

1 §157.133. Requirements for Stroke Facility Designation.

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

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12 (1) The Department of State Health Services (department) shall
13 determine the designation level for each location, based on, but not
14 limited to, the location's own resources and levels of care capabilities;
15 Trauma Service Area (TSA) capabilities; and compliance with the essential
16 criteria and standard requirements outlined in this section.

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

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23 (3) Health care facilities eligible for stroke designation include:

24 (A) A hospital in the state of Texas, licensed or otherwise meeting
25 the description (in accordance with Texas Administrative Code
26 (TAC) Chapter 133 Hospital Licensing; or

27 (B) a hospital owned and operated by the state of Texas, or

28 (C) a hospital owned and operated by the federal government; and

29 (D) Each facility shall have the capability to provide stabilization and
30 transfer or treatment for the acute stroke patient.

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32 (4) Each facility operating on a single hospital license with multiple
33 locations (multi-location license) shall be considered separately for designation.

34 (5) Designation does not include provider-based departments of the
35 designated facility, which are not contiguous with the designated facility.

36 (6) Departments or services within a facility shall not be separately
37 designated.

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

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

(i) Comprehensive Stroke Facility designation, Level I--The facility meets the current Brain Attack Coalition recommendations for Comprehensive Stroke Centers; 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 meets the current Brain Attack Coalition recommendations for Primary Stroke Centers; actively participates in the appropriate RAC; and submits data to the department as requested.

(iii) Acute Stroke-Ready Facility designation, Level III--The facility meets the current Brain Attack Coalition recommendations for Acute Stroke-Ready Hospitals; actively participates in the appropriate RAC; and submits data to the department as requested.

(9) Facilities seeking Comprehensive, 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.

(10) Facilities seeking Comprehensive, Primary or Acute Stroke-Ready facility designation shall be currently certified for the applicable level of care for the designation level applied.

(11) 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.

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

(b) Designation Process.

93 (1) Application Packet. A facility seeking designation, shall submit a
94 completed application packet to include:

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- 96 (A) An accurate and complete designation application form for the
97 appropriate level of designation;
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- 99 (B) full payment of the non-refundable, non-transferrable \$100
100 designation fee;
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- 102 (C) a copy of the disease specific certification issued by the survey
103 organization for the applicable level of designation;
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- 105 (D) a completed stroke designation survey report, including patient
106 care reviews if required by the department, submitted no later than 180 days of the date
107 of the survey;
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- 109 (E) If deficiencies, findings of not met, are identified on the survey
110 report and patient care reviews, the facility shall develop and implement a plan of
111 correction (POC). The POC shall include;
112 (i) A statement of the cited deficiency;
113 (ii) A statement describing the corrective action by the facility
114 to ensure compliance with the requirement;
115 (iii) The title of the individual(s) responsible for ensuring the
116 corrective action(s) is implemented;
117 (iv) The date by which the corrective action will be
118 implemented, not to exceed 90 days from the date the
119 facility received the official survey report; and
120 (v) How the corrective action(s) will be monitored.
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- 122 (F) Evidence of participation in the applicable Regional Advisory
123 Council; and
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- 125 (G) any subsequent documents submitted by the date requested by
126 the office.
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- 128 (H) If a healthcare facility seeking initial designation fails to meet the
129 requirements in subsection (f)(1)(A) – (G) of this section, the application shall be
130 denied.
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132 (2) Renewal of Designation. The applicant shall submit the documents
133 described in subsection (f)(1)(A) – (G) above, to the office not less than 90 days prior to
134 the designation expiration date.
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136 (A) If a facility seeking renewal of designation fails to meet the
137 requirements in subsection (f)(1)(A) – (G) of this section, the application shall be denied
138 and the original designation will expire on its expiration date.

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140 (3) It shall be necessary to repeat the stroke designation process as
141 described in this section prior to expiration of a facility's designation or the designation
142 expires.
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144 (c) Survey Process. A facility seeking designation shall undergo an onsite survey
145 as outlined in this section.
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147 (1) The facility shall be responsible for scheduling a certification or stroke
148 designation survey through an organization approved by the office.
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150 (2) The facility shall notify the office of the date of the planned survey.
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152 (3) The facility shall be responsible for any expenses associated with the
153 survey.
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155 (4) The office, at its discretion, may appoint an observer to accompany
156 the survey team. In this event, the cost for the observer shall be borne by the office.
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158 (5) The designation application, survey report and patient care reviews in its
159 entirety shall be part of a facility's quality assessment and performance improvement
160 (QAPI) program and subject to confidentiality as articulated in the Health and Safety
161 Code, §773.095.
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163 (d) Approval Process.
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165 (1) The office will review the entire application, the findings of the survey
166 report to determine the designation recommendation.
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168 (2) A recommendation for designation will be made to the commissioner if
169 the facility meets the requirements for designation found in this section.
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171 (3) If the commissioner concurs with the recommendation to designate, the
172 facility shall receive a letter of designation valid for 3 years and a certificate of
173 designation.
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175 (A) Display: The facility shall prominently and conspicuously display
176 the stroke designation certificate and the current letter awarding designation
177 from the Commissioner, in a public area of the licensed premises that is
178 readily visible to patients, employees, and visitors.
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180 (B) The stroke designation certificate shall be valid only when
181 displayed with the current letter awarding designation.
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183 (C) If the facility closes or is no longer stroke designated, the
184 certificate shall be returned to the office.

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186 (D) Alteration: the stroke designation certificate and the award letter
187 shall not be altered. Any alteration to either document voids stroke
188 designation for the remainder of that designation cycle.
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190 (e) The facility shall have the right to withdraw its application at any time prior to
191 being recommended for stroke facility designation by the office.
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193 (f) the office shall post the current designation status of each facility on the office
194 website.
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196 (g) Designated stroke facilities failing to meet and/or maintain critical services
197 outlined in this subsection, must provide notification about such failings immediately to
198 emergency medical services(EMS) providers, the healthcare facilities from which it
199 receives and to which it transfers stroke patients, its RAC and all other affected RACs;
200 and provide notification to the office within five days:
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202 (1) neurosurgery capabilities (Level I);

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

204 (3) 24 hours a day procedural capabilities (Level I)

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

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

207 (6) anesthesiology (Levels I);

208 (7) emergency physicians (all levels);

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

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

211 (10) stroke registry (all levels).
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214 (h) If the facility chooses to apply for a lower level of stroke designation, it may
215 do so at any time; however, it may be necessary to repeat the designation process.
216 There shall be a paper review by the office to determine if and when a full survey shall
217 be required. The office may waive the survey process.
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220 (i) If the facility chooses to relinquish or change its stroke designation, it must
221 provide not less than 30 days notice to the RAC and the office.
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230 (j) If a designated stroke facility ceases to provide services temporarily or
231 intermittently to meet and/or maintain compliance with the requirements of this section
232 or if it violates the TAC 133 Hospital licensing requirements, resulting in enforcement
233 action or under an agreed order, the department may deny, suspend or revoke the
234 designation.
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