CS/CS/CS/HB 785 passed the House on April 20, 2017, and subsequently passed the Senate on May 1, 2017.

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.

The Agency for Health Care Administration (AHCA) establishes criteria for primary and comprehensive stroke centers in Florida. Additionally, AHCA maintains an inventory of hospitals offering stroke services. However, many patients with an acute stroke live in areas without ready access to a primary or comprehensive stroke center. A recent study proposed a new designation, acute stroke-ready centers, for hospitals that are not primary stroke centers, but can provide timely, evidence-based care to most patients with an acute stroke. The bill creates a new level of stroke services entitled acute stroke ready centers.

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. The bill adds acute stroke-ready centers to the list of stroke centers that DOH supplies to emergency service providers in the state.

In 2009, the University of Miami Miller School of Medicine created the Florida Puerto Collaboration to Reduce Stroke Disparities, which created a voluntary stroke registry among hospitals in Florida and Puerto Rico. There are 64 Florida hospitals participating in the registry.

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 has an insignificant negative fiscal impact on AHCA and a significant negative fiscal impact on DOH, accommodated by a specific appropriation in the 2017-2018 General Appropriation Act of $200,000 in nonrecurring general revenue to the University of Miami.

The bill was approved by the Governor on June 26, 2017, ch. 2017-172, L.O.F., and will become effective on July 1, 2017.
I. SUBSTANTIVE INFORMATION

A. EFFECT OF 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. The brain needs a constant supply of oxygen and nutrients in order to function. Even a brief interruption in blood supply from a stroke can cause problems; brain cells begin to die after just a few minutes without blood or oxygen. 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. Stroke is one of the leading causes of death in the United States.

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.

Ischemic Stroke

Hemorrhagic Stroke

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

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2 UCLA STROKE CENTER, What is a Stroke?, http://stroke.ucla.edu/what-is-a-stroke (last visited May 1, 2017).
3 Id.
4 Id.
6 Id.
8 Id.
9 Id.
10 Id.
the brain.\textsuperscript{11} With both types of ischemic stroke, the blood clot or plaque blocks the flow of oxygenated blood to a portion of the brain.\textsuperscript{12}

The two types of hemorrhagic stroke are intracerebral and subarachnoid.\textsuperscript{13} In an intracerebral hemorrhage, a blood vessel inside the brain leaks blood or ruptures.\textsuperscript{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.\textsuperscript{15} In both types of hemorrhagic stroke, the leaked blood causes swelling of the brain and increased pressure in the skull.\textsuperscript{16}

Time is of the essence for stroke treatment; medical personnel begin treatment in an ambulance on the way to the emergency room.\textsuperscript{17} Treatment for a stroke also depends on how much time has passed since symptoms began and on whether it is ischemic or hemorrhagic.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{21}

**Stroke Centers in Florida**

Florida was one of the first four states to enact primary stroke center legislation.\textsuperscript{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.\textsuperscript{23}

*Primary Stroke Centers*

A primary stroke center certification recognizes hospitals that meet standards to support better outcomes for stroke care.\textsuperscript{24} These hospitals must also collect and utilize performance data to improve quality of care for stroke patients.\textsuperscript{25}

A 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

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\textsuperscript{11} Id. The blood clot or other substance traveling through the bloodstream is called an embolus.

\textsuperscript{12} Id.

\textsuperscript{13} Id.

\textsuperscript{14} Id.

\textsuperscript{15} Id.

\textsuperscript{16} Id.

\textsuperscript{17} CENTERS FOR DISEASE CONTROL AND PREVENTION, Stroke Treatment, https://www.cdc.gov/stroke/treatments.htm (Last visited May 1, 2017).

\textsuperscript{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 May 1, 2017).

\textsuperscript{19} Id.

\textsuperscript{20} Supra, note 17.


\textsuperscript{22} Id.; see s. 3, ch. 2004-325, Laws of Fla.

\textsuperscript{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.

\textsuperscript{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 May 1, 2017).

\textsuperscript{25} Id.
Certification Manual, 2nd Edition for AHCA to designate the hospital program as a primary stroke center. Certified primary stroke centers must:

- 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.

**Comprehensive Stroke Centers**

A comprehensive stroke center certification recognizes hospitals that meet standards to treat the most complex stroke cases. AHCA may designate a hospital program as a compressive stroke center if the hospital program has received primary stroke center designation, and has:

- Personnel with clinical expertise in specified disciplines available;
- Advanced diagnostic capabilities;
- Neurological surgery and endovascular interventions;
- Specialized infrastructure and
- Quality improvement and clinical outcomes measurement.

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26 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 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 May 1, 2017).

29 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 endarterectomy, 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, 7 days per week basis 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.

30 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, transesophageal and trans-esophageal echocardiography, tests of cerebral blood flow and metabolism, and comprehensive hematological and hypercoagulability profile testing.

31 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.

32 Rule 59A-3.2085(15)(b), F.A.C. The specialized infrastructure includes extensive requirements that ensure emergency medical services (EMS) uses 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.
Additionally, 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 and ICU and acute stroke unit with appropriately trained\(^{34}\) personnel;
- 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;
- 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.\(^{35}\)

**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.\(^{36}\) Each licensed emergency medical services provider must use a stroke- triage assessment tool that is substantially similar to DOH’s stroke-triage assessment tool.\(^{37}\) 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.\(^{38}\)

**Stroke Center Inventory**

AHCA must maintain an inventory of hospitals offering stroke services\(^{39}\) and must publish on its website a listing of the hospitals meeting the criteria as either a primary or comprehensive stroke center.\(^{40}\) A list of hospitals with a stroke center designation is also available through the facility locator tool on www.floridahealthfinder.gov.\(^{41}\)

Currently, there are no data reporting requirements for stroke centers related to quality measures.\(^{42}\) There are 274 emergency medical service providers, 222 acute care hospitals and 25 medical examiner districts that report patient data to DOH.\(^{43}\) However, the data is not standardized and much of

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\(^{33}\) 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.

\(^{34}\) The ICU must have medical and nursing personnel with special training, skills and knowledge in the management of patients with all forms of neurological/neurosurgical conditions that require intensive care; and the acute stroke unit must have medical and nursing personnel with training, skills and knowledge sufficient to care for patients with neurological conditions, particularly acute stroke patients, and be appropriately trained in neurological assessment and management.

\(^{35}\) Rule 59A-3.2085(15)(b), F.A.C.

\(^{36}\) S. 395.3041(2), F.S.

\(^{37}\) Id.

\(^{38}\) S. 395.3041(1), F.S.

\(^{39}\) S. 395.3038, F.S.

\(^{40}\) Supra, note 23.

\(^{41}\) Id.

\(^{42}\) Id.

the data that DOH currently collects comes from voluntary participation in DOH’s EMS Tracking and Reporting System (EMSTARS) program. This only includes data on response, provider impression, procedures and medication and destination.

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). The FPCRSD seeks to address stroke disparities among African Americans and Hispanics and to identify the best approaches to eliminate stroke care disparities in these groups. The FPCRSD 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.” 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.

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.

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44 The EMSTARS program allows emergency medical providers to capture incident level patient care records for every emergency activation.
45 Supra, note 43.
47 Id.
As of March 2014, there were 64 Florida hospitals, and nine Puerto Rican hospitals participating in the Florida-Puerto Rico Stroke Registry.  

**Acute Stroke Ready Centers**

Many patients with an acute stroke live in areas without ready access to a primary or comprehensive stroke center. In fact, more than half the United States population lives more than an hour away from a stroke center. 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. 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.

A recent study by the American Stroke Association proposed a new designation, acute stroke ready centers, 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. These hospitals could then transfer these patients to a primary or comprehensive stroke center, if necessary.

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

**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.

This bill also adds acute stroke ready centers to 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.

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50 THE UNIVERSITY OF MIAMI MILLER SCHOOL OF MEDICINE, FL-PR Stroke Registry Participants, [http://spirp.med.miami.edu/registry-participants](http://spirp.med.miami.edu/registry-participants) (last visited May 1, 2017).
51 Id.
52 Id.
53 Id.
54 Id.
55 Id.
56 Supra, note 23.
57 Supra, note 23.
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.

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.

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, which can be absorbed within existing resources.

   DOH would have incurred the cost of contracting with a private entity to establish and maintain the registry, which is subject to an appropriation. However, in the Fiscal Year 2017-2018 General Appropriations Act, the Legislature appropriated $200,000 in nonrecurring general revenue to the University of Miami for the stroke registry.\(^{58}\)

   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.

\(^{58}\) S. 3, SB 2500 (2017), Specific Appropriation 473. Subject to the Governor’s veto powers, the effective date of the General Appropriations Act is July 1, 2017.
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. The estimated cost of this is unknown at this time.60

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. The estimated cost of this is unknown at this time.62

D. FISCAL COMMENTS:

None.