



## FULL ANALYSIS

### I. SUBSTANTIVE ANALYSIS

#### A. DOES THE BILL:

- |                                      |   |  |   |
|--------------------------------------|---|--|---|
| 1. Reduce government?                | Yes <input type="checkbox"/>            | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/>            |
| 2. Lower taxes?                      | Yes <input type="checkbox"/>            | No <input type="checkbox"/>            | N/A <input checked="" type="checkbox"/> |
| 3. Expand individual freedom?        | Yes <input type="checkbox"/>            | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/>            |
| 4. Increase personal responsibility? | Yes <input type="checkbox"/>            | No <input type="checkbox"/>            | N/A <input checked="" type="checkbox"/> |
| 5. Empower families?                 | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/>            | N/A <input type="checkbox"/>            |

For any principle that received a "no" above, please explain:

The bill creates additional governmental regulation in the form of creating a certification process for stroke treatment centers.

The bill limits hospital's individual freedom from advertising as a stroke treatment center without the "proper" designation as a certified stroke treatment center from the state.

#### B. EFFECT OF PROPOSED CHANGES:

##### STROKES

There are two types of strokes: **ischemic** and **hemorrhagic**.

There are 2 kinds of **ischemic** stroke: thrombotic stroke and embolic stroke. Together, the two types of ischemic stroke account for about 80% of all strokes.

Thrombotic stroke, the most common type, happens when a blood clot (called a thrombus) blocks the blood flow to parts of the brain. A thrombus may form in an artery affected by atherosclerosis. Atherosclerosis is a condition in which the artery lining becomes thickened and narrowed by plaque. Plaque is made of fat, cholesterol, fibrin (a clotting material), and calcium. As plaque builds up in the arteries, blood flows slower and less smoothly, which can lead to clotting. A vessel narrowed by atherosclerosis is more likely to be blocked by a clot, stopping the blood flow. Thrombotic strokes usually happen at night or in the early morning. A transient ischemic attack (TIA), or "mini stroke," usually happens before a thrombotic stroke.

Embolic stroke is caused by a clot that travels from somewhere else in the body, usually the heart. The clot then blocks an artery leading to or in the brain. An embolic stroke happens when a piece of clot called an embolus breaks loose and is carried by the bloodstream to the brain, where the larger arteries branch off into smaller vessels. The blood clot reaches a point where it can go no farther. It becomes wedged, plugging a small cerebral artery and cutting off the blood supply to the brain.

Most emboli are caused by atrial fibrillation, and according to the American Heart Association, about 2 to 3 million Americans have this condition. Atrial fibrillation is an abnormal, rapid heartbeat where the two small upper chambers of the heart (called the atria) quiver instead of beating. Quivers cause the blood to pool, forming clots that can travel to the brain and cause a stroke.

There are 2 kinds of **hemorrhagic stroke** (caused by bleeding): cerebral hemorrhage and subarachnoid hemorrhage.

Cerebral or intracerebral hemorrhage is caused by a cerebral aneurysm, which is the ballooning out of a weak spot in a blood vessel of the brain. When the aneurysm bursts, there is bleeding into the brain. The amount of bleeding and the location in the brain determine how severe the cerebral hemorrhage is.

In many cases, people with cerebral hemorrhages die from increased pressure on their brains. But people who survive a cerebral hemorrhage tend to recover more fully and have fewer disabilities than those who have had strokes caused by a blockage (ischemic strokes). Ischemic strokes are more devastating because part of the brain dies when a blood vessel is blocked. The brain cannot make new cells to replace the cells that have died. But when a blood vessel in the brain bursts, pressure from the blood pushes against part of the brain. If the person survives, the pressure slowly goes away, and the brain may get back some of its former function.

A subarachnoid hemorrhage happens when a blood vessel on the surface of the brain bursts. The burst vessel bleeds into the space between the brain and skull, called the subarachnoid space. With this kind of hemorrhage, the blood does not get into the brain.

With both kinds of hemorrhagic stroke, the burst blood vessel may have been weakened by a head injury or by a condition present since birth. Hemorrhagic strokes also result from uncontrolled high blood pressure.

## PREVALENCE

According to the American Stroke Association, every 45 seconds, someone in America has a stroke. Every 3 minutes, someone dies of one. Strokes killed an estimated 163,538 people in 2001 and is the nation's third leading cause of death, ranking behind diseases of the heart and all forms of cancer. Stroke is a leading cause of serious, long-term disability in the United States. In Florida, during 1999, hospital discharged data shows that:

Total Number of Stroke Patients Discharged . . . . .	73,540
Total Number of Males. . . . .	35,154
Total Number of Females. . . . .	38,378
Number 44 and younger . . . . .	3%
Number 45-54 . . . . .	6%
Number 55-64 . . . . .	13%
Number 65-74 . . . . .	27%
Number 75 and older . . . . .	51%
Total charges . . . . .	\$1,229,171,753
Total hospital days . . . . .	363,683
Avg. length of stay. . . . .	5 days
Avg. charge per day . . . . .	\$4,200

In 2004, the estimated direct and indirect cost of stroke in the U.S. is \$53.6 billion. Each year, about 700,000 people experience a new or recurrent stroke. About 500,000 are first attacks, and 200,000 are recurrent attacks. From 1991 to 2001, the death rate from stroke declined 3.4 percent, but the actual number of stroke deaths rose 7.7 percent. Each year, about 40,000 more women than men have a stroke. Because women live longer than men, more women than men die of stroke each year. Women accounted for 61.4 percent of U.S. stroke deaths in 2001. The 2001 death rates per 100,000 population for stroke were 56.5 for white males and 85.4 for black males; and 54.5 for white females and 73.7 for black females. About 4.8 million stroke survivors are alive today.

In 1999, more than 1.1 million American adults reported difficulty with functional limitations, activities of daily living, etc., resulting from stroke. From the early 1970s to early 1990s, the estimated number of noninstitutionalized stroke survivors increased from 1.5 to 2.4 million. In the National Heart, Lung, and Blood Institute's Framingham Heart Study, among ischemic stroke survivors who were at least 65 years old, these disabilities were observed at six months post-stroke:

- ✓ 50 percent had some one-sided paralysis;
- ✓ 30 percent were unable to walk without some assistance;
- ✓ 26 percent were dependent in activities of daily living (grooming, eating, bathing, etc);

- ✓ 19 percent had aphasia (trouble speaking or understanding the speech of others);
- ✓ 35 percent had depressive symptoms; and
- ✓ 26 percent were institutionalized in a nursing home .

## Treatment

Often, even when stroke patients arrive at the hospital immediately after the first sign of stroke and when individual physicians are willing and able to evaluate them quickly to administer treatment, the pre-hospital and emergency department infrastructure may be unprepared. Hence, there is a growing need for more stroke centers with specialized stroke teams. Ideally, prior to the patient's arrival at a stroke center, trained EMS staff will conduct a preliminary patient evaluation and alert the stroke team in the emergency department at a nearby hospital or clinic. Once in the emergency room, a patient will be carefully evaluated for treatment eligibility using a computer tomography imaging (CT) scan to determine if the patient is experiencing any bleeding in the brain or has suffered recent head trauma. As these "eligibility" criteria are determined, the stroke team will begin an initial patient work-up, including vital signs, blood type and temperature, before beginning treatment. The patient may undergo a CT scan to monitor for intracranial hemorrhage (ICH) and will remain in the intensive care unit, where his or her progress will be closely monitored for at least 24 hours.

While the above is a description of optimal stroke evaluation, treatment and follow-up, unfortunately, it is not indicative of the level of care that many stroke patients currently can anticipate at their local hospital. In a national effort to increase the number of stroke centers and expert teams, several leading medical professional organizations, including the National Stroke Association (NSA), the American Stroke Association (ASA) and National Institute for Neurological Disorders and Stroke (NINDS) established the Brain Attack Coalition. Since the creation of the Coalition in 2000, the collective goal has been to develop specialized stroke teams throughout the country for the sole purpose of rapid patient evaluation. The program works by identifying individual physicians to lead, develop and mobilize teams to implement treatment and enforce NINDS guidelines for stroke patients in acute care hospitals.

The nation's leaders in improving health care for Americans, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is collaborating with the Brain Attack Coalition to recognize hospital stroke care programs that meet national quality standards.

Based on the recommendations for primary stroke centers published by the Brain Attack Coalition and the American Stroke Association's (ASA) statements/guidelines for stroke care, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has developed an advanced Disease-Specific Care Certification Program. It will provide the first nationwide certification program to evaluate stroke care provided by hospitals.

Conducted under the umbrella of JCAHO's Disease Specific Care Certification Program, the review of applicant organizations will assess:

- ✓ compliance with consensus-based national standards;
- ✓ effective use of primary stroke center recommendations and clinical practice guidelines to manage and optimize care; and
- ✓ performance measurement and improvement activities.

The on-site review process for Primary Stroke Center Certification will involve, in most cases, a one-day evaluation of stroke disease management services. Reviewers – experts such as neurologists, neuroscience nurses, emergency room nurses and doctors or stroke center administrators – will evaluate compliance with national standards and emphasize the management of stroke patients through clinical guidelines and performance measurement assessment.

The evaluation will assess qualifications and competence of practitioners; ongoing efforts to measure and improve process and outcomes; processes established to encourage patient self-management;

demonstrated leadership support for the program; and use of clinical information systems to monitor patient care management.

An expert panel, selected jointly by ASA and JCAHO, will make recommendations for a standardized performance measure set for stroke. The measure set will be available by early next year to augment the new certification program. In the interim, reviews of early-adopter hospitals that seek Primary Stroke Center Certification will require submission of four clinical process or outcome measures related to Primary Stroke Center care as listed in the Primary Stroke Center Certification addendum to the Disease-Specific Care Manual under Stroke Measurement areas.

Primary Stroke Centers that successfully demonstrate compliance with program requirements will be awarded certification for a one-year period. A one-year extension will be granted contingent on the submission of an acceptable Periodic Performance Review and the results of the organization's performance measurement and management activities.

The Joint Commission on Accreditation of Healthcare Organizations, which accredits hospitals nationwide, started to offer certification for stroke care in December 2003. Hospitals, which are certified, will also be part of a national study to evaluate best practices for stroke care. met more than 30 Joint Commission standards to get its certification

The Joint Commission expects to review about 80 applications in the first half of 2004 from hospitals nationwide to be certified as stroke centers. The creation of these stroke centers has helped decrease the time to treatment for many patients in communities where stroke centers have been established. Rapid evaluation combined with expert coordination of disciplines has led to a decrease in death and disability for thousands of patients who may have suffered a different fate without receiving therapy.<sup>1</sup>

## **Florida Law**

Currently, there is no statutory process for a hospital to be a certified as a stroke treatment center. According to the Department of Health, there are hospitals that are self-proclaimed stoke centers but there is no evidence that these facilities are capable of providing better care for stroke victims than any other acute care hospital.

The Hospital and Outpatient Services Unit (HOSU) within the Division of Health Quality Assurance of the Agency for Health Care Administration is responsible for licensing, registering, and regulating hospitals, outpatient and health care service facilities. The HOSU strives to ensure that these facilities and services comply with standards of safety and quality established by state and federal regulation. All Facilities that offer services more intensive than those required for room, board, personal services and general nursing care, must be licensed to operate in the state. Hospitals are defined as a facility which offers a range of services that are offered with beds for use beyond 24 hours by individuals requiring medical, surgical, psychiatric, testing, diagnosis, and treatment for illness, injury, deformity, infirmity, abnormality, disease, or pregnancy. Hospitals also have available clinical laboratory services, diagnostic X-ray services, and treatment facilities for surgery or obstetrical care, or other definitive medical treatment of similar extent.

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<sup>1</sup> Jorgensen HS. The effect of a stroke unit: reductions in mortality, discharge rate to nursing home, length of hospital stay, and cost. A community-based study. *Stroke* 1995;26(7): p.1178-82. <http://stroke.ahajournals.org/cgi/content/abstract/26/7/1178>

Indredavik B, Bakke F, Solberg R, Rokseth R, et al., Stroke unit treatment improves long-term quality of life: a randomized controlled trial. *Stroke* 1998;29(5): p. 895-9.

Jorgensen HS, Kammersgaard LP, Nakayama H, et al., Treatment and rehabilitation on a stroke unit improves 5-year survival. A community-based study. *Stroke*,1999. 30(5): p. 930-3.

Jorgensen HS, Kammersgaard LP, Houth J, et al. Who benefits from treatment and rehabilitation in a stroke Unit - A community-based study. *Stroke* 2000;31(2): p. 434-9.

Unaccredited facilities and initial licenses require certification and licensing surveys required by law. Under state and federal regulations, accredited hospitals are "deemed" to meet the requirements and do not receive an annual license and certification survey. All hospitals are subject to annual Life-Safety and biennial Risk Management surveys. In order to be licensed, facilities must meet state licensing requirements, submit a completed application, required documentation, and have a satisfactory survey completed. The initial licensing fee is \$1,500.00 or \$30.00 per bed, whichever is greater.

Renewal applications must be submitted every two years, 90 days in advance of expiration of a license. The renewal fee is \$1,500.00 or \$30.00 per bed, whichever is greater. The life safety inspection fee is \$40.00 or \$1.50 per bed, whichever is greater. For all non-accredited hospitals, the annual survey/inspection fee is \$400.00 or \$12.00 per bed, whichever is greater.

A contingency of licensing, any person needing emergency medical care or any woman in active labor shall not be denied access to appropriate emergency medical services and care. Emergency services and care means medical screening, examination and evaluation (triage) by a physician, or by other appropriate personnel under the supervision of a physician, to determine if an emergency medical condition exists.

## **HB 889**

The bill provides 12 whereas clauses which specify: the current and future prevalence; the debilitating nature; the associated cost of care; the lack of coordination of emergency services; and the unique care require for victims of stroke in the US and Florida.

The bill establishes legislative intent specifying that the rapid identification, diagnosis, and treatment of ischemic stroke can save the lives of stroke victims and in many cases can reverse paralysis, leaving victims with few or no neurological deficit and that a strong system for stroke survival is needed in the state's communities in order to treat stroke victims in a timely manner and to improve the overall treatment of stroke victims. By virtue of the law, the state intends to construct an emergency treatment system in this state in order that stroke victims may be quickly identified and transported to and treated in appropriate stroke treatment facilities.

The bill:

- Directs the Department of Health to adopt rules by January 1, 2005, guidelines as minimal clinical standards for stroke treatment centers, which may be as many as two levels of certification which include primary and comprehensive centers at hospital licensed pursuant to chapter 395, F.S.
- Directs the department to notify hospitals that are eligible to become certified stroke treatment centers; requires a hospital seeking eligibility as a stroke treatment center to file a letter of intent.
- Directs such hospitals to file completed applications with the department; directs the department to issue certificates to stroke treatment centers that meet the guidelines; authorizes the department to issue provisional certifications; provides that a stroke treatment center's certification automatically expires 2 years after the date of issuance; provides that a certification may be renewed; limits the certification to the hospital to which it was issue
- Directs the department to post a listing of certified stroke treatment centers on its Internet website; and requires the department 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; provides an exception; and authorizes the department to collect stroke registry data for certain purposes.
- Prohibits a person or entity from claiming that it is a facility is a stroke treatment center unless the facility is certified as provided by law. Authorizes the department to inspect stroke treatment centers. Requires emergency medical services to transport identified stroke victims to certified stroke treatment centers; and requires the department to adopt rules.

The bill provides for an effective date of July 1, 2004.

C. SECTION DIRECTORY:

**Section 1.** Provides legislative intent.

**Section 2.** Provides definitions applicable to certified stroke treatment centers.

**Section 3.** Directs the Department of Health to adopt, by a specified date, certain guidelines as minimal clinical standards for stroke treatment centers.

**Section 4.** Directs the department to notify hospitals that are eligible to become certified stroke treatment centers; requires a hospital seeking eligibility as a stroke treatment center to file a letter of intent; directs such hospitals to file completed applications with the department by a specified date; directs the department to issue certificates to stroke treatment centers that meet the guidelines; authorizes the department to issue provisional certifications; provides that a stroke treatment center's certification automatically expires 2 years after the date of issuance; provides that a certification may be renewed; limiting the certification to the hospital to which it was issued; directs the department to post a listing of certified stroke treatment centers on its Internet website; requiring the department 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; provides an exception; and authorizes the department to collect stroke registry data for certain purposes.

**Section 5.** Prohibits a person from claiming that a facility is a stroke treatment center unless the facility is certified as provided by law.

**Section 6.** Authorizes the department to inspect stroke treatment centers.

**Section 7.** Requires emergency medical services to transport identified stroke victims to certified stroke treatment centers; requiring the department to adopt rules;

**Section 8.** Provides for an effective date of July 1, 2004.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The designation as a Certified Stroke Treatment Center should have a positive impact on a hospital's ability to market its specialized services to the community.

An increase in the quality of life for stroke victims when treated with the latest advances in medical care is anticipated.

D. FISCAL COMMENTS:

None.

### III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenues.

3. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill specifies rulemaking authority for the Department of Health.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The Agency for Health Care Administration is responsible for the licensure of hospitals. It is more appropriate to have the certification process under the purview of the agency rather than the Department of Health.

### IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES