the physical plant; and staff interviews to include:

(i) Chief Executive Officer;

(ii) Chief Nursing Officer;

(iii) Stroke Medical Director;

(iv) the stroke program sponsor who is a member of the Executive Leadership team.

(7) The written, signed survey report shall be forwarded to the facility within 30 calendar days of the completion date of the survey. The facility is responsible for forwarding a complete copy of the survey report, including patient care reviews, to the office if it intends to continue the designation process.

(8) The designation 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.

(A) If a facility seeking designation fails to meet the requirements of this section, the application shall be denied and, for facilities seeking re-designation, the original designation will expire on its expiration date.

(B)The office will review the entire application,the findings of the survey report and complete an analysis of patient care reviews to determine the designation recommendation. The recommendation for designation will be made to the commissioner if the facility meets the requirements for designation found in this section.

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

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

(1) 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.

(2) The stroke designation certificate shall be valid only when displayed with the current letter awarding designation.

(3) If the facility closes or loses stroke designation, the certificate shall be returned to the office.

(f) Alteration: the stroke designation certificate and the award letter shall not be altered. Any alteration to either document voids stroke designation for the remainder of that cycle.

(g) Designated stroke facilities failing to meet and/or maintain critical services outlined in this subsection, must provide notification about such failings within five days to the office, its RAC, plus other affected RACs, EMS providers, and the healthcare facilities from which it receives and to which it transfers stroke patients:

(1) neurosurgery capabilities (Level I);

(2) neurointerventional surgery capabilities (Level I);

(3) neuro-critical care services (Level I)

(4) 24 hours a day procedural capabilities (Level I)

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

(6) anesthesiology (Levels I);

(6) emergency physicians (all levels);

(7) stroke medical director (all levels);

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

(9) stroke registry (all levels).

(h) 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 paper review by the office to determine if and when a full survey shall be required. The office may waive the survey process.

(i) 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.

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

(k) The office may review, inspect, evaluate, and audit all stroke patient records, stroke interdisciplinary and peer review performance improvement committee minutes, and other documents relevant to stroke care in any designated stroke facility or applicant/healthcare facility at any time to verify compliance with the statute and this rule, including the designation criteria.

(l) 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 133 Hospital licensing requirements,resulting in enforcement action or under an agreed order, the department may deny, suspend or revoke the designation.

(m) RACs will develop a stroke system plan based on standard guidelines for comprehensive system development. The stroke system plan is subject to review and approval by the department.

(n) Program Requirements.

(1) Program Plan. The facility shall develop a written plan of the organized stroke program that includes the scope of services available to all stroke patients, defines the stroke patient population evaluated and/or treated, transferred, or transported by the facility that is consistent with accepted standards of practice of stroke care, and ensure the health and safety of patients.

(A) The written plan and the program policies and procedures shall be reviewed and approved by the facility's governing body. The governing body shall ensure that the requirements of this section are implemented and enforced.

(B) The written stroke program plan shall include at a minimum,:

(i) The standards of stroke practice that the program policies and procedures are based upon that are adopted, implemented and enforced for the stroke services it provides;

(ii) A periodic review and revision schedule for all stroke care policies and procedures;

(iii) Written protocols, developed with approval by the facility's medical staff, on:

(I) stroke team activation;

(II) identification of stroke team responsibilities during the stabilization of a stroke patient;

(III) triage, admission and transfer criteria of stroke patients;

(IV) protocols for the administration of thrombolytics and other approved stroke treatments;

(V) stabilization and treatment of stroke patients; and

(VI) facility capability for stroke patients will be provided to the Regional Advisory Council.

(iv) Written triage, stabilization and transfer guidelines for stroke patients;

(v) Provision for ongoing interdisciplinary stroke performance improvement and peer review committee meetings;

(vi) A quality assurance and performance improvement (QAPI) program to evaluate performance of all stroke services that is hospital wide, ongoing, data driven and outcomes based;

(vii) Provisions for staff education;

(viii) Provision for participation by the SMD, SPM, SR, or other members of the stroke program in the applicable trauma service area regional advisory council;

(ix) Requirements for minimal credentials for staff participating in the care of stroke patients;

(x) Plans to ensure the continuation of an active stroke program in the event that the Stroke Medical Director or the Stroke Program Manager position becomes vacant;

(xi) Identify a program sponsor who is a member of the executive leadership at the facility; and

(xii) Provisions for disaster response to include evacuation of stroke patients to appropriate levels of care and participation in the regional disaster plan

(o) Stroke Medical Director (SMD). There shall be an identified Stroke Medical Director (SMD) responsible for the provision of stroke care services and credentialed by the facility for the treatment of stroke patients.

(1) The Stroke Medical Director shall have responsibility for the overall clinical direction and oversight of the stroke program and the services provided;

(2) The responsibilities and authority of the Stroke Medical Director shall include but are not limited to:

(A) Reviewing credentials of medical staff requesting privileges on the stroke team and making recommendations to the Medical Executive Committee for either approval or denial of such privileges;

(B) Regularly and actively participating in the care of stroke patients;

(C) Developing and providing ongoing maintenance of treatment protocols based on current standards of stroke care;

(D) Developing and participating in the ongoing education of the physicians, nursing staff, ancillary staff, and prehospital staff in the care of the stroke patient;

(E) Ensuring that the quality assessment and performance improvement (QAPI) is specific to stroke care [stroke performance improvement and peer review program], is ongoing, is data driven and effective; SMD serves as chair of stroke performance improvement and peer review meetings;

(F) Maintaining participation in the applicable regional advisory council;

(G) Actively participates in a leadership role in the facility and community.

(H) Averages 8 hours of continuing stroke medical education (CME) annually; and

(I) Maintains active staff privileges as defined in the facility's medical staff bylaws

(p) Stroke Program Manager (SPM). There must be an identified Stroke Program Manager responsible for monitoring stroke patient care throughout the continuum of care and through discharge.

(1) The SPM:

(A) Is a Registered Nurse;

(B) Has successfully completed 8 hours of stroke continuing education in the last 12 months and has successfully completed an approved National Institutes of Health Stroke Scale (NIHSS) certification course;

(C) Shall have the responsibility for monitoring the clinical outcomes, direction and oversight of the stroke program.

(2) Each facility shall identify a Stroke Program Manager who is responsible for the integration of stroke nursing standards of care.

(A) The responsibilities and authority of the SPM shall include:

(i) the authority and responsibility to monitor the stroke patient care from Emergency Department (ED) arrival through stabilization and transfer to a higher level of care or admission through discharge;

(ii) Participation in a leadership role in the facility and community; and

(iii) Shall receive education and training designed for his/her role which provides essential information on the structure, process, organization and administrative responsibilities of a PI program to include stroke outcomes and performance improvement.

(q) Stroke Registrar. There shall be an identified Stroke Registrar who:

(1) has had appropriate training to maintain stroke registry information for the facility's stroke patients; and

(2) has the ability to identify stroke data for the stroke performance improvement program for the purpose of trending and tracking outcomes.

(r) Stroke Designation Levels.

(1) Comprehensive Stroke Facility designation, Level I--The facility, meets the current Brain Attack Coalition recommendations; actively participates on the appropriate Regional Advisory Council (RAC); and submits data to the department as requested.

(2) Primary Stroke Facility designation, Level II--The facility meets the current Brain Attack Coalition recommendations; actively participates on the appropriate RAC; and submits data to the department as requested.

(3) Support Stroke Level III Facility provides resuscitation, stabilization and assessment of the stroke victim and either provides the treatment or arranges for immediate transfer to a higher level of stroke care either a Comprehensive (Level I) Stroke Center or Primary (Level II) Stroke Center; provides ongoing educational opportunities in stroke related topics for health care professionals and the public; and implements stroke prevention programs.

(A) Physician Services.

(i) Emergency Medicine – this requirement may be fulfilled by a physician credentialed by the facility to provide emergency medicine and meets the following:

(I) Is an emergency physician who provides care to the stroke patient and must be appropriately approved through the stroke program and completes an average of 2 hours per year of stroke specific education; or

(II) Is a non-board certified/board eligible Emergency Medicine Physician providing stroke coverage must be current in Advanced Cardiac Life Support (ACLS) and completes 2 hours of stroke education annually; and

(III) Maintains compliance with stroke protocols;

(IV) Participates in the stroke PI program; and

(V) The designated physician liaison shall attend 50% or greater of interdisciplinary stroke care PI and peer review committee meetings.

(ii) Radiology - Capability to have computerized tomography (CT) images interpreted, per current stroke standards of care by a physician competent in neuro-imaging interpretation.

(A) Nursing Services for all critical care and patient care areas shall provide evidence of the following:

(i) All nurses caring for stroke patients throughout the continuum of care have ongoing documented knowledge and skills in stroke nursing for patients of all ages to include stroke specific orientation, annual clinical competencies, and continuing education;

(ii) Written standards on nursing care for the stroke patients for all units (i.e. ED, ICU, OR, PACU, general inpatient, rehabilitation) in the stroke facility must be implemented;

(B) Emergency Department.

(i) The published physician on-call schedule must be available in the Emergency Department (ED);

(ii) A physician with special competence in the care of the stroke patient who is on-call (if not in-house 24/7) shall be present in the ED within 30 minutes of request from outside the hospital and on patient arrival from inside the hospital;

(iii) The physician on duty or on-call to the ED shall be activated on EMS communication with the ED or after a primary assessment of patients who arrive to the ED by private vehicle or for patients who are exhibiting signs and symptoms of an acute stroke;

(iii) Documentation of nursing staff working in the Emergency Department (ED) and providing initial stabilization care for stroke patients have successfully completed and hold current credentials in Advanced Cardiac Life Support (ACLS); NIHSS (competency or certification); Dysphagia screening; and Thrombolytic therapy administration within 18 months of date of employment in the ED.

(iv) At least one registered nurse who has stroke care training shall participate in the initial stabilization of the stroke patient. Nursing staff required for initial stabilization is based on patient acuity and "last known well time";

(v) Nursing documentation for stroke patients is systematic and meets stroke registry guidelines;

(vi) Two-way communication with all pre-hospital emergency medical services;

(vii) Equipment. Equipment and services for the evaluation, resuscitation, and life support for stroke patients shall be available.

(I) The facility shall provide equipment and supplied in complicance with 25 TAC 133.41 Hospital Functions and Services(e)(3)-(4).

(II) Additional Required Emergency Departemnt Equipment.

a. Airway control and ventilation equipment including laryngoscope and endotracheal tubes of all sizes;

b. Mechanical ventilator;

c. Supraglottic airway management device;

d.Standard intravenous fluids and administration devices;

e.Drugs and supplies necessary to provide thrombolytic therapy;

(C) Radiological Capability.

(i) Computerized Tomography available 24 hours a day;

(ii) An in-house technician shall be available 24 hours a day or be on-call and present in the ED within 30 minutes of request.

(D) Clinical Laboratory Service. Laboratory Service. Laboratory services shall be in-house and available 24 hours per day

(E) Performance Improvement.

(i) A stroke program must have an Interdisciplinary Performance Improvement and peer review committee to perform the activites of the PI program.

(ii) A facility seeking initial designation must show at least 6 months of audits for all qualifying stroke patients with evidence of resolution.

(ii) A facility shall develop, implement, maintain, and evaluate an effective, ongoing, facility-wide, data-driven interdisciplinary quality assessment and performance improvement (QAPI) program. The program shall be individualized to the facility and meet the criteria and standards described in this section.

(iii) The program smust reflect the complexity of the facility's stroke program plan and the services involved. All facility services (including those services furnished under contract or arrangement) shall focus on decreasing the deviations from the stroke standards of care to ensure optimal stroke outcomes, patient safety standards and cost effective care.

(i) The stroke center must demonstrate that the facility staff evaluates the provision of stroke care and patient services, identify opportunities for improvement, develop and implement improvement plans, and evaluate the implementation of those plans until resolution is achieved. Evidence shall support that aggregate patient data, including identification and tracking of stroke patient complications or variances from standards of care, is continuously reviewed for trends by the stroke interdisciplinary team.

(v) The Interdisciplinary QAPI committee meetings must be documented and include the attendance, activities, actions and follow-up for identified matters.

(vi) A designated stroke facility must have an ongoing PI program that includes at a minimum:

(I) All stroke activations;

(II) All stroke admissions;

(III) All transfers out;

(IV) All stroke-related readmissions;

(V) All stroke deaths.

(VI) All thrombolytic administration.

(vii) Performance improvement activities must be:

(I) continuous and ongoing throughout the designation period;

(II) available for review on a rolling three year period; and

(III) available for review at all times.

(viii) Feedback regarding stroke patient transfers-out from the ED and in-patient units shall be requested from receiving facilities.

(ix) Receiving facilities shall provide feedback and outcome data to facilities that transfer stroke patients in to their facility.

(F) Stroke Registry - data shall be accumulated and downloaded to the department.

(G) Participation with the regional advisory council's (RAC) PI program, including adherence to regional guidelines, review of pre-hospital stroke care, submitting data to the RAC as requested to include summaries of transfer denials and transfers to hospitals outside the RAC

(H) Duration of and reasons for diversion must be documented and reviewed by the Stroke PI program

(I) Regional Stroke System.

(i) Must participate in the regional stroke system ; and

(ii) Participates in the development of RAC transport guidelines for stroke patients, including destination and facility capability.

(J) Transfers.

(i) A process to expedite the transfer of a stroke patient to include written transfer protocols, written/verbal transfer agreements, and a regional stroke transfer plan for patients needing a higher level of care (Comprehensive or Primary Stroke Center); and

(ii) A system for establishing an appropriate landing zone in close proximity to the facility (if rotor wing services are available.)

(K) Public Education and Stroke Prevention.

(i) A public education program to address signs and symptoms of a stroke, activation of 911, stroke risk factors, and stroke prevention; and

(ii) Coordination and/or participation in community, RAC, and/or a Comprehensive/Primary Stroke Center stroke prevention activities.

(L) Training Programs. Formal programs in stroke continuing education provided by facility for staff based on needs identified from the Stroke Interdisciplinary QAPI program for:

(i) Staff physicians;

(ii) Nurses;

(iii) Allied health personnel, including advanced practice providers (physician assistants and nurse practitioners);

(iv) Community physicians; and

(v) Prehospital personnel.