

1 §157.133 Requirements for Stroke Facility Designation.

2 (a) The Department of State Health Services (department) will ensure that
3 Stroke Facility Designation promotes the goals, objectives, and purposes of
4 the stroke system.

5 (1) The goal of the stroke system is to reduce the morbidity and mortality
6 of the stroke patient.

7 (2) The objective of the stroke system is to improve the overall care of
8 stroke patients by rapid identification, timely triage, transport to and
9 treatment in an appropriate designated stroke facility.

10 (3) The purpose of this section is to set forth the requirements for a
11 healthcare facility to become a designated stroke facility.

12 (b) The Department of State Health Services (department) shall determine
13 the designation level for each facility by physical location, based on, but not
14 limited to, the current department recognized national stroke standards of
15 care, the location's own resources and level of care capabilities; and
16 compliance with the requirements outlined in this section.

17 (c) Minimum requirements for stroke designation

18 (1) Facilities eligible for stroke designation include:

19 (A) a hospital in the State of Texas, licensed or otherwise meeting the
20 description in accordance with Texas Administrative Code (TAC) Chapter 133
21 Hospital Licensing; or

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

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

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

27 (3) Each individual facility operating on a single hospital license with
28 multiple locations (multi-location license) shall apply for stroke designation
29 separately by physical location for designation.

30 (A) Departments or services within a facility shall not be designated
31 separately.

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

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

36 (4) The Facility shall include stroke patients received by the facility's non-
37 contiguous department in the facility stroke registry and stroke performance
38 improvement process.

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

41 (1) Comprehensive (Level I). The facility shall meet the current
42 department recognized national stroke standards of care for a
43 Comprehensive Stroke Center; participate in a Regional Advisory Council
44 (RAC) and regional stroke plan; and submit data to the department as
45 requested.

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46 (2) Advanced (Level II). The facility shall meet the current department
47 recognized national stroke standards of care for a non-Comprehensive
48 Thrombectomy Stroke Centers; participate in a RAC and regional stroke
49 plan; and submit data to the department as requested.

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50 (3) Primary (Level III). The facility shall meet the current department
51 recognized national stroke standards of care for a Primary Stroke Center;
52 participate in a RAC and regional stroke plan; and submit data to the
53 department as requested.

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54 (4) Acute Stroke-Ready (Level IV). The facility shall meet the current
55 department recognized national stroke standards of care for an Acute
56 Stroke-Ready Center; participate in a RAC and regional stroke plan; and
57 submit data to the department as requested.

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58 (e) Designation of a facility as a stroke center is valid based on the length of
59 the accrediting entity certification period.

60 (f) A facility seeking designation shall undergo an onsite survey as outlined
61 in this section.

62 (1) The facility shall be responsible for scheduling a stroke survey
63 through an organization recognized by the department.

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

81 (3) The facility shall be responsible for expenses associated with the
82 survey.

83 (4) The facility shall be responsible to accept surveyors with no conflict of
84 interest. If a conflict of interest is present, the facility shall request a
85 different surveyor through the surveying organization.

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

90 (6) The survey team shall evaluate facility compliance with current
91 department recognized national stroke standards of care and document any
92 noncompliance in the survey report and/or patient care reviews.

93 (7) failure to provide the survey team with access to records regarding
94 Quality Assessment and Performance Improvement (QAPI) will result in a
95 determination that the facility is not in compliance with the applicable law
96 and rules.

97 (g) A facility seeking designation, shall submit a completed application
98 packet.

99 (1) The completed application packet will include:

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

102 (B) full payment of the non-refundable, non-transferrable designation
103 fee of \$300;

104 (C) documentation of appropriate stroke certification issued by the
105 survey organization;

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

109 (E) a plan of correction (POC) shall address deficiencies identified on
110 the survey report or patient care reviews. The POC shall include:

111 (i) a statement of the cited deficiency;

Deleted: (5) Each member of the survey team shall: be currently employed at a designated stroke facility that is greater than 100 miles from the requesting facility; not be employed in the same Trauma Service Area (TSA) as the designating facility; not be employed at a facility that is a primary transfer facility with the facility being surveyed; and not have been requested by the facility.

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124 (ii) a statement describing the corrective action by the facility to
125 ensure compliance with the requirement;

126 (iii) the title of the individual(s) responsible for ensuring the
127 corrective action(s) is implemented;

128 (iv) the date the corrective action will be implemented;

129 (v) how the corrective action(s) will be monitored;

130 (vi) supporting documentation of completed corrections; and

131 (vii) corrective actions will be implemented within 90 days from the
132 date the facility received the official survey report.

133 (F) written evidence of participation in the applicable RAC(s); and

134 (G) any subsequent documents requested by the department.

135 (2) "Initial designation" applies to a facility designating for the first time,
136 designating at a different level, following a hiatus from designation, following
137 a change of ownership, or a change in the physical location.

138 (A) The facility shall submit the documents described in subsection
139 (g)(1)(A) – (G) above, to the department, no later than 120 days from the
140 date of the survey.

141 (B) If a facility seeking initial designation fails to meet the
142 requirements in subsection (g)(1)(A) – (G) of this section, the application
143 will not be processed.

144 (3) "Renewal of designation" applies to a facility applying at the same
145 level of designation and location.

146 (A) The facility shall submit the documents described in subsection
147 (g)(1)(A) – (G) above, to the department no later than 90 days prior to the
148 designation expiration date.

149 (B) A facility failing to meet the requirements in subsection (g)(1)(A) –
150 (G) of this section, the application will not be processed, and the original
151 designation will expire on the expiration date.

152 (4) The facility shall have the right to withdraw its application at any time
153 prior to being recommended for stroke facility designation by the
154 department.

155 (5) The facility shall repeat the stroke designation process as described in
156 this section prior to expiration of a facility's designation or the designation
157 expires.

158 (6) The stroke designation application packet, in its entirety, shall be
159 considered part of a facility's Quality Assessment and Performance
160 Improvement (QAPI) program and subject to confidentiality as articulated in
161 the Health and Safety Code, §773.095.

162 (7) The department will review the application packet to determine the
163 designation recommendation.

164 (8) The final designation level awarded to the facility may be different
165 than the level requested by the facility.

166 (9) If the department determines the facility meets the requirements for
167 designation, the department will provide the facility with an award letter and
168 a certificate of designation.

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

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174 (D) The facility shall not alter the stroke designation certificate. Any
175 alteration voids stroke designation for the remainder of that designation
176 cycle.

177 (h) The department shall maintain the current designation status of each
178 facility on the department website.

179 (i) If a facility disagrees with the department's decision regarding its
180 designation status, the facility has a right to a hearing, in accordance with
181 the department's rules for contested cases, and Government Code, Chapter
182 2001.

183 (j) Exceptions and Notifications

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Deleted: The department will provide successful renewal applicants with an award letter.

Deleted: and the current award letter from the Commissioner,

Deleted: (B) The stroke designation certificate shall be valid only when displayed with the current award letter.

Deleted: (C) If the facility closes or is not stroke designated, the facility shall return the certificate and current award letter to the department.

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198 (1) A designated facility must provide notification of a temporary event or
199 decision impacting the ability of a stroke facility to comply with designation
200 requirements to maintain the current designation status, or to increase the
201 stroke facility's capabilities that affect the region. This notice shall be
202 provided to the following:

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203 (A) the emergency medical services (EMS) providers and the
204 healthcare facilities to which it customarily transfers-out and/or transfers-in
205 stroke patients;

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206 (B) applicable RAC(s); and

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207 (C) the department.

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208 (2) If the facility is unable to comply with requirements to maintain the
209 current designation status, it shall submit to the department a POC as
210 described in subsection (g)(1)(E)(i) - (vii), and a request for a temporary
211 exception to the requirements. Any request for an exception shall be
212 submitted in writing from an executive officer of the facility. The department
213 shall review the request and the POC, and either grant or deny the exception
214 based on the public interest. If the facility has not come into compliance at
215 the end of the exception period, the department shall elect one of the
216 following:

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217 (A) designate the facility at the level appropriate to its revised
218 capabilities; or

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219 (B) accept the facility's surrender of its designation certification and
220 letter.

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221 (k) An application for a higher or lower level of designation may be
222 submitted to the department at any time.

223 (1) A designated stroke facility that is increasing its stroke capabilities
224 may choose to apply for a higher level of designation at any time. The
225 facility must follow the initial designation process to apply for the higher
226 level.

227 (2) A designated stroke facility that is unable to maintain compliance with
228 the level of the current designation may choose to apply for a lower level at
229 any time. There shall be a desk review by the department to determine if
230 and when a full survey shall be required.

241 (l) A facility relinquishing stroke designation shall provide 30 days advance
242 notice, before relinquishing its designation, to the department, the applicable
243 RAC(s), EMS providers and facilities which customarily transfer-out and/or
244 transfer-in stroke patients.

245 (m) A facility shall not use the terms "stroke facility," "stroke hospital,"
246 "stroke center," "comprehensive stroke center," "advanced stroke center,"
247 "primary stroke center," "acute stroke ready hospital," acute stroke ready
248 center," or similar terminology in its signs or advertisements or in the
249 printed materials and information it provides to the public, unless the facility
250 is currently designated as that level of stroke facility according to the
251 process described in this section.

252 (n) The department shall have the right to review, inspect, evaluate, and
253 audit all stroke patient records, stroke multidisciplinary quality assessment
254 and performance improvement documents, and any other documents
255 relevant to stroke care in any designated stroke facility or applicant facility
256 at any time to verify compliance with the statute and this rule.

257 (o) The department shall maintain confidentiality of such records to the
258 extent authorized by the Texas Public Information Act, Government Code,
259 Chapter 552, and consistent with current laws and regulations related to the
260 Health Insurance Portability and Accountability Act of 1996 and/or any other
261 relevant confidentiality law or regulation.

262 (p) Site reviews shall be scheduled by the department when deemed
263 appropriate.

264 (q) The department shall provide a site review report to the facility.

265 (r) If a designated stroke facility ceases to provide services to meet and/or
266 maintain compliance with the requirements of this section or if it violates the
267 TAC Chapter 133 Hospital Licensing requirements resulting in enforcement
268 action or under an agreed order, the department may deny, suspend, or
269 revoke the designation.

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271 Email Comments To:

272 DSHS.EMS-TRAUMA@dshs.texas.gov

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274 With subject line: Stroke Rules Comments