

Legend: (Proposed New Rule)
Regular Print = Proposed new language

§157.133. Requirements for Stroke Facility Designation.

(a) The Office of Emergency Medical Services (EMS)/Trauma Systems Coordination (office) shall recommend to the Commissioner of the department (commissioner) the designation of an applicant/healthcare facility (facility) as a stroke facility at the level(s) for each location of a facility the office deems appropriate.

(1) Comprehensive Stroke Facility designation, Level I--The facility, including a free-standing children's facility, meets the current Brain Attack Coalition essential criteria for an accredited comprehensive stroke center; 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, including a free-standing children's facility, meets the current Brain Attack Coalition essential criteria for an accredited primary stroke center; actively participates on the appropriate RAC; and submits data to the department as requested.

(3) Support Stroke Facility designation, Level III--The facility, including a free-standing children's facility, meets essential criteria for an accredited support stroke facility; actively participates on the appropriate RAC; and submits data to the department as requested.

(b) A healthcare facility is defined under these rules as a single location where inpatients receive hospital services or each location if there are multiple buildings where inpatients receive hospital services and are covered under a single hospital license. Each location shall be considered separately for designation.

(c) The designation process shall consist of three phases.

(1) First phase. The application phase begins with submitting to the office a timely and sufficient application for designation as a stroke facility and ends when the survey report is received by the office.

(2) Second phase. The review phase begins with the office's review of the survey report and ends with its recommendation to the commissioner whether or not to designate the facility.

(3) Third phase. The final phase begins with the commissioner reviewing the recommendation and ends with his/her final decision.

(d) Designation of a healthcare facility as a stroke facility is valid for two years.

(e) 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.

(f) A timely and sufficient application for a facility seeking initial designation shall include:

(1) the department's current "Complete Application" for the requested level of stroke facility designation, with all fields correctly and legibly filled-in and all requested documents attached, hand-delivered or sent by postal services to the office;

(2) full payment of the non-refundable \$100 designation fee enclosed with the submitted "Complete Application" form;

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

(4) a stroke designation survey completed within one year of the date of the receipt of the application by the office; and

(5) a complete survey report, including patient care reviews, that is within 180 days of the date of the survey and is hand-delivered or sent by postal services to the office.

(g) If a healthcare facility seeking initial designation fails to meet the requirements in subsection (f)(1) - (5) of this section, the application shall be denied.

(h) A timely and sufficient application for a stroke facility seeking redesignation shall include:

(1) the department's current "Complete Application" form for the requested level of stroke facility designation, with all fields correctly and legibly filled-in and all requested documents attached, hand-delivered or sent by postal services to the office one year or greater before the designation expiration date;

(2) full payment of the non-refundable \$100 designation fee enclosed with the submitted "Complete Application" form;

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

(4) a complete survey report, including patient care reviews, that is within 180 days of the date of the survey and is hand-delivered or sent by postal services to the office no less than 60 days prior to the designation expiration date.

(i) If a healthcare facility seeking redesignation fails to meet the requirements outlined in subsection (h)(1) - (4) of this section, the original designation will expire on its expiration date.

(j) The office's analysis of the submitted "Complete Application" form may result in recommendations for corrective action when deficiencies are noted and shall also include a review of:

(1) evidence of current participation in RAC/regional system planning; and

(2) the completeness and appropriateness of the application materials submitted, including the submission of a non-refundable application fee of \$100.

(k) Facilities seeking Comprehensive, Primary or Support stroke facility designation shall request a survey through The Joint Commission's stroke certification program or a comparable organization approved by the department.

(l) A designated stroke facility shall:

(1) 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

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

(m) Designated stroke facilities failing to meet and/or maintain critical essential criteria outlined in this subsection, shall 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) neurology capabilities (Level I, II);

(4) anesthesiology (Levels I);

(5) emergency physicians (all levels);

(6) stroke medical director (all levels);

(7) stroke nurse coordinator/program manager (all levels); and

(8) stroke registry (all levels).

(n) 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.

(o) If the facility chooses to relinquish or change its stroke designation, it shall provide at least 30 days notice to the RAC and the office.

(p) 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 or advertisements or in the 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.

(q) The office may review, inspect, evaluate, and audit all stroke patient records, stroke 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.

(r) If a designated stroke facility fails to meet and/or maintain standards, outlined herein, or if it violates the department hospital licensing regulations, the department may deny, suspend or revoke the designation.

(s) A RAC should 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.

(t) The department may review the RAC's stroke system plan to assure that:

(1) all counties within the trauma service area (TSA) have been included unless a specific county, or portion thereof, has been aligned within an adjacent system;

(2) all health care entities and interested specialty centers have been given an opportunity to participate in the planning process; and

(3) the following components have been addressed:

(A) stroke prevention;

(B) access to the system;

(C) communications;

(D) medical oversight;

(E) pre-hospital triage criteria;

(F) diversion policies;

(G) bypass protocols - guidelines for the emergency transport of patients, who are eligible within the timeframe for United States Food and Drug Administration (FDA) approved stroke care therapies, to the highest state designated stroke center;

(H) regional medical control;

(I) regional stroke treatment guidelines:

(i) guidelines consistent with current standards shall be developed, implemented, and evaluated;

(ii) individual agencies and medical directors may, and are encouraged, to exceed the minimum standards;

(iii) stroke patients will be cared for by health professionals with documented education and skill in the assessment and care of stroke throughout their pre-hospital and hospital course;

(iv) stroke patients will have their medical care, as documented by pre-hospital run forms and hospital charts, reviewed by the individual entity's medical director for appropriateness and quality of care; and

(v) stroke patients will have deviations from standard of care addressed through a documented stroke performance improvement process.

(J) facility triage criteria;

(K) inter-hospital transfers;

(L) planning for the designation of stroke facilities, including the identification of the comprehensive, primary, and support stroke facilities; and

(M) a performance improvement program that evaluates processes and outcomes from a system perspective.

(u) Department approval of the completed stroke system plan may qualify health care entities participating in the system to receive state funding for stroke care if funding is available.