The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	SB 1612
INTRODUCER:	Senator Brodeur
SUBJECT:	Adult Cardiovascular Care Standards
DATE:	February 5, 2024
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Brown	HP	**Pre-meeting**
2.			AHS	
3.			RC	

I. Summary:

SB 1612 amends s. 395.1055, F.S., to amend requirements in that section related to the Agency for Health Care Administration's (AHCA) rules governing adult cardiovascular services (ACS). The bill eliminates specific requirements for providers of diagnostic cardiac catheterization (DCC) services and amends requirements for Level I and Level II ACS to:

- Specify that Level I services include rotational or other atherectomy devices, electrophysiology, and treatment of chronic total occlusions;
- Eliminate minimum patient volume requirements required for licensure for both Level I and Level II ACS providers;
- Eliminate the requirement that rules for ACS services require nursing and technical staff to have a specified level of experience; and
- Require that ACS providers meet Society for Cardiac Angiography and Intervention guidelines.

The bill also requires the AHCA to update all AHCA rules related to hospitals and ambulatory surgical centers as often as necessary to remain consistent with new standards and guidelines published by federal health agencies and nationally recognized medical organizations.

The bill provides an effective date of July 1, 2024.

II. Present Situation:

Diagnostic Cardiac Catheterization Services and Adult Cardiovascular Services

Section 395.1055, F.S., establishes requirements for the AHCA to adopt in rule governing the provision of DCC services and ACS. Section 395.1055(16), F.S., requires the AHCA to adopt rules ensuring that each provider of DCC:

- Complies with the most recent guidelines of the American College of Cardiology and American Heart Association Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories.
- Performs only adult inpatient diagnostic cardiac catheterization services and will not provide therapeutic cardiac catheterization or any other cardiology services.
- Maintains sufficient appropriate equipment and health care personnel to ensure quality and safety.
- Maintains appropriate times of operation and protocols to ensure availability and appropriate referrals in the event of emergencies.
- Demonstrates a plan to provide services to Medicaid and charity care patients.

Section 395.1055(18), F.S., establishes requirements that the AHCA must adopt in rule governing the provision of ACS. The section divides ACS into two levels, Level I and Level II, with Level I ACS providers authorized to provide adult percutaneous cardiac intervention (PCI) without cardiac surgery and with Level II providers being authorized to perform PCI with cardiac surgery.

In order to provide Level I ACS, a hospital must demonstrate that, for the most recent 12-month period as reported to the AHCA, the hospital has provided a minimum of 300 adult inpatient and outpatient DCCs, or

- For the most recent 12-month period, has discharged or transferred at least 300 patients with the principal diagnosis of ischemic heart disease; and
- That it has a formalized, written transfer agreement with a hospital that has a Level II program, including written transport protocols to ensure safe and efficient transfer of a patient within 60 minutes.

In order to provide Level II ACS a hospital must demonstrate that:

- For the most recent 12-month period as reported to the AHCA, the hospital has performed a minimum of 1,100 adult inpatient and outpatient cardiac catheterizations, of which at least 400 must be therapeutic catheterizations; or
- For the most recent 12-month period, has discharged at least 800 patients with the principal diagnosis of ischemic heart disease.

Both Level I and Level II ACS providers must:

- Have nursing and technical staff that have demonstrated experience in handling acutely ill patients requiring intervention, based on the staff member's previous experience in dedicated cardiac interventional laboratories or surgical centers. If a staff member's previous experience is in a dedicated cardiac interventional laboratory at a hospital that does not have an approved adult open heart surgery program, the staff member's previous experience qualifies

only if, at the time the staff member acquired his or her experience, the dedicated cardiac interventional laboratory:
  - Had an annual volume of 500 or more percutaneous cardiac intervention procedures.
  - Achieved a demonstrated success rate of 95 percent or greater for percutaneous cardiac intervention procedures.
  - Experienced a complication rate of less than five percent for percutaneous cardiac intervention procedures.
  - Performed diverse cardiac procedures, including, but not limited to, balloon angioplasty and stenting, rotational atherectomy, cutting balloon atheroma remodeling, and procedures relating to left ventricular support capability.
- Comply with the most recent guidelines of the American College of Cardiology[1] and the American Heart Association for staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria, to ensure patient quality and safety.
- Establish appropriate hours of operation and protocols to ensure availability and timely referral in the event of emergencies.
- Demonstrate a plan to provide services to Medicaid and charity care patients.
- For a hospital that is licensed for DCC and provides Level I or Level II ACS, demonstrate that the hospital is participating in the American College of Cardiology's National Cardiovascular Data Registry or the American Heart Association's Get with the Guidelines–Coronary Artery Disease registry and documentation of an ongoing quality improvement plan ensuring that the licensed cardiac program meets or exceeds national quality and outcome benchmarks reported by the registry in which the hospital participates. A hospital licensed for Level II adult cardiovascular services must also participate in the clinical outcome reporting systems operated by the Society for Thoracic Surgeons.

Diagnostic Cardiac Catheterization

Diagnostic cardiac catheterization is a test or treatment for certain heart or blood vessel problems, such as clogged arteries or irregular heartbeats. It uses a thin, hollow tube called a catheter. The tube is guided through a blood vessel to the heart. Diagnostic cardiac catheterization gives important details about the heart muscle, heart valves and blood vessels in the heart. During the procedure, a doctor can test the pressures in the heart or do treatments such as opening a narrowed artery. Sometimes a piece of heart tissue is removed for examination.

Diagnostic cardiac catheterization is a common method to diagnose or treat a variety of heart problems, for example:
- Irregular heartbeats, called arrhythmias.
- Chest pain, called angina.
- Heart valve problems.

Possible diagnoses that could need DCC include:
- Coronary artery disease.
- Congenital heart disease.

[1] American College of Cardiology guidelines are available at https://ahca.myflorida.com/content/download/9664/file/2012_ACC_SCAI_Guidelines.pdf, (last visited Feb. 2, 2024).

- Heart failure.
- Heart valve disease.
- Damage to the walls and inner lining of tiny blood vessels in the heart, called small vessel disease or coronary microvascular disease.

During DCC, a doctor can:
- Look for narrowed or blocked blood vessels that could cause chest pain.
- Measure pressure and oxygen levels in different parts of the heart.
- See how well the heart pumps blood.
- Take a sample of tissue from your heart for examination under a microscope.
- Check the blood vessels for blood clots.
- Diagnostic cardiac catheterization may be done at the same time as other heart procedures or heart surgery.[2]

Percutaneous Coronary Intervention

Percutaneous coronary intervention (PCI), also commonly known as coronary angioplasty or angioplasty, is a nonsurgical technique for treating obstructive coronary artery disease, including unstable angina, acute myocardial infarction, and multi-vessel coronary artery disease.[3]

PCI uses a catheter to insert a small structure called a stent to reopen blood vessels in the heart that have been narrowed by plaque build-up, a condition known as atherosclerosis. Using a special type of X-ray called fluoroscopy, the catheter is threaded through blood vessels into the heart where the coronary artery has narrowed. When the tip is in place, a balloon tip covered with a stent is inflated. The balloon tip compresses the plaque and expands the stent. Once the plaque is compressed and the stent is in place, the balloon is deflated and withdrawn. The stent stays in the artery, holding it open.[4]

III. Effect of Proposed Changes:

SB 1612 amends s. 395.1055, F.S., to:
- Eliminate statutory requirements for DCC.

[2] Mayo Clinic, Cardiac Catheterization, available at Cardiac catheterization - Mayo Clinic, (last visited Feb. 2, 2024).
[3] Medscape: Percutaneous cardiac intervention, *available at* http://emedicine.medscape.com/article/161446-overview, (last visited Feb. 2, 2024).
[4] Heart and Stroke Foundation, *available at* https://www.heartandstroke.ca/heart/treatments/surgery-and-other-procedures/percutaneous-coronary-intervention, (last visited Feb. 2, 2024).

- Specify that Level I ACS includes PCI with rotational or other atherectomy devices,[5] electrophysiology,[6] and treatment of chronic total occlusions.[7]
- Eliminate the requirements that a Level I or Level II ACS provider must provide a specified number DCCs or have a specified number of patients with ischemic heart disease in the previous 12-month period prior to licensure.
- No longer specify that a transfer agreement between a Level I and Level II ACS provider must ensure the patient transfer within 60 minutes.
- Eliminate requirements for minimum experience for nursing and technical staff.
- Add the Society for Cardiac Angiography and Intervention to the list of organizations whose guidelines Level I and II ACS providers to comply with.
- Require all AHCA rules for hospitals and ambulatory surgical centers to be updated as often as necessary to remain consistent with new standards and guidelines published by federal health agencies and nationally recognized medical organizations.

The bill provides an effective date of July 1, 2024.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

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[5] Rotational atherectomy (RA) is an atheroablative technology that enables percutaneous coronary intervention for complex, calcified coronary lesions. RA works on the principle of 'differential cutting' and preferentially ablates hard, inelastic, calcified plaque. The objective of RA use has evolved from plaque debulking to plaque modification to enable balloon angioplasty and optimal stent expansion. *See* Gupta T, Weinreich M, Greenberg M, Colombo A, Latib A. Rotational Atherectomy: A Contemporary Appraisal. Interv Cardiol. 2019 Nov 18;14(3):182-189. doi: 10.15420/icr.2019.17.R1. PMID: 31867066; PMCID: PMC6918488.

[6] An electrophysiological study (EP study) is a test used to evaluate the heart's electrical system and to check for abnormal heart rhythms. Natural electrical impulses coordinate contractions of the different parts of the heart. This helps keep blood flowing the way it should. This movement of the heart creates the heartbeat, or heart rhythm. During an EP study, a doctor inserts small, thin wire electrodes into a vein in the groin (or neck, in some cases). He or she will then thread the wire electrodes through the vein and into the heart. To do this, he or she uses a special type of X-ray called fluoroscopy. Once in the heart, the electrodes measures the heart's electrical signals. Electrical signals are also sent through the electrodes to stimulate the heart tissue to try to cause the abnormal heart rhythm. This is done so that it can be evaluated and its cause can be found. It may also be done to help evaluate how well a medicine is working. *See* What is an electrophysiological study? Johns Hopkins Medicine, available at https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/electrophysiological-studies#:~:text=An%20electrophysiological%20study%20(EP%20study,flowing%20the%20way%20it%20should., (last visited Feb. 2, 2024).

[7] A Chronic total occlusion (CTO) is a complete or nearly complete blockage of one or more coronary arteries. The blockage, typically present for at least three months, is caused by a buildup of plaque within a coronary artery. When this happens, blood flow to the heart is compromised. CTO is a common heart disorder in patients with coronary artery disease. Between 20 and 25 percent of patients with coronary artery disease also have a chronically blocked artery. *See* Chronic Total Occlusion (CTO), University of Michigan Health, available at https://www.uofmhealth.org/conditions-treatments/chronic-total-occlusion-cto, (last visited Feb. 2, 2024).

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

Art. III, s. 6 of the Florida Constitution requires that "every law shall embrace but one subject and matter properly connected therewith, and the subject shall be briefly expressed in the title." SB 1612 is titled "An act relating to Adult Cardiovascular Care Standards." However, on lines 133-136, the bill adds a requirement for the AHCA to update its rules to remain consistent with new standards and guidelines, which is amending a provision that applies to all AHCA rules governing hospitals and ambulatory surgical centers, not just those providing standards related to ACS. As such, it is possible that SB 1612 may be found to violate Art. III, s. 6 of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

This bill may have an indeterminate fiscal impact on facilities providing DCC services and ACS relating to changes in rule requirements for those services.

C. Government Sector Impact:

This bill may have an indeterminate negative fiscal impact on the AHCA related to the requirement that the AHCA update its rules as often as necessary to remain consistent with new standards and guidelines published by federal health agencies and nationally recognized medical organizations.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 395.1055 of the Florida Statutes.

IX. Additional Information:

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

None.

B. Amendments:

None.