

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 596

INTRODUCER: Senator Leek

SUBJECT: Cardiac Services Providers

DATE: March 31, 2025

REVISED: _____

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

I. Summary:

SB 596 amends s. 395.1055, F.S., to require the Agency for Health Care Administration (AHCA) to grant licensure for Level I or Level II adult cardiovascular services (ACS) programs to a hospital that meets specified criteria, rather than requiring the AHCA to adopt such criteria in rule.

Specific to Level I programs, the bill eliminates the requirement that a hospital demonstrate a specified volume of patients needing ACS prior to licensure and the requirement that nursing and technical staff have demonstrated experience in providing ACS.

For both Level I and Level II programs, the bill requires that such programs comply with guidelines from the Society for Cardiovascular Angiography and Interventions and, if the hospital provides electrophysiology services, the Heart Rhythm Society, in addition to the current-law requirement that hospitals comply with guidelines from the American College of Cardiology and the American Heart Association.

Additionally, the bill requires the AHCA to update its rules to administer the requirements of part II, of ch. 408, F.S., as new industry standards and guidelines are published.

The bill provides an effective date of October 1, 2025.

II. Present Situation:

Adult Cardiovascular Services

ACS include one or more of the following services provided at a hospital that is licensed to provide such service.

Adult Diagnostic Cardiac Catheterization

Adult Diagnostic Cardiac Catheterization (DDC) is a test or treatment for certain heart or blood vessel problems, such as clogged arteries or irregular heartbeats. The procedure uses a thin, hollow tube called a catheter. The tube is guided through a blood vessel to the heart. DDC 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. Usually, a patient is awake during cardiac catheterization but given medicines to help with relaxation. The risk of major complications is generally low.¹

The AHCA licenses hospitals to provide DDC under requirements established in subsection (1) of Rule 59A-3.246, F.A.C. Currently, there are 22 hospitals in Florida licensed to provide adult DDC.²

Level I Adult Cardiovascular Services

Section 395.1055, F.S., specifies that a license to provide Level I ACS authorizes the licensed hospital to provide adult percutaneous cardiac intervention (PCI) without onsite cardiac surgery. PCI is a minimally invasive procedure to open blocked coronary arteries. An older name for PCI is coronary angioplasty with stenting, or angioplasty for short. Arteries are the blood vessels that carry oxygen-rich blood from the heart throughout the body. A PCI procedure uses a small balloon to reopen a blocked artery to increase blood flow. Usually, the cardiologist places a small, permanent tube (stent) to keep the artery open long-term. The stent usually contains medication that releases directly into the artery (drug-eluting stent) to reduce the risk of re-narrowing within the stent.³

In order to be licensed to provide Level I ACS, a hospital must meet the requirements established by the AHCA in Rule 59A-3.246(2), F.A.C. For initial licensure, these requirements include, but are not limited to, that the hospital must have provided a minimum of 300 adult inpatient and outpatient DDC or, for the most recent 12-month period, has discharged or transferred a minimum of 300 patients with the principal diagnosis of ischemic heart disease and the intent and ability to comply with the 2012 ACC/SCAI Guidelines and the 2014 Update on Percutaneous Coronary Intervention Without Onsite Surgical Backup.^{4, 5} Additionally, a hospital

¹ Mayo Clinic, *Cardiac Catheterization*, available at <https://www.mayoclinic.org/tests-procedures/cardiac-catheterization/about/pac-20384695> (last visited March 27, 2025).

² Florida Health Finder search, available at <https://quality.healthfinder.fl.gov/Facility-Provider/Hospital?&type=1> (last visited Mar. 27, 2025).

³ Cleveland Clinic, *Percutaneous Coronary Intervention*, 11/06/21, available at <https://my.clevelandclinic.org/health/treatments/22066-percutaneous-coronary-intervention> (last visited Mar. 27, 2025).

⁴ Bashore, T, Balter, S, Barac, A. et al. 2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update: A Report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents. *JACC*. 2012 Jun, 59 (24) 2221–2305, available at <https://www.sciencedirect.com/science/article/pii/S0735109712005104> (last visited Mar. 27, 2025).

⁵ Gregory J. Dehmer, MD, James C. Blankenship, MD, Mehmet Cilingiroglu, MD, James G. Dwyer, MD, Dmitriy N. Feldman, MD, Timothy J. Gardner, MD, Cindy L. Grines, MD, and Mandeep Singh, MD, MPH, SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup. *AHA/ASA Journals*, Volume 129, Number 24. March 17, 2014, available at <https://www.ahajournals.org/doi/10.1161/CIR.0000000000000037> (last visited Mar. 27, 2025).

licensed to provide Level I ACS must have a transfer agreement with a hospital licensed as a Level II ACS provider.

Staff at a Level I ACS provider must meet the following criteria:

- At initial licensure, each cardiologist must be an experienced physician who has performed a minimum of 50 interventional cardiology procedures, including at least 11 primary cardiology interventional procedures, exclusive of fellowship training, and within the previous 12 months from the date of the Level I adult cardiovascular licensure application.
- At licensure renewal, interventional cardiologists must perform a minimum of 50 interventional cardiology procedures per year averaged over a two-year period or be confirmed by the review process described in subparagraph 59A-3.246(3)(b)3., F.A.C.
- Technical catheterization laboratory staff must be credentialed as Registered Cardiovascular Invasive Specialist or must complete a hospital-based education and training program at a hospital providing Level I or Level II adult cardiovascular services. This training program must include a minimum of 500 hours proctored clinical experience, including participation in a minimum of 120 interventional cardiology procedures and didactic education components of hemodynamics, pharmacology, arrhythmia recognition, radiation safety, and interventional equipment.
- Coronary care unit nursing staff must be trained and experienced with invasive hemodynamic monitoring, operation of temporary pacemaker, management of Intra-Aortic Balloon Pump, management of in-dwelling arterial/venous sheaths and identifying potential complications such as abrupt closure, recurrent ischemia and access site complications.

Currently, there are 68 hospitals in Florida licensed to provide Level I ACS.⁶

Level II Adult Cardiovascular Services

A Level II ACS license authorizes a hospital to provide the performance of PCI with onsite cardiac surgery.⁷ In addition to the above requirements, a Level II ACS provider must demonstrate at initial licensure that for the most recent 12-month period, the hospital has provided a minimum of 1,100 adult inpatient and outpatient cardiac catheterizations, of which at least 400 must be therapeutic cardiac catheterizations, or, for the most recent 12-month period, has discharged at least 800 patients with the principal diagnosis of ischemic heart disease and each cardiac surgeon is required to be board certified.

Currently, there are 78 Florida hospitals licensed to provide Level II ACS.⁸

III. Effect of Proposed Changes:

SB 596 amends s. 395.1055, F.S., to require the AHCA to grant licensure to provide Level I or Level II ACS if a hospital meets the requirements established in statute, rather than requiring the AHCA to adopt rules for such licensure that include the minimum requirements provided in statute.

⁶ *Supra* n. 2

⁷ Section 395.1055(18)(a), F.S.

⁸ *Supra* n. 2

Specific to Level I ACS licensure, the bill *eliminates* the requirements that:

- A hospital must demonstrate that the hospital must have provided a minimum of 300 adult inpatient and outpatient DDC or, for the most recent 12-month period, has discharged or transferred a minimum of 300 patients with the principal diagnosis of ischemic heart disease and a related exception for hospitals located more than 100 road miles from a Level II ACS provider; and
- At a minimum, nursing and technical staff 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.

For both Level I and Level II programs, the bill requires that such programs comply with guidelines from the Society for Cardiovascular Angiography and Interventions and, if the hospital provides electrophysiology services, the Heart Rhythm Society, in addition to the current-law requirement that hospitals comply with guidelines from the American College of Cardiology and the American Heart Association.

Additionally, the bill requires the AHCA to update its rules to administer the requirements of part II, of ch. 408, F.S., as new industry standards and guidelines are published.

The bill provides an effective date of October 1, 2025.

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:

Article III Section 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.” The title of SB 596 is “an act relating to cardiac services providers.” However, lines 114-117 of the bill amend the AHCA’s grant of rulemaking authority to administer the requirements of part II, of ch. 408, F.S., which apply to *all* facilities that the AHCA regulates, and not just to cardiac services providers. As such, it is possible that lines 114-117 may be unconstitutional as the changes on those lines may exceed the scope of the bill provided in the bill’s title.

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

SB 596 amends s. 395.1055(18), F.S., to require the AHCA to grant licensure to provide Level I or Level II ACS if a hospital meets the requirements established in statute, rather than requiring the AHCA to adopt rules for such licensure that include the minimum requirements provided in statute.

However, subsection (17) of that statute, which is not amended by the bill, provides that “each provider of adult cardiovascular services or operator of a burn unit shall comply with *rules adopted by the agency which establish licensure standards that govern the provision of adult cardiovascular services* or the operation of a burn unit, as applicable. At a minimum, such rules must address staffing, equipment, physical plant, operating protocols, the provision of services to Medicaid and charity care patients, accreditation, licensure periods and fees, and enforcement of minimum standards.”

As such, it is unclear whether the AHCA would be required to license an ACS provider that meets the minimum requirements provided in subsection (18) even if the provider is unable to meet the minimum standards established by the AHCA pursuant to subsection (17).

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.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.
