HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/CS/HB 785 Stroke Centers
SPONSOR(S): Health & Human Services Committee, Health Care Appropriations Subcommittee; Health Quality Subcommittee; Magar and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1406

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	15 Y, 0 N, As CS	Langston	McElroy
2) Health Care Appropriations Subcommittee	12 Y, 0 N, As CS	Mielke	Pridgeon
3) Health & Human Services Committee	16 Y, 0 N, As CS	Langston	Calamas

SUMMARY ANALYSIS

A stroke is a serious medical condition that occurs when the blood supply to part of the brain is interrupted or severely reduced, depriving brain tissue of oxygen and nutrients. 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. Stroke is one of the leading causes of death in the United States.

The Agency for Health Care Administration (AHCA) establishes criteria for primary and comprehensive stroke centers in Florida. There are 118 Florida hospitals designated as a Primary Stroke Center in 37 counties and 41 Comprehensive Stroke Centers in 16 counties. Additionally, AHCA maintains an inventory of hospitals offering stroke services.

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. However, many patients with an acute stroke live in areas without ready access to a primary or comprehensive stroke center; more than half the United States population lived more than an hour away from a stroke center. 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. Acute stroke-ready hospitals provide initial diagnostic services, stabilization, emergent care and therapies to patients with an acute stroke who are seen in their emergency department, and would then transfer these patients to a primary or comprehensive stroke center.

The Department of Health (DOH) provides a stroke assessment tool to emergency medical service providers, which must use it or another tool that is substantially similar. DOH sends a list of primary stroke centers and comprehensive stroke centers to the medical director of each licensed emergency medical services provider in Florida annually.

CS/CS/CS/HB 785 amends s. 395.3038, F.S. to include a new level of stroke services entitled acute stroke ready centers and adds them to the list of stroke centers DOH supplies to emergency service providers in the state.

The bill requires DOH, subject to a specific appropriation, to contract with a private entity in Florida to establish and maintain a statewide stroke registry. Acute stroke ready centers, primary stroke centers, and comprehensive stroke centers must report nationally recognized performance measures to the registry, which must use a nationally recognized platform to collect such data. The bill grants liability protection for any entity that provides information required by the registry.

The bill removes obsolete deadlines for DOH to implement the stroke-triage assessment tool.

The bill has an insignificant negative fiscal impact on AHCA and a negative fiscal impact on DOH due to the contract requirement, subject to a specific appropriation.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

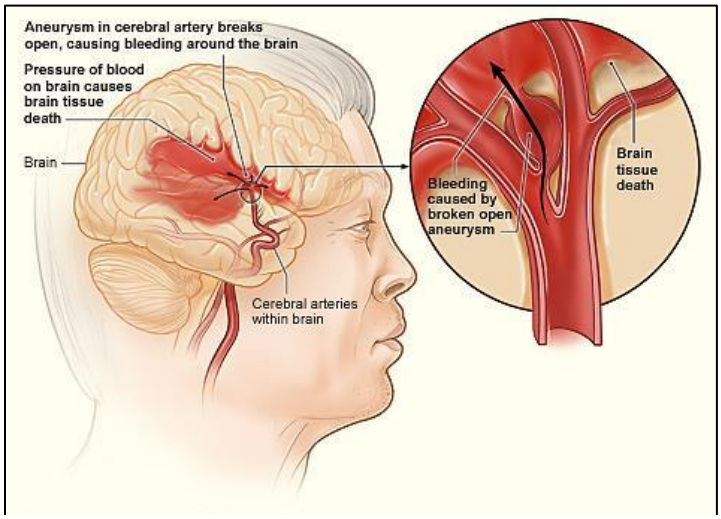
Background

Stroke

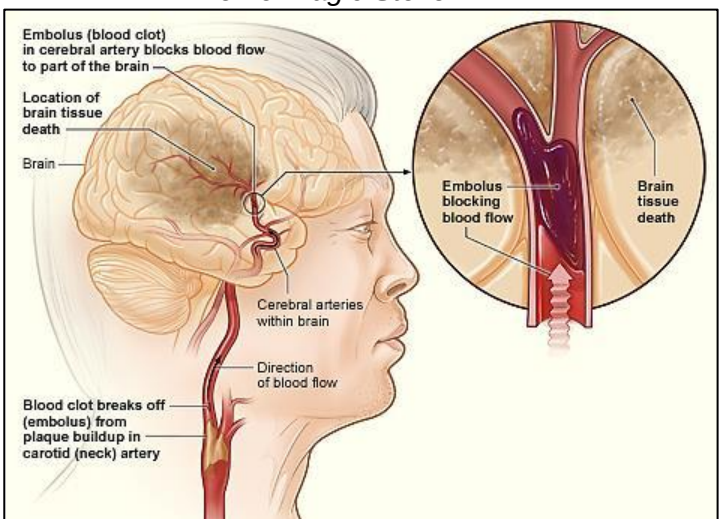
A stroke is a serious medical condition that occurs when the blood supply to part of the brain is interrupted or severely reduced, depriving brain tissue of oxygen and nutrients.[1] The brain needs a constant supply of oxygen and nutrients in order to function.[2] Even a brief interruption in blood supply from a stoke can cause problems; 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 body 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] Stroke is one of the leading causes of death in the United States.[5]

There are two main types of stroke: an ischemic stroke, the more common type, which occurs when an artery that supplies oxygenated blood to the brain becomes blocked; and a hemorrhagic stroke, which occurs if an artery in the brain leaks blood or ruptures.[6]

Ischemic Stroke[7]



Hemorrhagic Stoke[8]



The two types of ischemic stroke are thrombotic and embolic.[9] In a thrombotic stroke, a blood clot, called a thrombus, forms in an artery that supplies blood to the brain.[10] In an embolic stroke, a blood clot or other substance, such as plaque, a fatty material, travels through the bloodstream to an artery in

[1] MAYO CLINIC, *Stroke*, http://www.mayoclinic.org/diseases-conditions/stroke/home/ovc-20117264 (last visited March 2, 2017).
[2] UCLA STROKE CENTER, *What is a Stroke?*, http://stroke.ucla.edu/what-is-a-stroke (last visited March 2, 2017).
[3] Id.
[4] Id.
[5] NATIONAL HEART, LUNG, AND BLOOD INSTITUTE, *What Is a Stroke?*, https://www.nhlbi.nih.gov/health/health-topics/topics/stroke (last visited March 2, 2017).
[6] Id.
[7] NATIONAL HEART, LUNG, AND BLOOD INSTITUTE, *Types of Stroke*, https://www.nhlbi.nih.gov/health/health-topics/topics/stroke/types (last visited March 2, 2017).
[8] Id.
[9] Id.
[10] Id.

the brain.[11] With both types of ischemic stroke, the blood clot or plaque blocks the flow of oxygenated blood to a portion of the brain.[12]

The two types of hemorrhagic stroke are intracerebral and subarachnoid.[13] In an intracerebral hemorrhage, a blood vessel inside the brain leaks blood or ruptures.[14] In a subarachnoid hemorrhage, a blood vessel on the surface of the brain leaks blood or ruptures; when this happens, bleeding occurs between the inner and middle layers of the membranes that cover the brain.[15] In both types of hemorrhagic stroke, the leaked blood causes swelling of the brain and increased pressure in the skull.[16]

Treatment

Time is of the essence for stroke treatment; medical personnel begin treatment in an ambulance on the way to the emergency room.[17] Treatment for a stroke also depends on how much time has passed since symptoms began and on whether it is ischemic or hemorrhagic.[18] Treatment for an ischemic stroke may include medicines, such as antiplatelet medicines and blood thinners, and medical procedures, but a hemorrhagic stroke may be treated with surgery to find and stop the bleeding.[19] In addition to emergency care to treat the 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 United States Centers for Disease Control and Prevention, 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 was one of the first four states, in 2004, to enact primary stroke center legislation.[22] Pursuant to s. 395.3038, F.S., the Agency for Health Care Administration (AHCA) establishes criteria for primary and comprehensive stroke centers. There are 118 Florida hospitals designated as primary stroke centers in 37 counties and 41 comprehensive stroke centers in 16 counties. [23]

Primary Stroke Centers

A primary stroke center certification recognizes hospitals that meet standards to support better outcomes for stroke care.[24] 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

[11] Id. The blood clot or other substance traveling through the bloodstream is called an embolus.
[12] Id.
[13] Id.
[14] Id.
[15] Id.
[16] Id.
[17] CENTERS FOR DISEASE CONTROL AND PREVENTION, *Stroke Treatment*, https://www.cdc.gov/stroke/treatments.htm (Last visited March 2, 2017).
[18] NATIONAL HEART, LUNG, AND BLOOD INSTITUTE, *How Is a Stroke Treated?*, https://www.nhlbi.nih.gov/health/health-topics/topics/stroke/treatment (last visited March 2, 2017).
[19] Id.
[20] *Supra*, note 17.
[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 2, 2017)
[22] S. 3, ch. 2004-325, Laws of Fla.
[23] Florida Agency for Health Care Administration, Agency Analysis of 2017 House Bill 785, (Feb. 17, 2017) (analysis on file with Health Quality Subcommittee Staff). 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.
[24] 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 7, 2017).

the American Heart Association/American Stroke Association or equivalent guidelines.[25] These hospitals must also collect and utilize performance data to improve quality of care for stroke patients.[26]

In order for 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 criteria applicable to primary stroke centers as outlined in the Joint Commission Disease-Specific Care Certification Manual, 2nd Edition.[27]

Under the Joint Commission, certified primary stroke centers must meet the standards for Disease-Specific Care Certification:[28]

- 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[29]

Comprehensive Stroke Centers

A comprehensive stroke center certification recognizes hospitals that meet standards to treat the most complex stroke cases.[30] 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 24/7, as well as neuroscience ICU facilities and capabilities and experience and expertise treating patients with large ischemic strokes, intracerebral hemorrhage and subarachnoid hemorrhage.

In order for AHCA to designate a hospital program as a compressive stroke center, the hospital program must have received primary stroke center designation and also have personnel with clinical expertise in specified disciplines available,[31] advanced diagnostic capabilities,[32] neurological surgery

[25] Id.
[26] Id.
[27] Rule 59A-3.2085(15)(a), F.A.C. Currently, in lieu of the Joint Commission, hospitals may choose to use the Healthcare Facilities Accreditation Program or DNV GL (formerly known as Det Norske Veritas) for certification.
[28] 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.
[29] THE JOINT COMMISSION, *Facts about Primary Stroke Center Certification*, https://www.jointcommission.org/facts_about_primary_stroke_center_certification/ (last visited March 2, 2017).
[30] 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 7, 2017).
[31] Rule 59A-3.2085(15)(b), F.A.C. 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

and endovascular interventions, [33] and specialized infrastructure,[34] and quality improvement and clinical outcomes measurement.[35] The specialized infrastructure includes extensive requirements that emergency medical services (EMS) link to ensure that EMS uses of a stroke triage assessment tool, that EMS assessment/management at the scene is consistent with evidence-based practice, facilitate inter-facility transfers, and to maintain an on-going communication system with EMS providers regarding availability of services; and that a comprehensive stroke center must:

- Maintain an acute stroke team available 24 hours per day, 7 days per week, and a system for facilitating inter-facility transfers, and a defined access telephone numbers in a system for accepting appropriate transfer;
- Maintain 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; and 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;
- Provide inpatient post-stroke rehabilitation and ensure continuing arrangements post-discharge for rehabilitation needs and medical management;
- Fulfill the educational needs of its medical and paramedical professionals 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
- Have the 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.[36]

Stroke Patient Transportation

Section 395.3041(2), F.S., requires the Department of Health (DOH) to develop a stroke assessment tool. The tool is available on DOH's website and is provided to emergency medical service providers.[37] Each licensed emergency medical services provider must use a stroke-triage assessment tool that is

---

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, 7 days per week basis and in-house within 2 hours, and neurologist(s) with special expertise in the management of stroke patients should be available 24 hours per day, 7 days per week.

[32] Rule 59A-3.2085(15)(b), F.A.C. 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.

[33] Rule 59A-3.2085(15)(b), F.A.C. 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 craniectomy.

[34] Rule 59A-3.2085(15)(b), F.A.C.

[35] Rule 59A-3.2085(15)(b), F.A.C. 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, IVtPA, endovascular/interventional stroke therapy, intracerebral aneurysm coiling, and intracerebral aneurysm clipping should be monitored. A database and/or registry 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 IVtPA and endovascular/interventional stroke therapy.

[36] Rule 59A-3.2085(15)(b), F.A.C.

[37] S. 395.3041(2), F.S.

substantially similar to DOH's stroke-triage assessment tool.[38] Annually, by June 1, 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.[39]

Stroke Center Inventory

AHCA must maintain an inventory of hospitals offering stroke services.[40] A listing of hospitals meeting the criteria as either a primary stroke center or comprehensive stroke center, is published on AHCA's website.[41] A list of hospitals with a stroke center designation is also available through the facility locator tool on www.floridahealthfinder.gov.[42]

Currently, there are no data reporting requirements for stroke centers related to quality measures.[43] There are 274 emergency medical service providers, 222 acute care hospitals and 25 medical examiner districts that report patient data to DOH.[44] However, the data is not standardized and much of the data that DOH currently collects comes from voluntary participation in DOH's EMS Tracking and Reporting System (EMSTARS) program[45] and only includes data on response, provider impression, procedures and medication and destination.[46]

The Florida Puerto Rico Stroke Registry

In 2009, the University of Miami Miller School of Medicine created the Florida Puerto Collaboration to Reduce Stroke Disparities (FPCRSD) aims to address stroke disparities among African Americans and Hispanics and to identify the best approaches to eliminate stroke care disparities in these groups.[47] As part of this initiative, it also created a voluntary stroke registry among hospitals in Florida and Puerto Rico currently participating in the American Heart Association's (AHA) quality improvement initiative "Get With The Guidelines Stroke."[48] The Florida Puerto Rico Stroke Registry aims to:

- Leverage the power of data already collected through the AHA's stroke database to identify and address disparities in stroke care;
- Evaluate disparities in stroke care performance metrics by race, ethnicity, and geographic regions;
- Analyze the frequency of disparities at 30-days after a stroke in terms of outcomes (mortality, hospital readmission, stroke recurrence) medication adherence, and lifestyle modifications by race, ethnicity and geographic regions;
- Evaluate the frequency of disparities in longer-term outcomes (mortality, hospital readmission, stroke recurrence) among Medicare patients and the relationship of such outcomes with acute stroke performance metrics; and
- Implement education programs among healthcare stakeholders with a focus on identifying and implementing specific culturally-tailored quality improvement programs to address disparities.[49]

[38] Id.
[39] S. . 395.3041(1), F.S.
[40] S. 395.3038, F.S.
[41] *Supra*, note 23.
[42] Id.
[43] Id.
[44] Florida Department of Health, Agency Analysis of 2017 House Bill 785, (Feb. 1, 2017) (analysis on file with Health Quality Subcommittee Staff).
[45] The EMSTARS program allows emergency medical providers to capture incident level patient care records for every emergency activation.
[46] *Supra*, note 44.
[47] THE UNIVERSITY OF MIAMI MILLER SCHOOL OF MEDICINE, *Florida-Puerto Rico Collaboration to Reduce Stroke Disparities: About*, http://spirp.med.miami.edu/about (last visited March 7, 2017).
[48] Id.
[49] THE UNIVERSITY OF MIAMI MILLER SCHOOL OF MEDICINE, *Florida Puerto Rico Stroke Registry*, http://spirp.med.miami.edu/program-components/florida-puerto-rico-stroke-registry (last visited March 7, 2017).

Hospitals submit data on measures established by the AHA's "Get With The Guidelines Stroke." These reporting measures include:

- Demographic information for patients;
- Patient arrival mode;
- Time from last known well to triage (ED arrival);
- Time from ED arrival to initial imaging work-up;
- Time from hospital arrival to initiation of specified therapies;
- Types of complications seen with specified therapies;
- Reasons why eligible stroke patients were not treated with specified services;
- Rate of prescription of different types of anti-hypertensive medications, antithrombotic medication, or diabetic medications prescribed at discharge;
- In-hospital mortality and risk-adjusted mortality measures;
- Percent of patient records that are saved as complete;
- Percent of patients where the "Get With The Guidelines" criteria are met; and
- Joint Commission core measures for primary stroke centers.[50]

As of March 2014, there were 64 Florida hospitals, and nine Puerto Rican hospitals participating in the Florida-Puerto Rico Stroke Registry.[51]

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 United States population lives more than an hour away from a stroke center.[52] 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.[53] 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.[54]

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 emergency department, and would then transfer these patients to a primary or comprehensive stroke center.[55]

The Joint Commission, the Healthcare Facilities Accreditation Program, and DNV GL (formerly known as Det Norske Veritas) offer certification as acute stroke ready centers.[56]

[50] AMERICAN HEART ASSOCIATION/ AMERICAN STROKE ASSOCIATION, *Get With The Guidelines: Stroke Fact Sheet*, available at http://www.heart.org/idc/groups/heart-public/@wcm/@gwtg/documents/downloadable/ucm_310976.pdf (last visited March 7, 2017).
[51] THE UNIVERSITY OF MIAMI MILLER SCHOOL OF MEDICINE, *FL-PR Stroke Registry Participants*, http://spirp.med.miami.edu/registry-participants (last visited March 7, 2017).
[52] Mark J. Alberts, et a., *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), http://stroke.ahajournals.org/content/44/12/3382.full (last visited March 2, 2017).
[53] Id.
[54] Id.
[55] Id.
[56] *Supra*, note 23.

Effect of the Bill

Acute Stroke Ready Centers

CS/CS/CS/HB 785 amends s. 395.3038, F.S. to include a new level of stroke services, acute stroke ready centers. A hospital that meets the certification standards for acute stroke ready centers would receive the acute stroke ready center designation from AHCA in the same manner as primary and comprehensive stroke centers currently do. Currently, there are approximately 60 acute care hospitals that do not have primary or comprehensive stroke center designation and may be eligible for acute stroke ready center designation.[57]

This bill also adds acute stroke ready centers in the list of stroke centers DOH supplies to emergency service providers in the state.

Stroke Center Accreditation

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

Statewide Stroke Registry

The bill requires DOH, subject to a specific appropriation, to contract with a private entity in the state of Florida to establish and maintain a statewide stroke registry.

Acute stroke ready centers, primary stroke centers, and comprehensive stroke centers must report information specified by DOH, including nationally recognized performance measures, to the registry. The registry must use a nationally recognized platform to collect such data and ensure that the data is maintained and made available to improve or modify the stroke care system, ensure compliance with standards, and improve patient outcomes.

Stroke centers that do not comply with the reporting requirements to the registry will be subject to licensure denial, modification, suspension, or revocation by AHCA. Section 395.003(7)(a), F.S., authorizes AHCA to deny, modify, suspend, and revoke a license for the substantial failure to comply with any requirements of Part I of Chapter 395, F.S., which is where the statute establishing the stroke registry is located.

The bill grants liability protection from damages or any other relief for any entity that provides information required by the registry.

The bill removes obsolete deadlines for DOH to implement the stroke-triage assessment tool.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 395.3038, F.S., relating to state-listed stroke centers; notification of hospitals.
Section 2: Creates s. 395.30381, F.S., relating to statewide stroke registry.
Section 3: Amends s. 395.3041, F.S, relating to emergency medical services providers; triage and transportation of stroke victims to a stroke center.
Section 4: Provides an effective date of July 1, 2017.

[57] *Supra*, note 23.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

DOH will incur rulemaking costs to develop the electronic forms stroke centers will utilize to submit the required information. Current resources can absorb these costs. The DOH may also incur the cost of contracting with a private entity to establish and maintain the registry, which is subject to an appropriation. It is unknown what this may cost.

AHCA will incur rulemaking costs related to updating criteria for acute stroke ready centers and comprehensive stroke centers. Current resources can absorb these costs.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

Public hospitals, emergency medical service providers, and medical examiner offices that would be required to submit data to DOH may be required the purchase of new software and incur labor costs to collect, maintain and send required data to DOH.[58] The estimated cost of this is unknown at this time.[59]

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Private hospitals, emergency medical service providers, and medical examiner offices that would be required to submit data to DOH may be required to purchase software and incur labor costs to collect, maintain, and send required data to DOH.[60] The estimated cost of this is unknown at this time.[61]

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

[58] *Supra*, note 44.
[59] Id.
[60] Id.
[61] Id.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 8, 2017, the Health Quality Subcommittee adopted an amendment and reported the bill favorably as a committee substitute. The amendment:

- Required DOH to contract with a recognized medical organization to establish and maintain the statewide stroke registry.
- Required the contractor to maintain the registry and make available the reports for use in any study to reduce morbidity or mortality or to improve the stroke care system.
- Specified the information that stroke centers must report to the stroke registry.
- Removed the requirement that emergency medical service providers submit data to the registry.
- Required DOH, instead of AHCA to develop the electronic form for stroke centers to use to report to the registry, and requires DOH to make this form available on its website.

On March 21, 2017, the Health Care Appropriations Subcommittee adopted an amendment and reported the bill favorably as a committee substitute. The amendment:

- Permitted rather than required DOH to establish a statewide stroke registry and electronic forms for reporting.
- Required DOH to contract with a private entity only if an appropriation is made for the specific purpose of establishing and maintaining a stroke registry.

On March 30, 2017, the Health and Human Services Committee adopted an amendment and reported the bill favorably as a committee substitute. The amendment:

- Made the creation of a statewide stroke registry is contingent on a specific appropriation to DOH.
- Required stroke centers to report nationally recognized performance measures to the registry, instead of to DOH.
- Required the registry to use a nationally recognized platform to collect performance measure data from stroke centers.
- Removed the requirement that DOH develop forms for reporting to the registry.
- Removed DOH rulemaking authority for the registry.
- Reorganized s. 395.30381, F.S., to improve clarity.

This analysis is drafted to the committee substitute as passed by the Health and Human Services Committee.