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1 A bill to be entitled

2 An act relating to certified stroke treatment centers;
3 providing legislative intent; providing definitions;
4 directing the Department of Health to adopt, by a
5 specified date, certain guidelines as minimal clinical
6 standards for stroke treatment centers; directing the
7 department to notify hospitals that are eligible to become
8 certified stroke treatment centers; requiring a hospital
9 wishing to become a stroke treatment center to file a
10 letter of intent; directing such hospitals to file
11 completed applications with the department by a specified
12 date; directing the department to issue certificates to
13 stroke treatment centers that meet the guidelines;
14 authorizing the department to issue provisional
15 certifications; providing that a stroke treatment center's
16 certification automatically expires 2 years after the date
17 of issuance; providing that a certification may be
18 renewed; limiting the certification to the hospital to
19 which it was issued; directing the department to post a
20 listing of certified stroke treatment centers on its
21 Internet website; requiring the department to mail the
22 list to certain persons and entities; requiring a hospital
23 to notify the department at least 6 months in advance of
24 its decision to terminate stroke treatment; providing an
25 exception; authorizing the department to collect stroke
26 registry data for certain purposes; prohibiting a person
27 from claiming that a facility is a stroke treatment center
28 unless the facility is certified as provided by law;
29 authorizing the department to inspect stroke treatment

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30 centers; requiring emergency medical services to transport
 31 identified stroke victims to certified stroke treatment
 32 centers; requiring the department to adopt rules;
 33 providing an effective date.

34
 35 WHEREAS, stroke is the third leading killer in the United
 36 States and in Florida, and

37 WHEREAS, stroke is also the leading cause of serious long-
 38 term disability in this state, and

39 WHEREAS, 165,000 people die from stroke in the United
 40 States every year, including 10,000 persons in this state, and

41 WHEREAS, 60 percent of death from strokes occurs in women,
 42 and

43 WHEREAS, approximately 4.5 million survivors of stroke are
 44 alive today, and as many as 25 percent are permanently disabled,
 45 and

46 WHEREAS, nearly 30 percent of all people who suffer a
 47 stroke are under age 65, and

48 WHEREAS, it is estimated that strokes cost the United
 49 States nearly \$50 billion a year in total costs, with direct
 50 costs estimated at \$28 billion, and

51 WHEREAS, the state Medicaid budget pays a significant share
 52 of the direct cost of stroke, and

53 WHEREAS, as the population ages, death and disability from
 54 stroke will increase dramatically if this state does not
 55 implement strategies that will improve the survival of victims
 56 of stroke in all communities across this state, and

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57 WHEREAS, emergency medical services may be transporting
 58 stroke victims to hospitals that are not properly equipped to
 59 provide timely and effective treatment for stroke victims, and

60 WHEREAS, many hospitals are not properly equipped to render
 61 timely and effective treatment for stroke victims, and

62 WHEREAS, many hospitals that treat stroke victims do not
 63 discharge stroke patients with the proper information and tools
 64 on how to prevent recurrent strokes, NOW, THEREFORE,

65

66 Be It Enacted by the Legislature of the State of Florida:

67

68 Section 1. Legislative intent.--

69 (1) The Legislature finds that rapid identification,
 70 diagnosis, and treatment of ischemic stroke can save the lives
 71 of stroke victims and in many cases can reverse paralysis,
 72 leaving them with few or no neurological deficits.

73 (2) The Legislature further finds that a strong system for
 74 stroke survival is needed in the state's communities in order to
 75 treat stroke victims in a timely manner and to improve the
 76 overall treatment of stroke victims. Therefore, the Legislature
 77 intends to construct an emergency treatment system in this state
 78 in order that stroke victims may be quickly identified and
 79 transported to and treated in appropriate stroke treatment
 80 facilities.

81 Section 2. Definitions.--As used in this act, the term:

82 (1) "Accrediting organization" means the Joint Commission
 83 on Accreditation of Healthcare Organizations, the American
 84 Osteopathic Association, the Commission on Accreditation of

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85 Rehabilitation Facilities, or the Accreditation Association for
 86 Ambulatory Health Care, Inc.

87 (2) "Certified stroke treatment center" or "stroke
 88 treatment center" means any hospital licensed under chapter 395,
 89 Florida Statutes, that meets the guidelines adopted by the
 90 department to provide minimum standards for the 24-hour-a-day,
 91 year-round emergency treatment of ischemic stroke. The term
 92 includes all levels of stroke treatment centers certified by the
 93 department, including primary and comprehensive stroke centers.

94 (3) "Comprehensive stroke center" means any hospital
 95 licensed under chapter 395, Florida Statutes, that meets the
 96 guidelines adopted by the department to treat stroke patients
 97 who require a high intensity of medical and surgical care. These
 98 standards shall include, but not be limited to, the hospital's
 99 meeting all criteria for a primary stroke center and having
 100 health care personnel available with specific expertise in
 101 neurosurgery and vascular neurology, advanced neuroimaging
 102 capabilities, surgical and endovascular techniques, and other
 103 specific infrastructure and programmatic elements such as an
 104 intensive care unit.

105 (4) "Department" means the Department of Health.

106 (5) "Hospital" means any establishment that:

107 (a) Offers services more intensive than those required for
 108 room, board, personal services, and general nursing care and
 109 offers facilities and beds for use beyond 24 hours by
 110 individuals requiring diagnosis, treatment, or care for illness,
 111 injury, deformity, infirmity, abnormality, disease, or
 112 pregnancy.

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113 (b) Regularly makes available, at a minimum, clinical
114 laboratory services, diagnostic X-ray services, and treatment
115 facilities for surgery or obstetrical care, or other definitive
116 medical treatment of a similar extent.

117
118 The term does not include an institution conducted by or for the
119 adherents of any well-recognized church or religious
120 denomination that depends exclusively upon prayer or spiritual
121 means to heal, care for, or treat any person.

122 (6) "Primary stroke center" means any hospital licensed
123 under chapter 395, Florida Statutes, that meets the guidelines
124 adopted by the department to provide minimum standards for the
125 24-hour emergency treatment of stroke victims. These standards
126 shall include, but not be limited to, the hospital's having on
127 duty acute stroke teams with the ability to administer
128 intravenous thrombolytics, the availability and interpretation
129 of computed tomography scans 24 hours each day, rapid laboratory
130 testing, and use of a stroke registry in order to monitor
131 performance of stroke care.

132 (7) "Validation inspection" means an inspection of the
133 premises of a certified stroke treatment center by the
134 department to assess whether a review by an accrediting
135 organization has adequately evaluated the certified stroke
136 treatment center according to the department's minimum
137 standards.

138 Section 3. Stroke treatment center hospitals;
139 certification guidelines.--The department shall adopt by rule
140 one or more sets of guidelines published by nationally
141 recognized stroke centers no later than January 1, 2005. The

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142 guidelines adopted by the department shall be the minimum
 143 clinical standards in this state for treating ischemic stroke
 144 patients. The department may adopt guidelines for certifying
 145 different levels of stroke treatment centers, including primary
 146 and comprehensive stroke centers.

147 Section 4. Certified stroke treatment centers; selection;
 148 quality assurance; records.--

149 (1)(a) The department shall annually notify each acute
 150 care general hospital in the state that the department is
 151 accepting letters of intent from any hospital that proposes to
 152 become a stroke treatment center. To be eligible for
 153 certification as a stroke treatment center, a hospital must
 154 state that its intent to operate as a stroke treatment center is
 155 consistent with the certification guidelines adopted by the
 156 department. Letters of intent must be postmarked by midnight on
 157 October 1 of each year.

158 (b) The department shall send an application package to
 159 any hospital submitting a letter of intent by October 15. The
 160 application package shall include instructions for submitting
 161 specified information to the department in order to become a
 162 stroke treatment center. The certification guidelines adopted by
 163 the department shall be the basis for these instructions.

164 (c) Completed applications from a hospital must be
 165 received by the department by April 1 of each year. The
 166 department shall review each application to determine whether
 167 the hospital's application is complete and whether the hospital
 168 meets the department's guidelines for certification as a stroke
 169 treatment center as either a primary or comprehensive stroke
 170 center.

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171 (d) On April 30 of each year, a hospital must be certified
 172 as a stroke treatment center if the hospital meets the
 173 requirements set forth in this act.

174 (e) The department may issue a provisional certification
 175 to a new stroke treatment center or to a renewing stroke
 176 treatment center that is in substantial compliance with this act
 177 and the rules of the department. A provisional certification may
 178 be granted for not more than 1 year and expires automatically at
 179 the end of its term. A provisional certification may not be
 180 renewed.

181 (f) A hospital may protest a decision made by the
 182 department based on the department's review of an application
 183 pursuant to this section and shall proceed as provided in
 184 chapter 120, Florida Statutes. A hearing held under this section
 185 shall be conducted in the same manner as provided in ss. 120.569
 186 and 120.57, Florida Statutes. The case filed under chapter 120,
 187 Florida Statutes, may combine all disputes between parties.

188 (2) A stroke treatment center's certification, unless
 189 sooner suspended or revoked, automatically expires 2 years after
 190 the date of issuance. The certification may be renewed
 191 biennially upon application by the stroke treatment center. The
 192 certification shall be renewed if the center continues to meet
 193 the requirements set forth in this act and in the rules adopted
 194 by the department. An application for renewal of a certification
 195 must be completed on forms provided by the department and must
 196 be received by the department 90 days before expiration of the
 197 current certification.

198 (3)(a) A stroke treatment center's certification is valid
 199 only for the hospital to which it was issued and may not be

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200 sold, assigned, or otherwise transferred, voluntarily or
 201 involuntarily, to any other hospital. A certification is valid
 202 only for the location for which it was originally issued.

203 (b) An application for a new certification is required if:

204 1. A majority of the ownership or the controlling interest
 205 of a stroke treatment center is transferred or assigned; or

206 2. A lessee agrees to undertake or provide services to the
 207 extent that legal liability for operation of the facility rests
 208 with the lessee.

209
 210 An application for certification showing these changes must be
 211 made at least 60 days before the date of the sale, transfer,
 212 assignment, or lease.

213 (4) A current list of all certified stroke treatment
 214 centers shall be published on the department's Internet website
 215 with a clearly marked link on the website's front page. The
 216 department shall send, by certified mail, the current list of
 217 certified stroke treatment centers to the medical directors of
 218 all emergency medical service providers, fire departments, and
 219 private ambulance companies in the state. Whenever the list
 220 changes, the revised list must be sent to the designated
 221 recipients as soon as possible.

222 (5)(a) Notwithstanding any provision of chapter 381,
 223 Florida Statutes, a hospital licensed under ss. 395.001-
 224 395.3025, Florida Statutes, that operates a certified stroke
 225 treatment center may not permanently terminate stroke treatment
 226 services without providing the department at least 6 months'
 227 written notice of its intent to terminate such services. The
 228 notice must be given to the department, to all hospitals and

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229 emergency medical service providers, and to the medical
 230 directors of emergency medical services located in the service
 231 area of the stroke treatment center.

232 (b) This subsection does not apply to a short-term
 233 unavailability of stroke treatment services. A hospital shall
 234 notify all local emergency medical service providers whenever a
 235 stroke treatment center is unable to provide stroke treatment
 236 services.

237 (6) Except as otherwise provided by law, the department or
 238 its agent may collect stroke registry data, as prescribed by
 239 rule of the department, for the purposes of evaluating stroke
 240 triage, evaluating transportation and treatment effectiveness,
 241 ensuring compliance with the standards of verification, and
 242 monitoring patient outcomes.

243 (7) An onsite visit by the department or its agent may be
 244 conducted at any reasonable time and may include, but need not
 245 be limited to, a review of records in the possession of a stroke
 246 treatment center, emergency medical service provider, or medical
 247 examiner regarding the care, transportation, examination, or
 248 treatment of stroke patients. A visit must be announced in
 249 advance and incorporated as a part of regular inspection of
 250 emergency medical services whenever possible.

251 Section 5. Prohibition; renewal, denial, modification,
 252 suspension, and revocation of certification.--

253 (1) A person may not advertise to the public, by way of
 254 any medium whatsoever, that a hospital is a stroke treatment
 255 center, a certified stroke treatment center, or a cerebral
 256 vascular specialty treatment facility unless the hospital has
 257 first been certified as required by law.

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258 (2) If the department finds that a stroke treatment center
 259 fails to comply with the requirements of this act or the rules
 260 adopted by the department, the department may deny, modify,
 261 suspend, or revoke the stroke treatment center's certification.

262 Section 6. Certification inspections of stroke treatment
 263 centers.--

264 (1) The department shall make, or cause to be made, any
 265 inspection or investigation of a stroke treatment center that it
 266 deems necessary, including:

267 (a) An inspection directed by the department.

268 (b) A validation inspection.

269 (c) A complaint investigation, including a full
 270 investigation of the certification of a stroke treatment center,
 271 which includes a review of all certification guidelines. All
 272 complaints received by the department are subject to review and
 273 investigation by the department.

274 (d) An investigation of a stroke treatment center's
 275 emergency access.

276 (2) The department shall accept, in place of its own
 277 periodic inspections for certification, the survey or inspection
 278 of an accrediting organization if the certification of the
 279 stroke treatment center is not provisional and the stroke
 280 treatment center authorizes release of, and the department
 281 receives, proof of certification by the accrediting
 282 organization. The department shall adopt by rule criteria for
 283 accepting proof of certification by an accrediting organization
 284 in place of the certification inspection conducted by the
 285 department.

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286 Section 7. Emergency medical service providers;
 287 transportation of stroke victims to stroke treatment centers.--

288 (1) Each emergency medical service provider licensed under
 289 chapter 401, Florida Statutes, shall transport identified stroke
 290 victims to a certified stroke treatment center, except as
 291 otherwise provided for in the provider's protocol for
 292 transporting stroke victims.

293 (2) All emergency medical service providers operating in
 294 the state must develop a transportation protocol detailing how
 295 identified stroke patients will be transported to designated
 296 stroke treatment center hospitals. Emergency medical service
 297 providers must provide a copy of their stroke transportation
 298 protocol to the department within 90 days after the effective
 299 date of this act. The department must keep the transportation
 300 protocols on file and make them available to any person upon
 301 request. If a provider's stroke transportation protocol is
 302 changed at any time, the new protocol must be filed with the
 303 department within 30 days after its implementation.

304 (3) The department shall adopt guidelines for identifying
 305 stroke victims. Each emergency medical service provider must
 306 develop a stroke triage protocol based on the published
 307 guidelines. The guidelines must include requirements of licensed
 308 emergency medical service providers for performing and
 309 documenting identification of stroke victims. Review of stroke
 310 triage protocols shall be conducted every 3 years by the
 311 department and shall be conducted through consultation with
 312 interested parties, including, but not limited to, each approved
 313 stroke center, physicians specializing in stroke care and
 314 emergency care, emergency medical service providers licensed

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315 under chapter 401, Florida Statutes, and the providers'
316 respective medical directors. The department shall make model
317 stroke triage protocols available to any person.

318 (4) The department shall adopt and enforce all rules
319 necessary to administer this section.

320 Section 8. This act shall take effect July 1, 2004.