HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1259 Provider of Cardiovascular Services
SPONSOR(S): Select Committee on Health Innovation, Andrade and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1612

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Select Committee on Health Innovation	11 Y, 0 N, As CS	Guzzo	Calamas
2) Health & Human Services Committee	16 Y, 0 N	Guzzo	Calamas

SUMMARY ANALYSIS

The Agency for Health Care Administration (AHCA) licenses three levels of hospital programs for Adult Cardiovascular Services (ACS), including adult inpatient diagnostic cardiac catheterization, Level I ACS, and Level II ACS.

Licensed Level I ACS programs provide diagnostic and therapeutic cardiac catheterization services, including percutaneous cardiac intervention (PCI involves placing a stent in an artery to allow the flow of blood), on a routine and emergency basis. Level I ACS programs must have written transfer agreements with at least one hospital licensed as a Level II ACS program, which must allow the safe transfer of a patient within 60 minutes. Level I ACS programs are not allowed to perform open heart surgery, use rotational or other atherectomy devices, or treat chronic total occlusions.

The bill amends licensure requirements for Level I ACS programs. Specifically, it authorizes programs to perform adult PCI for treatment of chronic total occlusions, and to use rotational or other atherectomy devices, or electrophysiology when performing PCI.

The bill has no fiscal impact on state or local government.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Hospital Licensure

The Agency for Health Care Administration (AHCA) regulates hospitals under chapter 395, F.S., and the general licensure provisions of part II, of chapter 408, F.S. Hospitals offer a range of health care services with beds for use beyond 24 hours by individuals requiring diagnosis, treatment, or care.[1] Hospitals must make regularly available at least clinical laboratory services, diagnostic X-ray services, and treatment facilities for surgery or obstetrical care, and other definitive medical treatment.[2]

Section 395.1055, F.S., authorizes AHCA to adopt rules for hospitals which must include minimum standards to ensure:[3]

- A sufficient number of qualified types of personnel and occupational disciplines are on duty and available at all times to provide necessary and adequate patient care;
- Infection control, housekeeping, sanitary conditions, and medical record procedures are established and implemented to adequately protect patients;
- A comprehensive emergency management plan is prepared and updated annually;
- Licensed facilities are established, organized, and operated consistent with established standards and rules;
- Licensed facility beds conform to minimum space, equipment, and furnishing standards;
- Each hospital has a quality improvement program designed according to standards established by their current accrediting organization;
- Licensed facilities make available on their websites, and in hard copy format upon request, a description of and a link to their patient charge and performance outcome data;
- All hospitals providing organ transplantation, neonatal intensive care services, inpatient psychiatric services, inpatient substance abuse services, or comprehensive medical rehabilitation meet the minimum licensure requirements adopted by AHCA.

Separate standards may be provided for general and specialty hospitals, ambulatory surgical centers, and statutory rural hospitals.[4] The minimum standards for hospital licensure are contained in Chapter 59A-3, F.A.C.

Percutaneous Cardiac Intervention

Percutaneous cardiac intervention (PCI), commonly known as coronary angioplasty or angioplasty, is a nonsurgical technique for treating obstructive coronary artery disease.[5] PCI uses a catheter to insert a stent in the heart to reopen blood vessels that have been narrowed by plaque build-up, a condition known as atherosclerosis.[6] The catheter is threaded through blood vessels into the heart where the coronary artery is narrowed.[7] Once in place, a balloon tip covered with a stent is inflated to compress

[1] S. 395.002(12), F.S.
[2] *Id.*
[3] S. 395.1055(1), F.S.
[4] S. 395.1055(2), F.S.
[5] George A Stouffer, III, and Pradeep K Yadav, *Percutaneous Coronary Intervention (PCI)*, MEDSCAPE, Oct. 12, 2016, available at http://emedicine.medscape.com/article/161446-overview (last visited January 31, 2024).
[6] Percutaneous coronary intervention (PCI or angioplasty with stent), Heart and Stroke, available at https://www.heartandstroke.ca/heart/treatments/surgery-and-other-procedures/percutaneous-coronary-intervention (last visited January 31, 2024).
[7] *Id.*

the plaque and expand the stent.[8] When the plaque is compressed and the stent is in place, the balloon is deflated and withdrawn, leaving the stent to hold the artery open.[9]

In 2014, the Society for Cardiovascular Angiography and Interventions, the American College of Cardiology (ACC) and the American Heart Association (AHA) issued an Expert Consensus document on PCI without on-site surgical backup, which acknowledged advances and best practices in PCI performed in hospitals without on-site surgery (Level I adult cardiovascular services facilities).[10] The Expert Consensus document noted that while PCI peaked in 2006, PCIs at hospitals without on-site surgery have increased since 2007.[11] The Expert Consensus document recommends the PCI programs without on-site surgery have experienced nursing and technical laboratory staff with training in interventional laboratories.[12] The Expert Consensus document continues to recommend PCI procedures should not be performed in facilities performing fewer than 200 procedures, with few exceptions.[13] The Expert Consensus document also recommends that a 95% success rate and a less than 5% complication rate are more important factors than overall volume of procedures performed.[14]

Increasingly, these types of procedures are being done outside of a hospital setting, in office-based cardiac catheterization laboratories and ambulatory surgical centers (ASCs). In 2020, the US Centers for Medicare & Medicaid Services expanded coverage to include PCI in an ASC setting.[15] The new rule also removed the requirements for ASCs to have transfer agreements with acute care hospitals, and for physicians practicing at ASCs to have privileges at the acute care hospital with which they have a transfer agreement.

There are no state regulations for ASCs regarding these types of procedures other than compliance with building codes for treatment rooms. Studies have demonstrated that PCIs performed at sites without Level II surgery support have low rates of complications and similar outcomes to PCIs performed with surgery on site.[16]

Adult Cardiovascular Services

In 2007, certificate of need (CON)[17] review was eliminated for adult cardiovascular services (ASC) and such services are currently only subject to licensure requirements.[18] Section 395.1055, F.S., establishes three levels of hospital program licensure for ACS, including adult inpatient diagnostic cardiac catheterization, Level I ACS, and Level II ACS.

[8] *Id.*
[9] *Id.*
[10] Gregory J. Dehmer, et al., *SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup*, Society for Cardiovascular Angiography and Interventions, the American College of Cardiology Foundation, and the American Heart Association, Inc., (Mar. 17, 2014) available at https://www.ahajournals.org/doi/10.1161/CIR.0000000000000037 (last visited January 31, 2024).
[11] *Id.*
[12] *Id.*
[13] *Id.* The Expert Consensus document cites data from a 2010-2011 National Cardiovascular Data Registry showing that half (49%) of reporting facilities performed fewer than 400 PCIs annually and of these, 65% of the facilities without on-site surgery backup had an annual case volume of less than 200 PCIs.
[14] *Supra*, note 10.
[15] 42 C.F.R. § 410.49.
[16] Alice K. Jacobs, M.D., Sharon-Lise T. Normand, Ph.D., Joseph M. Massaro, Ph.D., et al., *Nonemergency PCI at Hospitals with or without On-Site Cardiac Surgery*, New England Journal of Medicine (April 2013), available at https://www.nejm.org/doi/full/10.1056/nejmoa1300610 (last visited January 31, 2024), *see also* Thomas Aversano, M.D., Cynthia C. Lemmon, R.N., B.S.N., M.S., and Li Liu, M.D., *Outcomes of PCI at Hospitals with or without On-Site Cardiac Surgery*, New England Journal of Medicine (May 2012), available at https://www.nejm.org/doi/full/10.1056/nejmoa1114540 (last visited January 31, 2024).
[17] A certificate of need is a written statement issued by AHCA evidencing community need for a new, converted, or expanded nursing home, intermediate care facility for the developmentally disabled, or hospice. *See* s. 408.036, F.S.
[18] Ch. 2007-214, Laws of Fla.

Level I ACS Programs

Licensed Level I ACS programs provide diagnostic and therapeutic cardiac catheterization services, including PCI, on a routine and emergency basis, but do not have on-site open-heart surgery capability.[19] Level I ACS programs must have written transfer agreements with at least one hospital licensed as a Level II ACS program, which must allow the safe transfer of a patient within 60 minutes.[20]

Licensed Level I ACS programs must comply with the most recent guidelines of the American College of Cardiology and American Heart Association Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories.[21] Additionally, they must comply with the reporting requirements of the American College of Cardiology-National Cardiovascular Data Registry.[22]

Level I ACS programs are prohibited from performing the following procedures:[23]

- Any therapeutic procedure requiring transseptal puncture;
- Any lead extraction for a pacemaker, biventricular pacer or implanted cardioverter defibrillator;
- Any rotational or other atherectomy devices; and
- Treatment of chronic total occlusions.

As of January 10, 2024, there were 69 hospitals licensed to provide Level I ACS.[24]

Effect of the Bill

CS/HB 1259 authorizes Level I ACS programs to perform adult PCI for treatment of chronic total occlusions,[25] and to use rotational or other atherectomy devices,[26] or electrophysiology[27] when performing PCI.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 395.1055, F.S., relating to rules and enforcement.
Section 2: Provides an effective date of July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

[19] S. 395.1055(18)(b)1.
[20] Rule 59A-3.246(2)(c), F.A.C.
[21] Rule 59A-3.246(2)(a)5., F.A.C.
[22] Rule 59A-3.246(2)(a)7., F.A.C.
[23] Rule 59A-3.246(2)(a)10., F.A.C.
[24] Agency for Health Care Administration, Agency Analysis of 2024 HB 1259 (Jan. 10, 2024).
[25] When a coronary artery becomes completely blocked – not simply narrowed – it is called a total occlusion, and if complete blockage lasts for three months or longer, it is referred to as "chronic total occlusion." *See* Yale Medicine, Chronic Total Occlusion Overview, available at https://www.yalemedicine.org/conditions/chronic-total-occlusion (last visited January 31, 2024).
[26] An atherectomy device is a catheter with a blade or laser on its end used to remove plaque from an artery. Types of atherectomy devices include: rotational atherectomy (tiny blades cut plaque in a circular motion); excisional atherectomy (a single blade cuts plaque in one direction); laser ablation atherectomy (a laser removes the plaque); and orbital atherectomy (a spinning tool that works like sandpaper to remove plaque). *See* Cleveland Clinic, PAD: Atherectomy; Overview What is Atherectomy for PAD?, available at https://my.clevelandclinic.org/health/treatments/17310-pad-atherectomy (last visited January 24, 2024).
[27] Electrophysiologic studies or "EP testing" is used to diagnose and treat abnormal heart rhythms. It involves the insertion of a catheter into a blood vessel that leads to the heart which inserts electrodes in the heart to measure electrical activity in the heart. *See* Cleveland Clinic, Electrophysiology (EP) Study, available at https://my.clevelandclinic.org/health/diagnostics/23054-electrophysiology-study (last visited January 31, 2024).

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

AHCA has sufficient rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On February 2, 2024, the Select Committee on Health Innovation adopted an amendment and reported the bill favorably as a committee substitute. The amendment:

- Restores current law related to licensure standards for diagnostic cardiac catheterization programs, Level I ACS programs, and Level II ACS programs.
- Authorizes rotational or other atherectomy devices, electrophysiology, and treatment of chronic total occlusions for Level I ACS programs.

The analysis is drafted to the committee substitute as passed by the Select Committee on Health Innovation.