

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: CS/SB 1460

INTRODUCER: Health Policy Committee; and Senators Book and Powell

SUBJECT: Stroke Centers

DATE: March 19, 2019

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	Fav/CS
2.	_____	_____	AHS	_____
3.	_____	_____	AP	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1460 revises the criteria under which a hospital qualifies as a stroke center and adds a new class of stroke centers to the current-law list of stroke centers that the Agency for Health Care Administration (AHCA) is required to maintain and make available on its website and to the Department of Health (DOH).

The bill directs the AHCA to include thrombectomy-capable stroke centers (TSC) in its list of stroke centers, in addition to acute stroke-ready centers (ASRC), primary stroke centers (PSC), and comprehensive stroke centers (CSC) that current law requires the AHCA to include in the list.

The bill eliminates a hospital's ability to be included in the AHCA's list of stroke centers by attesting with an affidavit that it meets the criteria for qualifying as a stroke center or that it has been certified as a stroke center by a nationally recognized accrediting organization. Under the bill, in order to be included in the AHCA's list, a hospital must submit documentation verifying its certification as a stroke center, which may include offering and performing endovascular therapy consistent with standards identified by a nationally recognized, guidelines-based organization approved by the AHCA.

The bill prohibits a hospital from advertising that it is a state-listed stroke center unless the hospital has submitted verifying documentation to the AHCA, as opposed to merely notifying the AHCA as under current law.

The bill directs the DOH to include data from TSCs in its annual list to the medical directors of licensed emergency medical service (EMS) providers and directs the medical directors to develop and implement transportation and rerouting protocols for stroke patients with the intent to reroute them to ASRCs, PSCs, CSCs, and TSCs.

The effect date of the bill is July 1, 2019.

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 stroke 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

¹ The Mayo Clinic, *Stroke*, available at <http://www.mayoclinic.org/diseases-conditions/stroke/home/ovc-20117264>, (last visited Mar. 12, 2019).

² UCLA Health, *What is a Stroke?* available at <http://stroke.ucla.edu/what-is-a-stroke>, (last visited Mar. 12, 2019).

³ Id.

⁴ Id.

⁵ National Institutes of Health, National Heart, Lung and Blood Institute, *Stroke - Also known as a Cerebrovascular Accident*, available at <https://www.nhlbi.nih.gov/health/health-topics/topics/stroke>, (last visited Mar. 12, 2019).

⁶ Id.

⁷ Id.

⁸ Id.

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

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. Signs and symptoms of a stroke may include:

- Sudden weakness;
- Paralysis 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

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.

¹⁵ Id.

¹⁶ Center for Disease Control and Prevention, *Stroke Treatment* (updated May. 18, 2017) available at <https://www.cdc.gov/stroke/treatments.htm>, (last visited Mar. 12, 2019).

¹⁷ National Institutes of Health, National Heart, Lung and Blood Institute, *Treatment*, available at <https://www.nhlbi.nih.gov/health/health-topics/topics/stroke/treatment> (last visited Mar. 12, 2019).

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.

stroke.²⁰ According to the federal Centers for Disease Control and Prevention (CDC), research indicates that patients receiving care at PSCs have a higher survival and recovery rate than those treated in hospitals without this type of specialized care.²¹

Stroke Centers in Florida

Florida first enacted legislation relating to PSCs and CSCs in 2004.²² In 2017, the Legislature added ASRCs to the list of PSCs and CSCs, which is made available to licensed emergency medical services (EMS) providers.²³ The AHCA has adopted a rule establishing the criteria for ASRCs, PSCs, and CSCs.²⁴ There are currently no Florida hospitals designated as ASRCs, 114 designated as PSCs in 40 counties, and 48 CSCs in 22 counties.²⁵

National Accrediting Organizations

The Joint Commission, the Healthcare Facilities Accreditation Program, and the DNV GL (formerly known as Det Norske Veritas) offer certifications to hospitals as an ASRC, PSC, CSC, and TSC.²⁶

Licensure

A hospital may apply for designation as an ASRC, PSC, or CSC by submitting a hospital licensure application²⁷ and attaching a License Application Stroke Center Affidavit, both of which must be signed by the hospital's chief executive officer, attesting that the stroke program meets:

- The criteria for one of the designations as specified by rule, or
- Is certified as a stroke center by The Joint Commission, the Health Facilities Accreditation Program, or DNV GL.²⁸

A hospital seeking stroke center certification must establish specific procedures for screening patients to recognize that numerous conditions, including cardiac disorders, often mimic stroke

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/dhds/pubs/docs/primary_stroke_center_report.pdf, (last visited Mar. 12, 2019)

²² Section 3, ch. 2004-325, Laws of Fla.

²³ Chapter 2017-172, Laws of Fla.

²⁴ Section 395.3038(1), F.S. and Fla. Admin. Code R. 59A-3.246(4), (2019).

²⁵ Agency for Health Care Administration, Hospital & Outpatient Service Unit, Reports, *Stroke Centers* (updated Mar. 1, 2019), available at http://www.fdhc.state.fl.us/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/Reports.shtml (last visited Mar. 12, 2019).

²⁶The Joint Commission, *Certification for Acute Stroke Ready Center*, https://www.jointcommission.org/certification/acute_stroke_ready_hospitals.aspx; *Certification Comprehensive Stroke Center*, available at https://www.jointcommission.org/certification/advanced_certification_comprehensive_stroke_centers.aspx; *Certification for Primary Stroke Centers*, available at https://www.jointcommission.org/certification/primary_stroke_centers.aspx; *Certification for Thrombectomy-Capable Stroke Centers*, available at https://www.jointcommission.org/certification/certification_for_thrombectomycapable_stroke_centers.aspx, (last visited Mar. 13, 2019).

²⁷ Fla. Admin. Code R. 59A-3.066(2), (2019).

²⁸ Fla. Admin. Code R. 59A-3.246(4)(a), (2019).

in children. Medical staff must ensure that transfer to an appropriate facility for specialized care is provided to children and young adults with known childhood diagnoses.²⁹

Acute Stroke Ready Centers (ASRC)

An ASRC is a hospital that is designated by the AHCA as meeting Florida regulation requirements based on national guidelines to meet the initial needs of stroke patients and support better outcomes for stroke care as part of a stroke care system.³⁰ A hospital with an ASRC certification is required to notify the ACHA if it no longer meets the criteria.³¹

Many patients with an acute stroke live in areas without ready access to a PSC or CSC; more than half the U.S. population lives more than an hour away from a stroke center.³² 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.³³ 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.³⁴

An ASRC 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. An ASRC team must consist of a physician and one or more of the following:

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

Each ASRC team member must receive four or more hours of education related to cerebrovascular disease annually. An ASRC must fulfill the educational needs of its acute stroke team members, emergency department staff, and pre-hospital personnel by offering ongoing professional education at least twice per year.

An ASRC must designate a physician with knowledge of cerebrovascular disease to serve as the ASRC medical director. The medical director is responsible for implementing the stroke services protocols. The qualifications for the medical director of an ASRC are determined by the hospital governing board.

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

- A dedicated emergency department;

²⁹ Fla. Admin. Code R. 59A-3.346(4)(b), (2019).

³⁰ Agency for Health Care Administration, Facility/Provider Definitions, *Acute Stroke Ready Center*, available at: <http://www.floridahealthfinder.gov/about-ahca/facility-locator-glossary.aspx> (last visited Mar. 12, 2019).

³¹ Section 395.3038, F.S.

³² 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 Mar.12, 2019).

³³ *Id.*

³⁴ *Id.*

- Clinical laboratory services;³⁵
- 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.³⁶

Primary Stroke Centers (PSC)

A PSC certification recognizes hospitals that meet standards to support better outcomes for stroke care.³⁷ 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 and American Stroke Association or equivalent guidelines.³⁸

These hospitals must also collect and utilize performance data to improve quality of care for stroke patients.³⁹

In order for the AHCA to designate a hospital program as a PSC, the hospital program must be certified by the Joint Commission as a PSC or meet the certification criteria applicable to PSCs as outlined in the Joint Commission Disease-Specific Care Certification Manual, 2nd Edition.⁴⁰ The manual requires a PSC to:⁴¹

- 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 the hospital's application of and compliance with clinical practice guidelines published by the American Heart Association and American Stroke Association or equivalent, evidence-based guidelines.⁴²

³⁵ Fla. Admin. Code R. 59A-3.255(6)(g), (2019).

³⁶ Fla. Admin. Code R. 59A-3.246(4)(c), 5., (2019).

³⁷ American Heart Association, *Facts: Primary Stroke Centers*, available at <https://www.yourethecure.org/facts-primary-stroke-centers> (last visited Mar. 12, 2019).

³⁸ Id.

³⁹ *Supra* note 32.

⁴⁰ Fla. Admin. Code R. 59A-3.2085(15)(a), (2019).

⁴¹ The standards are published in the 2019 *Disease-Specific Care Review Process Guide*, available at https://www.jointcommission.org/assets/1/6/2019_Disease_Specific_Care_Organization_RPG.pdf (last visited Mar. 12, 2019).

⁴² The Joint Commission, *Discover the Most Comprehensive Stroke Certifications* (March, 2019), available at https://www.jointcommission.org/certification/primary_stroke_centers.aspx (last visited Mar. 12, 2019).

A PSC must have an acute stroke team available 24 hours a day, 7 days a week, capable of responding to patients who are in the emergency department or an inpatient unit within 15 minutes of being called. A PSC team must consist of a physician and one or more of the following:

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

Each acute stroke team member must receive eight or more hours of education related to cerebrovascular disease annually. A PSC must fulfill the educational needs of its acute stroke team members, emergency department staff, and prehospital personnel by offering ongoing professional education at least twice per year.

A PSC must designate a physician with knowledge of cerebrovascular disease to serve as the PSC medical director. The medical director is responsible for implementing the stroke services protocols. The qualifications for the medical director are determined by the hospital's governing board.

A PSC must have the following services available 24 hours a day, 7 days a week:

- A dedicated emergency department;
- Clinical laboratory services;⁴³
- Diagnostic imaging to include head CT, CT angiography (CTA), brain and cardiac magnetic resonance imaging (MRI), magnetic resonance angiography (MRA), and transthoracic and/or transesophageal echocardiography;
- Intravenous thrombolytics;
- Anticoagulate reversal medication available for administration; and
- Neurologist services, available in person or via tele-medicine.

The following services may be available on-site or via a transfer agreement:

- Neurosurgical services within two hours of being deemed clinically necessary;
- Physical, occupational, or speech therapy; and
- Neurovascular interventions for aneurysms, stenting of carotid arteries, carotid endarterectomy, and endovascular therapy.

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

A multidisciplinary institutional Quality Improvement Committee must monitor quality benchmarks and review clinical complications on a regular basis. Specific benchmarks, outcomes, and indicators must be defined, monitored, and reviewed by the Quality Improvement Committee on a regular basis for quality assurance purposes.⁴⁴

⁴³ See Fla. Admin. Code R. 59A-3.255(6)(g), (2019), for specific laboratory requirements.

⁴⁴ Fla. Admin. Code R.59A-3.246(4)(d), (2019).

Comprehensive Stroke Centers (CSC)

A CSC certification recognizes hospitals that meet standards to treat the most complex stroke cases.⁴⁵ These hospitals must meet all the criteria of a PSC. They must also have advanced imaging techniques and personnel trained in vascular neurology, neurosurgery, and endovascular procedures available 24 hours a day, 7 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 CSC, the hospital program must have received PSC designation and also have the following:

- Personnel with clinical expertise in specified disciplines available;⁴⁶
- Advanced diagnostic capabilities;⁴⁷
- Neurosurgical and endovascular interventions available;⁴⁸
- Specialized infrastructure; and
- Quality improvement and clinical outcomes measurements.⁴⁹

The specialized infrastructure includes extensive requirements that the EMS and CSC 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
- Ongoing communication with EMS providers regarding availability of services.

A CSC must maintain:

- An acute stroke team available 24 hours a day, 7 days a week;
- A system for facilitating inter-facility transfers;
- Defined access telephone numbers in a system for accepting appropriate transfers;
- 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 or 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;

⁴⁵ The American Heart Association, *Get with the Guidelines – Stroke Clinical Tools*, available at <https://www.heart.org/en/professional/quality-improvement/get-with-the-guidelines/get-with-the-guidelines-stroke/get-with-the-guidelines-stroke-clinical-tools> (last visited Mar. 12, 2019).

⁴⁶ See Fla. Admin. Code R. 59A-3.2085(15)(b) (2019), for specific qualifications. 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 two hours, and neurologist(s) with special expertise in the management of stroke patients should be available 24 hours per day, 7 days per week.

⁴⁷ Id.

⁴⁸ *Supra* note 42.

⁴⁹ Id.

- Inpatient post-stroke rehabilitation and ensure continuing arrangements post-discharge for rehabilitation needs and medical management;
- The education of its medical and paramedical professionals by offering ongoing professional education for all disciplines;
- An ongoing effort to educate inpatients, their families, and the public about risk factor reduction or management, primary and secondary prevention, the warning signs and symptoms of stroke, and medical management and rehabilitation for stroke patients;
- 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.⁵⁰

Thrombectomy-Capable Stroke Centers (TSC)

The Joint Commission, in collaboration with the American Heart Association and American Stroke Association, is offering a new advanced stroke certification for TSCs in response to the need to identify hospitals that meet rigorous standards for performing endovascular thrombectomy (EVT).⁵¹

To achieve TSC certification, a hospital must:

- Demonstrate compliance with the new standards for TSC certification;⁵²
- Meet the minimum mechanical thrombectomy volume requirements, outlined in the following chart:

Joint Commission Quality Measures for Disease-Specific Care Certification⁵³

Measure Set No.	Measure Short Name	Ischemic Stroke	Hemorrhagic Stroke
STK-1	Venous Thromboembolism (VTE) Prophylaxis	X	X
STK-2	Discharged on Antithrombotic Therapy	X	
STK-3	Anticoagulation Therapy for Atrial Fibrillation/Flutter	X	
STK-4	Thrombolytic Therapy	X	
STK-5	Antithrombotic Therapy By End of Hospital Day 2	X	

⁵⁰ Id.

⁵¹ The Joint Commission, *Certification for Thrombectomy-Capable Stroke Centers*, available at https://www.jointcommission.org/certification/certification_for_thrombectomycapable_stroke_centers.aspx (last visited Mar. 12, 2019)

⁵² All certified Thrombectomy-Capable Stroke Center (TSC) programs will be required to collect and report data for the eight Joint Commission stroke (STK) measures in addition to five selected comprehensive stroke (CSTK) measures relating to ischemic strokes for a total performance measurement requirement of 13 measures. In addition to collecting and reporting this data, organizations are expected to use this information for ongoing performance improvement efforts. The Joint Commission, *Thrombectomy-Capable Stroke Performance Measurement Requirements*, available at https://www.jointcommission.org/certification/thrombectomycapable_stroke_performance_measurement_requirements.aspx (last visited Mar. 12, 2019)

⁵³ Id.

Measure Set No.	Measure Short Name	Ischemic Stroke	Hemorrhagic Stroke
STK-6	Discharged on Statin Medication	X	
STK-8	Stroke Education	X	X
STK-10	Assessed for Rehabilitation	X	X

- Demonstrate the ability to perform mechanical thrombectomy, 24 hours a day, 7 days a week;
- Maintain dedicated intensive care beds for acute ischemic stroke patients;
- Meet the expectations for the availability of staff and practitioners closely aligned with CSC expectations;
- Collect and review data regarding adverse patient outcomes following mechanical thrombectomy; and
- Collect data for 13 standardized performance measures listed in the chart above.⁵⁴

Stroke Center Inventory

The AHCA maintains a list of hospitals offering stroke services.⁵⁵ The list of hospitals meeting the criteria as a ASRC, PSC, or CSC is published on the AHCA's website.^{56,57} There are also 286 EMS providers⁵⁸ that report patient stroke data to the DOH.⁵⁹ However, the data are not standardized, and many of the data that the DOH currently collects come from voluntary participation in the DOH's EMS Tracking and Reporting System (EMSTARS) program⁶⁰ and only includes data on response, provider impression, procedures and medication, and destination.⁶¹

Health care records submitted to the DOH from licensed EMS providers are confidential and exempt from public records requests under s. 401.30(4), F.S.

Stroke Patient Transportation

The DOH has also developed a stroke assessment tool.⁶² The tool is available on the DOH's website and is provided to EMS providers.⁶³ Each licensed EMS provider must use a stroke triage assessment tool that is substantially similar to the DOH's stroke triage assessment tool.⁶⁴

⁵⁴ *Supra* note 55.

⁵⁵ Section 395.3038, F.S.

⁵⁶ *Supra* note 255.

⁵⁷ *Id.* A list of hospitals with a stroke center designation is also available through the facility locator tool on www.floridahealthfinder.gov, (last visited Mar. 12, 2019).

⁵⁸ Department of Health, *EMS Provider Licensure Report*, available at <http://www.floridahealth.gov/licensing-and-regulation/ems-service-provider-regulation-and-compliance/ems-providers.html> (last visited Mar. 12, 2019).

⁵⁹ Agency For Health Care Administration, *Hospital ER Services*, available at http://www.fdhc.state.fl.us/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/reports/Hospital_ER_Services.pdf, (last visited Mar. 13, 2019).

⁶⁰ The EMSTARS program allows emergency medical providers to capture incident level patient care records for every emergency activation.

⁶¹ *Supra* note 59.

⁶² Section 395.3041(2), F.S.

⁶³ Section 395.3041(2), F.S.

⁶⁴ *Id.*

Annually, by June 1, the DOH sends the list of ASRCs, PSCs, and CSCs to the medical director of each licensed EMS provider in Florida.⁶⁵

III. Effect of Proposed Changes:

CS/SB 1460 amends s. 395.3038, F.S., to add TSCs to the AHCA's list of certified stroke centers.

The bill requires that listed hospitals must be certified by a nationally recognized certifying organization as meeting the criteria for an ASRC, PSC, TSC, or CSC. The AHCA's list must include only those hospitals that have submitted documentation to the AHCA verifying their certification as an ASRC, PSC, TSC or CSC. That documentation may include, but is not limited to, any stroke center that offers and performs mechanical endovascular therapy (EVT) consistent with the standards identified by a nationally recognized, guidelines-based organization approved by the AHCA.

The bill eliminates the use of an affidavit attesting that the hospital's stroke program meets the criteria for one of the stroke center designations, as specified by AHCA rule, as an alternate method for the hospital to be listed.

The bill directs that if a hospital chooses to no longer be certified by a nationally recognized certifying organization, or has not attained national certification as an ASRC, PSC, CSC, or TSC, the hospital must notify the AHCA and the AHCA must immediately remove the hospital from its list of stroke centers.

The bill strikes AHCA's rule-making authority to establish criteria for an ASRC, PSC, and CSC which were required to be substantially similar to the certification standards for the same categories of stroke centers of a nationally recognized accrediting organization.

The bill amends s. 395.30381, F.S., to require that the stroke performance data on ASRCs, PSCs, and CSCs, received by DOH from the private data collection entity charged with maintaining the statewide stroke registry (EMSTARS), include TCSs and performance measures on compliance with nationally recognized guidelines.

The bill amends s. 395.3039, F.S., to prohibit a hospital from advertising that it is a state-listed ASRC, PSC, CSC, or TSC, unless the hospital has submitted documentation to the AHCA verifying that it is certified and meets the certification criteria of a nationally recognized certifying organization.

The bill amends s. 395.3041, F.S., to direct the DOH to include data from TSCs in its annual list to the medical directors of licensed EMS providers. The bill directs the medical directors of licensed EMS providers to develop and implement transportation and rerouting protocols, in addition to assessment and treatment protocols, for stroke patients with the intent to reroute them to ASRCs, PSCs, CSCs, and TSCs. The protocols must include plans for the triage and transport of suspected stroke patients, including, but not limited to, patients who may have an emergent

⁶⁵ Section 395.3041(1), F.S.

large vessel occlusion, to an appropriate facility within a specified timeframe after such patients exhibit the sudden onset of stroke-related symptoms.

The bill directs the DOH and the medical directors of licensed EMS providers to specifically consider the capability of an emergency receiving facility to improve outcomes for patients who are suspected, based on clinical severity, of having an emergent large vessel occlusion in developing the protocols.

The effective date of the bill is July 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Hospitals that maintain ASRCs, PSCs, CSCs, or TSCs, are required under CS/SB 1460 to be certified by a nationally recognized certifying organization and may incur a cost for their application for certification. They may need to purchase new software and incur labor costs to collect, maintain, and send the required data to the DOH. Such costs, if any, are indeterminate.

C. Government Sector Impact:

The DOH may need additional resources to fund its contract with the private entity engaged to establish and maintain the statewide stroke registry, due to the need to begin collecting and analyzing the additional data required under the bill.

VI. Technical Deficiencies:

CS/SB 1460 removes from the underlying bill the requirement for the DOH to join forces with licensed EMS service providers to develop and implement transportation and rerouting protocols for stroke patients. However, on line 119, the CS fails to also remove the DOH from the process of considering what to include in the protocols. An amendment to correct this technical deficiency should be considered.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 395.3038, 395.30381, 395.3039, and 395.3041.

IX. Additional Information:**A. Committee Substitute – Statement of Substantial Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on March 18, 2019:

The CS:

- Removes specific entities that may certify that an ASRCs, PSCs, CSCs, or TSCs meets the standards of a specific type of stroke center and requires only that the certifying entity must be a nationally recognized, guidelines-based organization approved by the AHCA; and
- Removes the DOH from the protocol development and implementation process with licensed EMS medical directors for transportation and rerouting of stroke patients with the intent to reroute them to ASRCs, PSCs, CSCs, and TSCs.

B. Amendments:

None.