

By Senator Fasano

11-1064A-04

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

1 provided by law; authorizing the department to  
2 inspect stroke treatment centers; requiring  
3 emergency medical services to transport  
4 identified stroke victims to certified stroke  
5 treatment centers; requiring the department to  
6 adopt rules; providing an effective date.

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8 WHEREAS, stroke is the third leading killer in the  
9 United States and in Florida, and

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

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

14 WHEREAS, 60 percent of death from strokes occur in  
15 women, and

16 WHEREAS, approximately 4.5 million survivors of a  
17 stroke are alive today, and as many as 25 percent are  
18 permanently disabled, and

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

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

24 WHEREAS, the state Medicaid budget pays a significant  
25 share of the direct cost of stroke, and

26 WHEREAS, as the population ages, death and disability  
27 from stroke will increase dramatically if this state does not  
28 implement strategies that will improve the survival of victims  
29 of stroke in all communities across this state, and

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1 WHEREAS, emergency medical services may be transporting  
2 stroke victims to hospitals that are not properly equipped to  
3 provide timely and effective treatment for stroke victims, and

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

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

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

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12 Section 1. Legislative intent.--

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

17 (2) The Legislature further finds that a strong system  
18 for stroke survival is needed in our communities in order to  
19 treat stroke victims in a timely manner and to improve the  
20 overall treatment of stroke victims. Therefore, the  
21 Legislature intends to construct an emergency treatment system  
22 in this state in order that stroke victims may be quickly  
23 identified and transported to and treated in appropriate  
24 stroke treatment facilities.

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

27 (1) "Accrediting organization" means the Joint  
28 Commission on Accreditation of Healthcare Organizations, the  
29 American Osteopathic Association, the Commission on  
30 Accreditation of Rehabilitation Facilities, or the  
31 Accreditation Association for Ambulatory Health Care, Inc.

1           (2) "Certified stroke treatment center" or "stroke  
2 treatment center" means any hospital licensed under chapter  
3 395, Florida Statutes, which meets the guidelines adopted by  
4 the department to provide minimum standards for the  
5 24-hour-a-day, year-round emergency treatment of ischemic  
6 stroke. The term includes all levels of stroke treatment  
7 centers certified by the department including primary and  
8 comprehensive stroke centers.

9           (3) "Comprehensive stroke center" means any hospital  
10 licensed under chapter 395, Florida Statutes, which meets the  
11 guidelines adopted by the department to treat stroke patients  
12 who require a high intensity of medical and surgical care.  
13 These standards shall include, but not be limited to, the  
14 hospital meeting all criteria for a primary stroke center and  
15 having health care personnel available with specific expertise  
16 in neurosurgery and vascular neurology, advanced neuroimaging  
17 capabilities, surgical and endovascular techniques, and other  
18 specific infrastructure and programmatic elements such as an  
19 intensive care unit.

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

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

22           (a) Offers services more intensive than those required  
23 for room, board, personal services, and general nursing care,  
24 and offers facilities and beds for use beyond 24 hours by  
25 individuals requiring diagnosis, treatment, or care for  
26 illness, injury, deformity, infirmity, abnormality, disease,  
27 or pregnancy; and

28           (b) Regularly makes available at least clinical  
29 laboratory services, diagnostic X-ray services, and treatment  
30 facilities for surgery or obstetrical care, or other  
31 definitive medical treatment of similar extent.

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2 The term does not include an institution conducted by or for  
3 the adherents of any well-recognized church or religious  
4 denomination that depends exclusively upon prayer or spiritual  
5 means to heal, care for, or treat any person.

6 (6) "Primary stroke center" means any hospital  
7 licensed under chapter 395, Florida Statutes, which meets the  
8 guidelines adopted by the department to provide minimum  
9 standards for the 24-hour emergency treatment of stroke  
10 victims. These standards shall include, but not be limited to,  
11 hospitals having on duty acute stroke teams with the ability  
12 to administer intravenous thrombolytics, the availability and  
13 interpretation of computed tomography scans 24 hours each day,  
14 rapid laboratory testing, and use of a stroke registry in  
15 order to monitor performance of stroke care.

16 (7) "Validation inspection" means an inspection of the  
17 premises of a certified stroke treatment center by the  
18 department to assess whether a review by an accrediting  
19 organization has adequately evaluated the certified stroke  
20 treatment center according to the department's minimum  
21 standards.

22 Section 3. Stroke treatment center hospitals;  
23 certification guidelines.--The department shall adopt by rule  
24 one or more sets of guidelines published by nationally  
25 recognized stroke centers no later than January 1, 2005. The  
26 guidelines adopted by the department shall be the minimum  
27 clinical standards in this state for treating ischemic stroke  
28 patients. The department may adopt guidelines for certifying  
29 different levels of stroke treatment including primary and  
30 comprehensive stroke centers.

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1           Section 4. Certified stroke treatment centers;  
2 selection; quality assurance; records.--

3           (1)(a) The department shall annually notify each acute  
4 care general hospital in the state that the department is  
5 accepting letters of intent from any hospital that proposes to  
6 become a stroke treatment center. To be eligible for  
7 certification as a stroke treatment center, a hospital must  
8 state that its intent to operate as a stroke treatment center  
9 is consistent with the certification guidelines adopted by the  
10 department. Letters of intent must be postmarked by midnight  
11 on October 1 of each year.

12           (b) The department shall send an application package  
13 to any hospital submitting a letter of intent by October 15.  
14 The application package shall include instructions for  
15 submitting specified information to the department in order to  
16 become a stroke treatment center. The certification guidelines  
17 adopted by the department shall be the basis for these  
18 instructions.

19           (c) Completed applications from a hospital must be  
20 received by the department by April 1 of each year. The  
21 department shall review each application to determine if the  
22 hospital's application is complete and whether the hospital  
23 meets the department's guidelines for certification as a  
24 stroke treatment center as either a primary or comprehensive  
25 stroke center.

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

29           (e) The department may issue a provisional  
30 certification to a new stroke treatment center or to a  
31 renewing stroke treatment center that is in substantial

1 compliance with this act and the rules of the department. A  
2 provisional certification may be granted for not more than 1  
3 year and expires automatically at the end of its term. A  
4 provisional certification may not be renewed.

5 (f) A hospital may protest a decision made by the  
6 department based on the department's review of an application  
7 pursuant to this section and shall proceed as provided in  
8 chapter 120, Florida Statutes. A hearing held under this  
9 section shall be conducted in the same manner as provided in  
10 ss. 120.569 and 120.57, Florida Statutes. The case filed under  
11 chapter 120, Florida Statutes, may combine all disputes  
12 between parties.

13 (2) A stroke center's certification, unless sooner  
14 suspended or revoked, automatically expires 2 years after the  
15 date of issuance. The certification may be renewed biennially  
16 upon application by the stroke treatment center. The  
17 certification shall be renewed if the center continues to meet  
18 the requirements set forth in this act and in the rules  
19 adopted by the department. An application for renewal of a  
20 certification must be received by the department 90 days  
21 before expiration of the current certification on forms  
22 provided by the department.

23 (3)(a) A stroke treatment center's certification is  
24 valid only for the hospital to which it was issued and may not  
25 be sold, assigned, or otherwise transferred, voluntarily or  
26 involuntarily, to any other hospital. A certification is valid  
27 only for the location for which it was originally issued.

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

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

4           2. A lessee agrees to undertake or provide services to  
5 the extent that legal liability for operation of the facility  
6 rests with the lessee.

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8 An application for certification showing these changes must be  
9 made at least 60 days before the date of the sale, transfer,  
10 assignment, or lease.

11           (4) A current list of all certified stroke treatment  
12 centers shall be published on the department's website with a  
13 clearly marked link on the website's front page. The  
14 department shall send, by certified mail, the current list of  
15 certified stroke treatment centers to the medical director of  
16 all emergency medical services providers, fire departments,  
17 and

18           (5) Except as provided in this subsection, property  
19 assessed under this section shall be assessed at just value as  
20 of January 1 of the year following a change of ownership.  
21 Thereafter, the annual changes in the assessed value of the  
22 property are subject to the limitations in subsections (1) and  
23 (2). For the purpose of this section, a change in ownership  
24 means any sale, foreclosure, or transfer of legal title or  
25 beneficial title in equity to any person, except as provided  
26 in this subsection. There is no change of ownership if:

27           (a) Subsequent to the change or transfer, the same  
28 person is entitled to the homestead exemption as was  
29 previously entitled and:

30           1. The transfer of title is to correct an error; or

31           2. The transfer is between legal and equitable title;



1           (b) The transfer is between husband and wife,  
2 including a transfer to a surviving spouse or a transfer due  
3 to a dissolution of marriage;

4           (c) The transfer occurs by operation of law under s.  
5 732.4015; or

6           (d) Upon the death of the owner, the transfer is  
7 between the owner and another who is a permanent resident and  
8 is legally or naturally dependent upon the owner. private  
9 ambulance companies in the state. Whenever the list changes,  
10 the revised list must be sent to the designated recipients as  
11 soon as possible.

12           (6)(a) Notwithstanding any provision of chapter 381,  
13 Florida Statutes, a hospital licensed under ss.  
14 395.001-395.3025, Florida Statutes, which operates a certified  
15 stroke treatment center may not permanently terminate stroke  
16 treatment services without providing the department at least 6  
17 months' written notice of its intent to terminate these  
18 services. The notice must be given to the department, to all  
19 hospitals and emergency medical service providers, and to the  
20 medical directors of emergency medical services located in the  
21 service area of the state treatment center.

22           (b) This subsection does not apply to a short-term  
23 unavailability of stroke treatment services. A hospital shall  
24 notify all local emergency medical services providers whenever  
25 a stroke treatment center is unable to provide stroke  
26 treatment services.

27           (7) Except as otherwise provided by law, the  
28 department or its agent may collect stroke registry data, as  
29 prescribed by rule of the department, for the purposes of  
30 evaluating stroke triage, evaluating transportation and  
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1 treatment effectiveness, ensuring compliance with the  
2 standards of verification, and monitoring patient outcomes.

3 (8) An onsite visit by the department or its agent may  
4 be conducted at any reasonable time and may include, but need  
5 not be limited to, a review of records in the possession of a  
6 stroke treatment center, emergency medical service provider,  
7 or medical examiner regarding the care, transportation,  
8 examination, or treatment of stroke patients. A visit must be  
9 announced in advance and incorporated as a part of regular  
10 inspection of emergency medical services whenever possible.

11 Section 5. Prohibition; renewal, denial, modification,  
12 suspension, and revocation of certification.--

13 (1) A person may not advertise to the public, by way  
14 of any medium whatsoever, that a hospital is a stroke  
15 treatment center, a certified stroke treatment center, or a  
16 cerebral vascular specialty treatment facility unless the  
17 hospital has first been certified as required by law.

18 (2) If the department finds that a stroke treatment  
19 center fails to comply with the requirements of this act or  
20 the rules adopted by the department, the department may deny,  
21 modify, suspend, or revoke the stroke treatment center's  
22 certification.

23 Section 6. Certification inspections of stroke  
24 treatment centers.--

25 (1) The department shall make, or cause to be made,  
26 any inspection or investigation of a stroke treatment center  
27 which it deems necessary, including:

28 (a) An inspection directed by the department.

29 (b) A validation inspection.

30 (c) A complaint investigation, including a full  
31 investigation of the certification of a stroke treatment

1 center, which includes a review of all certification  
2 guidelines. All complaints received by the department are  
3 subject to review and investigation by the department.

4 (d) An investigation of a stroke treatment center's  
5 emergency access.

6 (2) The department shall accept, in place of its own  
7 periodic inspections for certification, the survey or  
8 inspection of an accrediting organization if the certification  
9 of the stroke treatment center is not provisional and the  
10 stroke treatment center authorizes release of, and the  
11 department receives, proof of certification by the accrediting  
12 organization. The department shall adopt by rule criteria for  
13 accepting proof of certification by an accrediting  
14 organization in place of the certification inspection  
15 conducted by the department.

16 Section 7. Emergency medical service providers;  
17 transportation of stroke victims to stroke treatment  
18 centers.--

19 (1) Each emergency medical services provider licensed  
20 under chapter 401, Florida Statutes, shall transport  
21 identified stroke victims to a certified stroke treatment  
22 center, except as otherwise provided for in the provider's  
23 protocol for transporting stroke victims.

24 (2) All emergency medical services providers operating  
25 in the state must develop a transportation protocol detailing  
26 how identified stroke patients will be transported to  
27 designated stroke center hospitals. Emergency medical services  
28 providers must provide a copy of their stroke transportation  
29 protocol to the department within 90 days after this act  
30 becoming a law. The department must keep the transportation  
31 protocols on file and make them available to any person upon

1 request. If a provider's stroke transportation protocol is  
2 changed at any time, the new protocol must be filed with the  
3 department within 30 days after its implementation.

4 (3) The department shall adopt guidelines for  
5 identifying stroke victims. Each emergency medical services  
6 provider must develop a stroke triage protocol based on the  
7 published guidelines. The guidelines must include requirements  
8 of licensed emergency medical services providers for  
9 performing and documenting identification of stroke victims.  
10 Review of stroke triage protocols shall be conducted every 3  
11 years by the department and shall be conducted through  
12 consultation with interested persons, including, but not  
13 limited to, each approved stroke center; physicians  
14 specializing in stroke care and emergency care; emergency  
15 medical service providers licensed under chapter 401, Florida  
16 Statutes; and the providers' respective medical directors. The  
17 department shall make model stroke triage protocols available  
18 to any person.

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

21 Section 8. This act shall take effect July 1, 2004.  
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SENATE SUMMARY

Provides legislative intent with respect to certified stroke treatment centers. Directs the Department of Health to adopt certain stroke-center guidelines as minimal clinical standards. Directs the department to notify hospitals that might choose to become certified stroke treatment centers. Requires hospitals to file a letter of intent. Directs hospitals to file completed applications with the department. Directs the department to issue certificates to stroke treatment centers that meet the stroke-center guidelines. Authorizes the department to issue provisional certifications. Provides that a stroke center's certification automatically expires 2 years after the date of issuance. Provides that a stroke center's certification may be renewed. Limits a stroke center's certification to the hospital to which it was issued. Directs the department to post a listing of certified stroke treatment centers on its website and to mail the list to certain persons and entities. Requires a hospital to notify the department at least 6 months in advance of its decision to terminate stroke treatment. Authorizes the department to inspect stroke treatment centers. Requires emergency medical service providers to transport identified stroke victims to certified stroke treatment centers. (See bill for details.)