The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1406
INTRODUCER:	Senator Powell and others
SUBJECT:	Stroke Centers
DATE:	March 24, 2017
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Stovall	HP	**Pre-meeting**
2.			AHS	
3.			AP	

I. Summary:

SB 1406 requires the Agency for Health Care Administration (ACHA) to add acute stroke ready centers to the list of primary stroke centers and comprehensive stroke centers, which is made available to emergency medical service providers. All three levels of stroke centers are treated similarly for purposes of being added to, or removed from, the list. The bill removes language instructing the ACHA to base stroke center rules on criteria established solely by the Joint Commission; and expands rule criteria to all nationally recognized accreditation organizations.

The DOH is directed to develop a statewide stroke registry to house data submitted by stroke centers, emergency medical service providers, and medical examiners, which will include patient care quality assurance proceedings, records, or reports associated with the treatment or service provided to a person suffering a stroke. The data will be used to:

- Evaluate stroke care effectiveness;
- Ensure compliance with stroke center standards; and
- Monitor patient outcomes.

The AHCA must adopt by rule electronic standardized forms for stroke centers to report the data to the Department of Health (DOH).

The DOH may choose to establish and maintain the registry, or contract it out. The bill provides protection from liability for any entity that provides information required by the registry.

The bill provides an effective date of July 1, 2017.

II. Present Situation:

What is a Stroke?

A stroke is a serious medical condition that occurs when the blood supply to the brain is interrupted or severely reduced, depriving brain tissue of oxygen and nutrients.[1] The brain needs a constant supply of oxygen and nutrients in order to function.[2] Even a brief interruption in blood supply from a stoke can cause significant problems.

During a stroke, brain cells begin to die after just a few minutes without blood or oxygen.[3] Brain cell death causes loss of brain function, including impaired ability with movement, speech, thinking and memory, bowel and bladder, eating, emotional control, and other vital bodily functions. A small stroke may result in problems such as weakness in an arm or leg, whereas larger strokes may cause paralysis, loss of speech, or even death.[4] A stroke is one of the leading causes of death in the United States.[5]

There are two main types of strokes: an ischemic stroke and a hemorrhagic stroke. The former, is the most common type, and occurs when an artery in the brain becomes blocked. The latter occurs when a brain artery leaks blood or ruptures.[6]

There are two types of ischemic strokes: thrombotic and embolic.[7] In a thrombotic stroke, a blood clot (thrombus) forms in an artery that supplies blood to the brain.[8] In an embolic stroke, a blood clot, or other substance such as plaque or fatty material, travels through the bloodstream to an artery in the brain.[9] With both types of ischemic stroke, the blood clot or other substance blocks the flow of oxygenated blood to a portion of the brain.[10]

The two types of hemorrhagic stroke are intracerebral and subarachnoid.[11] In an intracerebral hemorrhage, a blood vessel inside the brain leaks blood or ruptures.[12] In a subarachnoid hemorrhage, a blood vessel on the surface of the brain leaks blood or ruptures, and bleeding occurs between the inner and middle layers of the membrane that covers the brain.[13] In both types of hemorrhagic stroke, the leaked blood causes swelling of the brain and increased pressure in the skull. This swelling and pressure causes brain damage.[14]

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[1] The Mayo Clinic, *Stroke* http://www.mayoclinic.org/diseases-conditions/stroke/home/ovc-20117264, (last visited March 22, 2017).
[2] UCLA Health, *What is a Stroke?* http://stroke.ucla.edu/what-is-a-stroke, (last visited March 23, 2017).
[3] Id.
[4] Id.
[5] National Institutes of Health, National Heart, Lung and Blood Institute, *What Is a Stroke?* (updated Jan. 27, 2017) *available at* https://www.nhlbi.nih.gov/health/health-topics/topics/stroke, (last visited Mar. 23, 2017).
[6] Id.
[7] Id.
[8] Id.
[9] Id. The blood clot or other substance traveling through the bloodstream is called an embolus.
[10] Id.
[11] Id.
[12] Id.
[13] Id.
[14] Id.

Signs and Symptoms of a Stroke

The signs and symptoms of a stroke often develop quickly. However, they can develop over hours or even days as well. Signs and symptoms of a stroke may include:

- Sudden weakness;
- Paralysis (an inability to move) or numbness of the face, arms, or legs, especially on one side of the body;
- Confusion;
- Trouble speaking or understanding speech;
- Trouble seeing in one or both eyes;
- Problems breathing;
- Dizziness, trouble walking, loss of balance or coordination, and unexplained falls;
- Loss of consciousness; and
- Sudden and severe headache.[15]

Stroke Treatment

Time is of the essence in the treatment of a stroke. Medical personnel begin treatment in the ambulance on the way to the hospital.[16] Treatment for a stroke depends on how much time has elapsed since the symptoms began to appear; and whether the stroke is ischemic or hemorrhagic.[17]

Treatment for an ischemic stroke may include medicines,[18] such as antiplatelet medicines and blood thinners, and medical procedures, but a hemorrhagic stroke may require surgery to find and stop the bleeding.[19] In addition to emergency care to treat a stroke, an individual may also receive treatment to prevent another stroke and rehabilitation to treat the side effects of the stroke.[20] According to the Centers for Disease Control and Prevention (CDC), research indicates that patients receiving care at primary stroke centers have a higher incidence of survival and recovery than those treated in hospitals without this type of specialized care.[21]

Stroke Centers in Florida

Florida first enacted legislation relating to primary and comprehensive stroke centers in 2004.[22] The AHCA establishes the criteria for both the primary and comprehensive stroke centers.[23]

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[15] Id.
[16] Center for Disease Control and Prevention, *Stroke Treatment* (updated Feb. 10, 201) *available at* https://www.cdc.gov/stroke/treatments.htm, (last visited March 23, 2017).
[17] National Institutes of Health, National Heart, Lung and Blood Institute, *How Is a Stroke Treated?*(updated Jan. 27, 2017) *available at* https://www.nhlbi.nih.gov/health/health-topics/topics/stroke/treatment (last visited March 23, 2017).
[18] Id. Such medication includes a tissue plasminogen activator (TPA), which dissolves, or breaks up the clot. TPA is an injection which must be given within 4 hours of stroke symptoms onset.
[19] Id.
[20] *Supra* note 16.
[21] Centers for Disease Control and Prevention, A *Summary Of Primary Stroke Center Policy In The United States* (2011), *available at* https://www.cdc.gov/dhdsp/pubs/docs/primary_stroke_center_report.pdf, (last visited March 23, 2017)
[22] Section 3, ch. 2004-325, Laws of Fla.
[23] Section 395.3038, F.S.

There are 118 Florida hospitals designated as primary stroke centers in 37 counties, and 41 comprehensive stroke centers in 16 counties. [24]

Primary Stroke Centers

A primary stroke center certification recognizes hospitals that meet standards to support better outcomes for stroke care.[25] Such hospitals must have a dedicated stroke-focused program, be staffed by qualified medical professionals trained in stroke care, and provide individualized care to meet stroke patients' needs based on recommendations of the Brain Attack Coalition and guidelines published by the American Heart Association/American Stroke Association or equivalent guidelines.[26] These hospitals must also collect and utilize performance data to improve quality of care for stroke patients.[27]

In order for the AHCA to designate a hospital program as a primary stroke center, the hospital program must be certified by the Joint Commission as a primary stroke center, or meet the certification criteria applicable to primary stroke centers as outlined in the Joint Commission Disease-Specific Care Certification Manual, 2nd Edition.[28] The manual requires a primary stroke center to:[29]

- Use a standardized method of delivering care;
- Support patient self-management activities;
- Tailor treatment and intervention to individual needs;
- Promote the flow of patient information across settings and providers, while protecting patient rights, security and privacy;
- Analyze and use standardized performance measure data to continually improve treatment plans; and
- Demonstrate their application of and compliance with clinical practice guidelines published by the American Heart Association/American Stroke Association or equivalent evidence-based guidelines.[30]

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[24] Agency for Health Care Administration, *Senate Bill 1406 Analysis* (Feb. 17, 2017) (on file with Senate Committee on Health Policy). Although stroke services is dependent upon the availability of qualified health care professionals, the majority of primary stroke centers have fewer than 300 inpatient beds and the majority of comprehensive stroke centers have more than 300 beds.

[25] American Heart Association, *Primary Stroke Center Certification* https://www.heart.org/HEARTORG/Professional/HospitalAccreditationCertification/PrimaryStrokeCenterCertification/Primary-Stroke-Center-Certification_UCM_439155_SubHomePage.jsp, (last visited March 23, 2017).

[26] Id.

[27] Id.

[28] Fla. Admin. Code R. 59A-3.2085(15)(a)

[29] The standards are published in the Comprehensive Certification Manual for Disease-Specific Care. They incorporate the "Recommendations for the Establishment of Primary Stroke Centers" developed by the Brain Attack Coalition. The chapters address program management, delivering or facilitating clinical care, supporting self-management, clinical information management, and performance improvement and measurement.

[30] The Joint Commission, *Facts about Primary Stroke Center Certification* (Jan. 6, 2015) https://www.jointcommission.org/facts_about_primary_stroke_center_certification/ (last visited March 23, 2017).

Comprehensive Stroke Centers

A comprehensive stroke center certification recognizes hospitals that meet standards to treat the most complex stroke cases.[31] These hospitals must meet all the criteria of a primary stroke center; they must also have advanced imaging techniques and personnel trained in vascular neurology, neurosurgery and endovascular procedures available 24 hours a day, seven days a week, as well as neuroscience intensive care unit (ICU) and experience and expertise treating patients with large ischemic strokes, intracerebral hemorrhage and subarachnoid hemorrhage.

In order for the AHCA to designate a hospital program as a compressive stroke center, the hospital program must have received primary stroke center designation and also have the following:

- Personnel with clinical expertise in specified disciplines available;[32]
- Advanced diagnostic capabilities;[33]
- Neurosurgical and endovascular interventions available;[34]
- Specialized infrastructure;[35] and
- Quality improvement and clinical outcomes measurements.[36] T

[31]The American Heart Association, *Comprehensive Stroke Center Certification* https://www.heart.org/HEARTORG/Professional/HospitalAccreditationCertification/ComprehensiveStrokeCenterCertification/Comprehensive-Stroke-Center-Certification_UCM_455446_SubHomePage.jsp, (last visited March 23, 2017).

[32] Fla. Admin. Code R. 59A-3.2085(15)(b). This must include designated comprehensive stroke center medical director; neurologists, neurosurgeons, surgeons with expertise performing carotid endartrectomy, diagnostic neuroradiologists, and physicians with expertise in endovascular neuroInterventional procedures and other pertinent physicians; emergency department physicians and nurses trained in the care of stroke patients; nursing staff in the stroke unit with particular neurologic expertise who are trained in the overall care of stroke patients; nursing staff in intensive care unit with specialized training in care of patients with complex and/or severe neurological/neurosurgical conditions; advanced practice nurses with particular expertise in neurological and/or neurosurgical evaluation and treatment, physicians with specialized expertise in critical care for patients with severe and/or complex neurological/neurosurgical conditions; physicians with specialized expertise in critical care for patients with severe and/or complex neurological/neurosurgical conditions; physicians with expertise in performing and interpreting trans-thoracic echocardiography, transesophageal echocardiography, carotid duplex ultrasound and transcranial Doppler; physicians and therapists with training in rehabilitation, including physical, occupational and speech therapy; and a multidisciplinary team of health care professionals with expertise or experience in stroke, representing clinical or neuropsychology, nutrition services, pharmacy, including a Pharmacy Doctorate with stroke expertise, case management and social workers. Additionally, medical personnel with neurosurgical expertise must be available in a CSC on a 24 hours per day, sever days per week basis and in-house within two hours, and neurologist(s) with special expertise in the management of stroke patients should be available 24 hours per day, seven days per week.

[33] Fla. Admin. Code R. 59A-3.2085(15)(b). This includes magnetic resonance imaging and related technologies, catheter angiography, Coaxial Tomography angiography, extracranial ultrasonography, carotid duplex, Transcranial Doppler, transthoracic and trans-esophageal echocardiography, tests of cerebral blood flow and metabolism, and comprehensive hematological and hypercoagulability profile testing.

[34] Fla. Admin. Code R. 59A-3.2085(15)(b). This includes angioplasty and stenting of intracranial and extracranial arterial stenosis, endovascular therapy of acute stroke, endovascular treatment of intracranial aneurysms, endovascular and surgical repair of arteriovenous malformations (AVMs) and arteriovenous fistulae (AVFs), surgical clipping of intracranial aneurysms, intracranial angioplasty for vasospasm, surgical resection of AVMs and AVFs, placement of ventriculostomies and ventriculoperitoneal shunts, evacuation of intracranial hematomas, carotid endarterectomy, and decompressive craniotomy.

[35] Fla. Admin. Code R. 59A-3.2085(15)(b).

[36] Fla. Admin. Code R. 59A-3.2085(15)(b). The purpose of a quality improvement program is analysis of data, correction of errors, systems improvements, and ongoing improvement in patient care and delivery of services. Specific benchmarks, outcomes, and indicators should be defined, monitored, and reviewed on a regular basis for quality assurance purposes. Outcomes for procedures such as carotid endarterectomy, carotid stenting, IV TPA, endovascular/interventional stroke therapy, intracerebral aneurysm coiling, and intracerebral aneurysm clipping should be monitored. A database and/or registry

The specialized infrastructure includes extensive requirements that the emergency medical services (EMS) and comprehensive stroke center leadership are linked to ensure:

- EMS use a stroke triage assessment tool;
- EMS patient assessment and management at the scene is consistent with evidence-based practice;
- Inter-facility transfers; and
- On-going communication with EMS providers regarding availability of services; and that a comprehensive stroke center must:

The comprehensive stroke center must maintain:

- An acute stroke team available 24 hours per day, 7 days per week;
- A system for facilitating inter-facility transfers;
- Defined access telephone numbers in a system for accepting appropriate transfer;
- Specialized inpatient units including an ICU with medical and nursing personnel who have special training, skills and knowledge in the management of patients with all forms of neurological/neurosurgical conditions that require intensive care;
- An acute stroke unit with medical and nursing personnel who have training, skills and knowledge sufficient to care for patients with neurological conditions, particularly acute stroke patients, and who are appropriately trained in neurological assessment and management;
- Inpatient post-stroke rehabilitation and ensure continuing arrangements post-discharge for rehabilitation needs and medical management;
- Its medical and paramedical professionals education by offering ongoing professional education for all disciplines; and provide education to the public and inpatients and families on risk factor reduction/management, primary and secondary prevention, the warning signs and symptoms of stroke, and medical management and rehabilitation for stroke patients;
- Provide a career development track to develop neuroscience nursing, particularly in the area of cerebrovascular disease; and
- Professional and administrative infrastructure necessary to conduct clinical trials and should have participated in stroke clinical trials within the last year and actively participate in ongoing clinical stroke trials.[37]

Stroke Patient Transportation

The DOH has also developed a stroke assessment tool.[38] The tool is available on the DOH's website and is provided to emergency medical service providers.[39] Each licensed emergency medical services provider must use a stroke-triage assessment tool that is substantially similar to

should be established that allows for tracking of parameters such as length of stay, treatments received, discharge destination and status, incidence of complications (such as aspiration pneumonia, urinary tract infection, deep venous thrombosis), and discharge medications and comparing to institutions across the country. Additionally, the comprehensive stroke center must participate in a national and/or state registry (or registries) for acute stroke therapy clinical outcomes, including IV TPA and endovascular/interventional stroke therapy.

[37] Fla. Admin. Code R. 59A-3.2085(15)(b).

[38] Section 395.3041(2), F.S.

[39] Section 395.3041(2), F.S.

the DOH's stroke-triage assessment tool.[40] Annually, by June 1, each year the DOH sends the list of primary stroke centers and comprehensive stroke centers to the medical director of each licensed emergency medical services provider in Florida.[41]

Stroke Center Inventory

The AHCA maintains an inventory of hospitals offering stroke services.[42] A listing of hospitals meeting the criteria as either a primary stroke center or comprehensive stroke center is published on the AHCA's website.[43,44]

Currently, there are no data reporting requirements for stroke centers related to quality measures.[45] There are 274 emergency medical service providers, 222 acute care hospitals and 25 medical examiner districts that report patient data to the DOH.[46] However, the data is not standardized and much of the data that the DOH currently collects comes from voluntary participation in the DOH's EMS Tracking and Reporting System (EMSTARS) program[47] and only includes data on response, provider impression, procedures and medication, and destination.[48]

Acute Stroke Ready Centers

Many patients with an acute stroke live in areas without ready access to a primary or comprehensive stroke center; more than half the U.S. population lives more than an hour away from a stroke center.[49] Hospitals in areas with low population densities and relatively small numbers of patients with strokes may be less likely to have the resources to become a stroke center and may lack the experience and expertise to provide ongoing care for a stroke.[50] In such settings, there is a need to distinguish between those that offer enhanced care and expertise for acute stroke versus those with only basic or no organized abilities and expertise.[51]

A recent study by the American Stroke Association proposed a new designation for hospitals that are not primary stroke centers, but can provide timely, evidence-based care to most patients with an acute stroke; these acute stroke-ready hospitals provide initial diagnostic services, stabilization, emergent care and therapies to patients with an acute stroke who are seen in their

[40] Id.
[41] Section 395.3041(1), F.S.
[42] Section 395.3038, F.S.
[43] *Supra*, note 24.
[44] Id. A list of hospitals with a stroke center designation is also available through the facility locator tool on www.floridahealthfinder.gov, (last visited March 23, 2017).
[45] Id.
[46] *Supra* note 24.
[47] The EMSTARS program allows emergency medical providers to capture incident level patient care records for every emergency activation.
[48] *Supra* note 46.
[49] Mark J. Alberts, et al, *Formation and Function of Acute Stroke–Ready Hospitals Within a Stroke System of Care Recommendations From the Brain Attack Coalition*, Stroke, Vol. 44, Issue 12 (Nov. 25, 2013), *available at* http://stroke.ahajournals.org/content/44/12/3382.full, (last visited March 23, 2017).
[50] Id.
[51] Id.

emergency department, and would then transfer these patients to a primary or comprehensive stroke center.[52]

Accrediting Organizations

The Joint Commission, the Healthcare Facilities Accreditation Program, and the DNV GL (formerly known as Det Norske Veritas) offer certification as an acute stroke ready centers.[53]

III. Effect of Proposed Changes:

Acute Stroke Ready Centers

The bill includes a new level of stroke services: an acute stroke ready center. A hospital could receive an acute stroke ready center designation by attesting to the ACHA on the appropriate form that, among other things, it is accredited by a nationally recognized accrediting organization or meets the criteria for accreditation. A hospital with an acute stroke ready center designation is required to notify the ACHA if it no longer meets the criteria.

The bill removes language instructing the ACHA to base stroke center rules on criteria established solely by the Joint Commission; and expands criteria to all nationally recognized accreditation organizations.

Acute stroke ready centers must be added to the list of stroke centers the DOH supplies to emergency service providers in the state. The bill requires the AHCA to develop and adopt by rule electronic standardized forms for stroke centers to report data to the DOH, including patient care quality assurance proceedings, records, or reports associated with any treatment or service provided to a person suffering a stroke.

Currently, there are approximately 60 acute care hospitals that do not have primary or comprehensive stroke center designation and may be eligible for an acute stroke ready center designation. The majority of these hospitals have less than 100 beds.[54]

Statewide Stroke Registry

The bill creates s. 395.30381, F.S., to require the DOH to develop a statewide stroke registry. All stroke centers, emergency medical providers, and medical examiners must submit data, including patient care quality assurance proceedings, records, or reports associated with the treatment or service provided to a person suffering a stroke to the registry. The DOH is required to use this information to:

- Evaluate stroke care effectiveness;
- Ensure compliance with stroke center standards established pursuant to s. 395.3038, F.S.; and
- Monitor patient outcomes.

[52] Id.
[53] *Supra* note 24.
[54] *Supra* note 244.

The DOH may choose to establish and maintain the registry, or contract it out to a private entity. The bill provides protection from liability for any entity that provides information required by the registry. The DOH is required to adopt rules to implement the registry.

Stroke centers that do not comply with the reporting requirements to the registry will be subject to licensure denial, modification, suspension, or revocation by the AHCA.[55] The bill removes obsolete deadlines for the DOH to implement the stroke-triage assessment tool.

The bill provides an effective date of July 1, 2017.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Public hospitals, emergency medical service providers, and medical examiner offices that are required to submit data to the DOH under the bill, may be required to purchase new software and incur labor costs to collect, maintain and send the required data to the DOH. The estimated cost of this is unknown at this time.

C. Government Sector Impact:

The DOH will incur rulemaking costs to implement the registry. The DOH may also incur costs to develop and maintain the registry or to contract with a private entity to establish and maintain the registry. There is no appropriation provided in the bill to establish the registry.

[55] Section 395.003(7)(a), F.S., authorizes the AHCA to deny, modify, suspend, and revoke a license for the substantial failure to comply with any requirements of part I of ch 395, F.S., which is where the statute establishing the stroke registry is located.

The AHCA will incur rulemaking costs related to updating criteria for acute stroke ready centers and comprehensive stroke centers. According to the AHCA, current resources can absorb these costs.[56]

VI. Technical Deficiencies:

None.

VII. Related Issues:

A public records exemption (separate bill) may be necessary to protect the confidentiality of information in the statewide stroke registry.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 395.3038 and 395.3041.

This bill creates the following section 395.30381, of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

[56] *Supra* note 24.