

**HOUSE OF REPRESENTATIVES STAFF ANALYSIS
FINAL BILL ANALYSIS**

BILL #: CS/CS/HB 993 Stroke Centers

SPONSOR(S): Health & Human Services Committee and Health Market Reform Subcommittee, Plakon and others

TIED BILLS: IDEN./SIM. BILLS: CS/CS/SB 1460

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Market Reform Subcommittee	14 Y, 0 N, As CS	Royal	Crosier
2) Health & Human Services Committee	17 Y, 0 N, As CS	Royal	Calamas

FINAL HOUSE FLOOR ACTION: 114 Y's 0 N's
GOVERNOR'S ACTION: Approved

SUMMARY ANALYSIS

CS/CS/HB 993 passed the House on May 1, 2019 as CS/CS/SB 1460.

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.

Pursuant to s. 395.3038, F.S., the Agency for Health Care Administration (AHCA) must post on its website an inventory of hospitals that meet the criteria for stroke services. To be included in the inventory, a hospital must attest to AHCA that the program meets criteria established by AHCA or that it is certified by a nationally recognized accrediting organization.

The Department of Health (DOH) maintains a statewide stroke registry for use to improve or modify the stroke care system, ensure compliance with standards, and improve patient outcomes. Stroke centers must report information specified by DOH, including nationally recognized performance measures, to the registry. By June 1 of each year, DOH must provide the medical directors of each licensed emergency medical services provider in the state the list of stroke centers, by type.

The bill requires all stroke centers to be certified by a nationally recognized accrediting organization in order to be included in AHCA's list of stroke centers. Stroke centers currently on the list that are not certified must become certified by July 1, 2021. The bill also allows certified thrombectomy-capable stroke centers (TSCs) to be included in the list of stroke centers and requires them to comply with the reporting requirements of the statewide stroke registry. The bill prohibits stroke centers that are not certified from advertising that they are on the list of stroke centers maintained by AHCA.

The bill adds TSCs to the list of stroke centers that DOH must provide to the medical director of each licensed emergency medical service provider by June 1 every year and requires the protocols for dealing with stroke patients established by emergency medical services providers to consider the capability of an emergency receiving facility to improve outcomes for those patients suspected of having an emergent large vessel occlusion.

The bill does not have a fiscal impact on state or local governments.

The bill was approved by the Governor on June 25, 2019, chapter 2019-135, Laws of Florida. The bill provides an effective date of July 1, 2019.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

STORAGE NAME: h0993z1.HMR.DOCX

DATE: 6/26/2019

I. SUBSTANTIVE INFORMATION

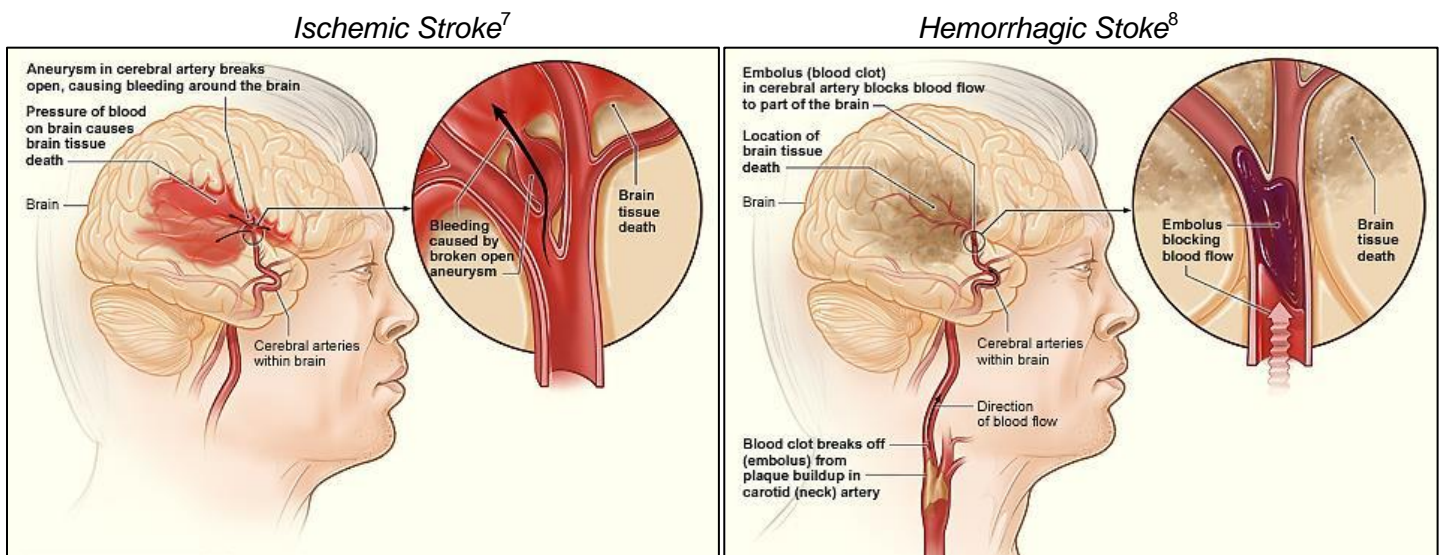
A. EFFECT OF CHANGES:

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.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 stroke 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



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 22, 2019).

² UCLA Stroke Center, *What is a Stroke?*, <http://stroke.ucla.edu/what-is-a-stroke> (last visited March 22, 2019).

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 22, 2019).

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 22, 2019).

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 A hemorrhagic stroke may be treated with surgery to find and stop the bleeding,¹⁹ while treatment for an ischemic stroke may include medicines, such as antiplatelet medicines and blood thinners, and medical procedures, such as a thrombectomy.²⁰ During a thrombectomy, a doctor threads a catheter through an artery in the patient's groin up to the patient's brain and uses a tiny mechanical device to break up or remove the clot.²¹

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.²² 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.²³

Stroke Centers in Florida

Florida was one of the first four states, in 2004, to enact primary stroke center legislation.²⁴ Pursuant to s. 395.3038, F.S., the Agency for Health Care Administration (AHCA) must post on its website an inventory of hospitals that meet the criteria for stroke services. To be included in the inventory, a hospital must attest in an affidavit that the program meets criteria established by AHCA rule or that it is certified by a nationally recognized accrediting organization. There are three designations for stroke centers: Acute Stroke Ready Center (ASRC), Primary Stroke Center (PSC), and Comprehensive Stroke Center (CSC). There are 112 Florida hospitals designated as PSCs, 48 designated as CSCs and none designated as ASRCs.²⁵

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*, available at <https://www.cdc.gov/stroke/treatments.htm> (Last visited March 22, 2019).

¹⁸ National Heart, Lung, and Blood Institute, *Stroke Treatment* available at <https://www.nhlbi.nih.gov/health/health-topics/topics/stroke/treatment> (last visited March 22, 2019).

¹⁹ Id.

²⁰ Oregon Health & Science University Brain Institute, *Thrombectomy*, available at: <https://www.ohsu.edu/xd/health/services/brain/getting-treatment/diagnosis/stroke/treatment-options/surgery-neuro-interventions/thrombectomy.cfm> (last visited March 22, 2019).

²¹ Id.

²² *Supra*, note 17.

²³ 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 22, 2019)

²⁴ S. 3, ch. 2004-325, Laws of Fla.

²⁵ Florida Agency for Health Care Administration, *Agency Analysis of SB 1460*, (Feb. 26, 2019) (analysis on file with Health Market Reform Subcommittee Staff). Although stroke services is dependent upon the availability of qualified health care professionals, the

Primary Stroke Centers

A primary stroke center certification recognizes hospitals that meet standards to support better outcomes for stroke care.²⁶ 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.²⁷ These hospitals must also collect and utilize performance data to improve quality of care for stroke patients.²⁸

In order for AHCA to designate a hospital program as a primary stroke center, the hospital program must have an acute stroke team available 24 hours per day, 7 days per week, capable of responding to patients who are in the emergency department or an inpatient unit within 15 minutes of being called.²⁹ The team must consist of a physician and one or more of the following³⁰:

- A registered professional nurse;
- An advanced registered nurse practitioner; or
- A physician assistant.

Each acute stroke team member must receive 8 or more hours of education related to cerebrovascular disease annually. A PSC must offer ongoing professional education at least twice per year to its acute stroke team members, emergency department staff, and prehospital personnel.³¹

A PSC must have a medical director with knowledge of cerebrovascular disease to serve who is responsible for implementing the stroke services protocols. The hospital's governing board must set any additional qualifications for the medical director.³²

A PSC must have the following services available 24 hours per day, 7 days per week³³:

- A dedicated emergency department;
- Clinical laboratory services;
- Diagnostic imaging;³⁴
- Administration of intravenous thrombolytic;
- Reversal of anticoagulation; and
- Neurologist services, available in person or via telemedicine.

The PSC must have a quality improvement program designed to analyze data, correct errors, and identify system improvements and ongoing improvement in patient care and delivery of services. A

majority of primary stroke centers have fewer than 300 inpatient beds and the majority of comprehensive stroke centers have more than 300 beds.

²⁶ American Heart Association, *Primary Stroke Center Certification*,

http://www.heart.org/HEARTORG/Professional/HospitalAccreditationCertification/PrimaryStrokeCenterCertification/Primary-%20%20Stroke-Center-Certification_UCM_439155_SubHomePage.jsp (last visited March 22, 2019).

²⁷ Id.

²⁸ Id.

²⁹ Rule 59A-3.246, F.A.C.

³⁰ Id.

³¹ Id.

³² Id.

³³ Id.

³⁴ Id., Diagnostic imaging includes head computed tomography (CT), CT angiography (CTA), brain and cardiac magnetic resonance imaging (MRI), magnetic resonance angiography (MRA), and transthoracic and/or transesophageal echocardiography

PSC must have a multidisciplinary institutional Quality Improvement Committee that meets on a regular basis to monitor quality benchmarks as set by the committee and review clinical complications.³⁵

Comprehensive Stroke Centers

A comprehensive stroke center certification recognizes hospitals that meet standards to treat the most complex stroke cases.³⁶ 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 personnel with clinical expertise in specified disciplines available,³⁷ advanced diagnostic capabilities,³⁸ neurological surgery and endovascular interventions,³⁹ and specialized infrastructure,⁴⁰ and quality improvement and clinical outcomes measurement.⁴¹ The specialized infrastructure includes extensive requirements for emergency medical services (EMS) to ensure that EMS use a stroke triage assessment tool, EMS assessment/management at the scene is consistent with evidence-based practice, inter-facility transfers are facilitated, and an on-going communication system with EMS providers regarding availability of services is maintained. In addition to these requirements, a comprehensive stroke center must:

³⁵ Id.

³⁶ 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 22, 2019).

³⁷ Supra, FN 29. 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 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.

³⁸ Supra, FN 29. 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.

³⁹ Supra, FN 29. 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.

⁴⁰ Supra, FN 29.

⁴¹ Supra, FN 29. 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.

- Maintain an acute stroke team available 24 hours per day, 7 days per week, and a system for facilitating inter-facility transfers, and 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.⁴²

Acute Stroke Ready Centers

Acute Stroke Ready Centers (ASRC) provide initial diagnostic services, stabilization, emergent care and therapies to patients with an acute stroke who are seen in their emergency department, and then transfer these patients to a primary or comprehensive stroke center.⁴³ The Joint Commission, the Healthcare Facilities Accreditation Program, and DNV GL (formerly known as Det Norske Veritas) offer certification as acute stroke ready centers.⁴⁴

In order for AHCA to designate a hospital program as an acute stroke ready center, the hospital program must have an acute stroke team available 24 hours a day, 7 days a week, and be capable of responding to patients who are in the emergency department or an inpatient unit within 15 minutes of being called.⁴⁵ An ASRC team must consist of a physician and one or more of the following⁴⁶:

- A registered professional nurse;
- An advanced registered nurse practitioner; or
- A physician assistant.

An ASRC must also designate a physician with knowledge of cerebrovascular disease to serve as the ASRC medical director who is responsible for implementing the stroke services protocols. The hospital's governing board must set any additional qualifications for the medical director.

⁴² Supra, FN 29.

⁴³ 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), <http://stroke.ahajournals.org/content/44/12/3382.full> (last visited March 22, 2019).

⁴⁴ Supra, FN 25.

⁴⁵ Supra, FN 29.

⁴⁶ Id.

Each ASRC team member must receive four or more hours of education related to cerebrovascular disease annually. An ASRC must offer ongoing professional education at least twice per year for its acute stroke team members, emergency department staff, and prehospital personnel.⁴⁷

An ASRC must have the following services available 24 hours a day, 7 days a week⁴⁸:

- A dedicated emergency department;
- Clinical laboratory services;
- Diagnostic imaging capability for a head computed tomography (CT) and magnetic resonance imaging (MRI);
- Intravenous thrombolytics available;
- Anticoagulate reversal medication available;
- Neurologist services available in person or via telemedicine; and
- A transfer agreement with a PSC or CSC.

Statewide Stroke Registry

The Department of Health (DOH) maintains a statewide stroke registry with data submitted by ASRCs, PSCs, and CSCs, which is available for use to improve or modify the stroke care system, ensure compliance with standards, and improve patient outcomes.⁴⁹ ASRCs, PSCs, and CSCs must report information specified by DOH, including nationally recognized performance measures, to the registry. Stroke centers that do not comply with the reporting requirements to the registry are subject to licensure denial, modification, suspension, or revocation by AHCA.⁵⁰ Current law grants liability protection from damages or any other relief for any ASRC, PSC, and CSC for providing the information required by the registry. By June 1 of each year, DOH must provide the medical directors of each licensed emergency medical services provider in the state the list of ASRCs, PSCs, and CSCs.⁵¹ The medical director of each licensed emergency medical services provider must develop and implement a protocol for the assessment, treatment, and transportation destination of stroke patients with the intent to assess, treat, and transport stroke patients to the most appropriate hospital.⁵²

Thrombectomy-Capable Stroke Centers

The Joint Commission, in collaboration with the American Heart Association and American Stroke Association, is offering a new advanced stroke certification for Thrombectomy-Capable Stroke Centers (TSC) in response to the need to identify hospitals that meet rigorous standards for performing thrombectomies.⁵³

To achieve TSC certification, a hospital must⁵⁴:

⁴⁷ Id.
⁴⁸ Id.
⁴⁹ S. 395.30381, F.S.
⁵⁰ S. 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.
⁵¹ S. 395.3041(1), F.S.
⁵² Id.
⁵³ The Joint Commission, *Certification for Thrombectomy-Capable Stroke Centers*, available at https://www.jointcommission.org/certification/certification_for_thrombectomycapable_stroke_centers.aspx (last visited March 22, 2019)
⁵⁴ Id.; The Joint Commission, *Stroke Certification*, available at: <https://www.jointcommission.org/assets/1/6/TJC-Stroke-brochure-vfinal-low-rez1.PDF> (last viewed March 22, 2019); The Joint Commission, *The Joint Commission Stroke Certification Programs – Program Concept Comparison* available at https://www.jointcommission.org/comparison_grid_stroke_certification_programs/ (last visited March 22, 2019).

- Have performed thrombectomy and post-procedure care for at least 15 patients with ischemic stroke over the past 12 months (or 30 over past 24 months).
- Have an acute stroke team available 24 hours, 7 days a week with the ability to be at bedside within 15 minutes;
- Have a neurologist accessible 24 hours, 7 days a week via in person or telemedicine;
- Have a program director with a background in neurology that is able to provide clinical and administrative guidance to the program;
- Have designated stroke beds;
- Have certain diagnostic imaging capabilities;
- Have the ability to provide intravenous therapy thrombolytics;
- Track, monitor, and report specified performance measures;
- Meet minimum thrombectomy volume requirements;
- Demonstrate the ability to perform thrombectomy, 24 hours a day, 7 days a week;
- Maintain dedicated intensive care beds for acute ischemic stroke patients; and
- Collect and review data regarding adverse patient outcomes following thrombectomy.

TSC certification also requires the hospital's neurointerventionists who routinely take calls to perform a thrombectomy meet certain certification or educational requirements and have performed 15 thrombectomies over the past 12 months (or 30 over past 24 months).⁵⁵

TSC certification also requires that nurses and other emergency department staff have two hours annually of stroke education, stroke nurses and core stroke team must have eight hours annually of stroke education, and at least two stroke education activities are provided to the public annually.⁵⁶

Effect of the Bill

The bill requires all stroke centers to be certified by a nationally recognized accrediting organization in order to be included in AHCA's list of stroke centers. Stroke centers currently on the list that are not certified must become certified by July 1, 2021. The bill prohibits stroke centers that are not certified from advertising that they are on the list of stroke centers maintained by AHCA. The bill also allows certified TSCs to be included in the list of stroke centers.

The bill requires TSCs to comply with the reporting requirements of the statewide stroke registry at DOH and grants TSCs the same liability protection from damages or any other relief that other stroke centers have for providing information required by the registry.

The bill adds TSCs to the list of stroke of centers that DOH must provide to the medical director of each licensed emergency medical service provider by June 1 every year and requires the protocols for dealing with stroke patients established by emergency medical services providers to consider the capability of an emergency receiving facility to improve outcomes for those patients suspected of having an emergent large vessel occlusion.

The bill provides an effective date of July 1, 2019.

⁵⁵ The Joint Commission, The Joint Commission Stroke Certification Programs – Program Concept Comparison available at https://www.jointcommission.org/comparison_grid_stroke_certification_programs/ (last visited March 22, 2019). The Joint Commission also sets specific experience requirements for the neurologists.

⁵⁶ Id.

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:

Stroke centers that wish to be included in the list maintained by AHCA will incur costs associated with certification.

D. FISCAL COMMENTS:

None.