HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 283 Cardiac Programs
SPONSOR(S): Raschein
TIED BILLS: **IDEN./SIM. BILLS:** SB 408

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	11 Y, 0 N	Langston	Crosier
2) Health Care Appropriations Subcommittee	11 Y, 0 N	Clark	Pridgeon
3) Health & Human Services Committee	18 Y, 0 N	Langston	Calamas

SUMMARY ANALYSIS

The Agency for Health Care Administration (AHCA) regulates hospitals, including adult cardiovascular services (ACS), under chapter 395, F.S., and the general licensure provisions of part II of chapter 408, F.S. Licensed Level I ACS programs provide diagnostic and therapeutic cardiac catheterization services, on a routine and emergency basis, but do not have on-site open-heart surgery capability. Level II ACS programs provide the same services as a Level I ACS program, but have on-site open-heart surgery capability.

A hospital seeking a Level I ACS program license must demonstrate that, for the most recent 12-month period as reported to AHCA, it:

- Provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations; or
- Discharged or transferred at least 300 inpatients with the principal diagnosis of ischemic heart disease and that it has a transfer agreement with a hospital that has a Level II ACS program, including written transport protocols to ensure safe and efficient transfer of a patient within 60 minutes.

HB 283 bill expands the type of patients that may be counted to meet the minimum volume threshold for treatment of ischemic heart, by counting all patients with ischemic heart disease, rather than only inpatients.

Currently, a hospital that is more than 100 road miles from the closest Level II ACS program that is able to meet all criteria except for the emergency transfer time may still qualify as a Level I ACS program.

The bill provides a new exception for such hospitals to qualify for the Level I ACS program if the hospital can demonstrate that it:

- Provided a minimum of 100 adult inpatient and outpatient diagnostic cardiac catheterizations for the most recent 12-month period; or
- Discharged or transferred at least 300 patients with a principle diagnosis of ischemic heart disease for the most recent 12-month period.

The Lower Keys Medical Center in Key West is the only diagnostic cardiac catheterization that could qualify for the exception under this bill to become a Level I ACS program.

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

The bill provides an effective date of July 1, 2018.

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]

Hospitals must meet initial licensing requirements by submitting a completed application and required documentation, and the satisfactory completion of a facility survey. Section 395.1055, F.S., authorizes AHCA to adopt rules for hospitals; these rules must include minimum standards to ensure:

- 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; and
- Licensed facility beds conform to minimum space, equipment, and furnishing standards.[3]

The minimum standards for hospital licensure are contained in Chapter 59A-3, F.A.C.

Percutaneous Coronary Intervention

Percutaneous coronary intervention (PCI) commonly known as coronary angioplasty or angioplasty, is a nonsurgical technique for treating obstructive coronary artery disease.[4] 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.[5] The catheter is threaded through blood vessels into the heart where the coronary artery is narrowed.[6] Once in place, a balloon tip covered with a stent is inflated to compress the plaque and expand the stent.[7] 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.[8]

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[1] S. 395.002(12), F.S.
[2] Id.
[3] S. 395.1055(1), F.S.
[4] 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 12, 2018).
[5] 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 12, 2018).
[6] Id.
[7] Id.
[8] Id.

Regulation of Adult Cardiovascular Services

Adult cardiovascular services (ACS), were previously regulated through the Certificate-of-Need (CON)[9] program. In 2007, Florida eliminated CON review for adult cardiac catheterization and adult open-heart surgery services[10] and regulation was accomplished through the licensure process. Hospitals that provided ACS at the time the CON review process was eliminated were grandfathered into the current licensure program.[11] However, those hospitals were required to meet licensure standards applicable to existing programs for every subsequent licensure period.[12]

Section 408.0361, F.S., establishes two levels of hospital program licensure for ACS. A level I program is authorized to perform adult PCI without onsite cardiac surgery and a level II program is authorized to perform PCI with onsite cardiac surgery.[13]

Adult Diagnostic Cardiac Catheterization Program

Diagnostic cardiac catheterization is a procedure requiring the passage of a catheter into one or more chambers of the heart, with or without coronary arteriograms,[14] for diagnosing congenital or acquired cardiovascular diseases, or for measuring blood pressure flow.[15] It also includes the selective catheterization of the coronary ostia[16] with injection of contrast medium into the coronary arteries.[17]

AHCA regulates the operation of adult inpatient diagnostic cardiac catheterization programs through licensure. This license permits the program to perform only diagnostic procedures;[18] the license does not allow for the performance of therapeutic procedures.[19] [20] Providers of diagnostic cardiac catheterization services comply with the most recent guidelines of the American College of Cardiology and American Heart Association for cardiac catheterization and cardiac catheterization laboratories.[21]

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[9] The CON regulatory process under chapter 408, F.S., requires specified health care services and facilities to be approved by AHCA before they are made available to the public. To obtain a CON a facility must demonstrate a need for a new, converted, expanded, or otherwise significantly modified health care facility or health service. Section 408.036, F.S., specifies which health care projects are subject to review and provides three levels of review: full, expedited and exempt. Unless a hospital project is exempt from the CON program under s. 408.036(3), F.S., it must undergo a full comparative review or an expedited review.

[10] Ch. 2007-214, Laws of Fla. CON review remains in effect for pediatric cardiac catheterization and pediatric open-heart surgery. Rule 59C-1.002(41), F.A.C.

[11] Existing providers and any provider with a notice of intent to grant a CON or a final order of the agency granting a CON for ACS or burn units were considered grandfathered and received a license for their programs effective July 1, 2004. The grandfathered license was effective for three years or until July 1, 2008, whichever was longer. S. 408.0361(2), F.S.; s. 2, ch. 2004-382, Laws of Fla.

[12] S. 408.0361(2), F.S.

[13] S. 408.0361(3)(a), F.S.

[14] An arteriogram is an imaging test that uses x-rays and a contrast dye to see inside the arteries of the heart.

[15] Rule 59A-3.2085(13)(b)1., F.A.C.

[16] A coronary ostia is either of the two openings in the aortic sinuses – the pouches behind each of the three leaflets of the aortic valve – that mark the origins of the left and right coronary arteries.

[17] Rule 59A-3.2085(13)(b)1., F.A.C.

[18] Diagnostic procedures include left heart catheterization with coronary angiography and left ventriculography; right heart catheterization; hemodynamic monitoring line insertion; aortogram; emergency temporary pacemaker insertion; myocardial biopsy; diagnostic trans-septal procedures; intra-coronary ultrasound (CVIS); fluoroscopy; and hemodynamic stress testing. Rule 59A-3.2085(13)(b)4., F.A.C.

[19] Examples of therapeutic procedures are PCI or stent insertion, intended to treat an identified condition or the administration of intra-coronary drugs, such as thrombolytic agents. Rule 59A-3.2085(13)(b)3., F.A.C.

[20] S. 408.0361(1)(b), F.S.

[21] S. 408.0361(1)(a), F.S.; Rule 59A-3.2085(13)(g), F.A.C., requires compliance with the guidelines found in the American College of Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards: Bashore, et al., *ACC/SCAI Clinical Expert Consensus Document on Catheterization Laboratory Standards*, Journal of the American College of Cardiology, Vol. 37, No. 8, June 2001: 2170-214, available at http://www.scai.org/asset.axd?id=d4338c24-9beb-4f5a-8f14-a4edaeff7461&t=633921658057830000 (last visited January 12, 2018). These guidelines address, among other things, clinical proficiency, patient outcomes, equipment maintenance and management, quality improvement program development, and minimum caseload volumes for cardiac catheterization laboratories as well as patient preparations, procedural issues, performance issues, and post procedural issues for the performance of cardiac catheterization.

As of November 1, 2017, there are 21 general acute care hospitals with an adult diagnostic cardiac catheterization program in Florida.[22]

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.[23] For a hospital seeking a Level I ACS program license, it must demonstrate that, for the most recent 12-month period as reported to AHCA, it has:

- Provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations; or
- Discharged or transferred at least 300 inpatients with the principal diagnosis of ischemic heart disease;[24] and that it has 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. [25]

The criteria cannot be met by combining the two volume options; either the sessions volume is met or the inpatient principle diagnosis volume is met.[26] Once a hospital obtains the designation it does not need to verify volume thresholds to maintain the designation.

Licensed Level I ACS programs must comply with the guidelines that apply to diagnostic cardiac catheterization services[27] and PCI, including guidelines for staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.[28] Additionally, they must comply with the reporting requirements of the American College of Cardiology-National Cardiovascular Data Registry.[29]

Subsection 408.0361(3), F.S., allows a hospital that is more than 100 road miles from the closest Level II hospital that is able to meet all criteria except for the emergency transfer of patients within 60 minutes to qualify as a Level I ACS.

As of November 1, 2017, there are 56 general acute care hospitals with a Level I ACS program in Florida.[30]

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[22] Agency for Health Care Administration, *Hospital & Outpatient Services Unit: Reports*, available at http://www.fdhc.state.fl.us/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/reports/Adult_Inpatient_Diagnostic_Cath_Labs.pdf (last visited January 12, 2018).

[23] Rule 59A-3.2085(16)(a), F.A.C. Level I programs are prohibited from performing any therapeutic procedure requiring trans-septal puncture, any lead extraction for a pacemaker, biventricular pacer or implanted cardioverter defibrillator.

[24] Heart condition caused by narrowed heart arteries. This is also called “coronary artery disease” and “coronary heart disease.”

[25] S. 408.0361(3)(b), F.S.

[26] Agency for Health Care Administration, Analysis of 2018 House Bill 283, Oct. 5, 2017 (on file with Health and Human Services Committee Staff).

[27] Rule 59A-3.2085(16)(a)5., F.A.C.

[28] Rule 59A-3.2085(16)(a)2., F.A.C., requires compliance with the American College of Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards: Bashore, et al., *ACC/SCA&I Clinical Expert Consensus Document on Catheterization Laboratory Standards*, Journal of the American College of Cardiology, Vol. 37, No. 8, June 2001: 2170-214. The rule also requires compliance the *ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention)* available at http://circ.ahajournals.org/content/113/1/156.full.pdf+html (last visited January 12, 2018), which revises the guidelines for procedural complications, quality assurance, volume of elective procedures, the role of on-site cardiac surgical back-up, treatment of patients with certain diagnoses or medical history, the use of specified procedures and devices, and the use of certain drugs.

[29] Rule 59A-3.2085(16)(a)8., F.A.C. The reporting requirements include patient demographics; provider and facility characteristics; history/risk factors, cardiac status, treated lesions; intracoronary device utilization and adverse event rates; appropriate use criteria for coronary revascularization; and compliance with ACC/AHA clinical guideline recommendations.

[30] Agency for Health Care Administration, *Hospital & Outpatient Services Unit: Reports,* available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/reports/Level_I_ACS_Listing.pdf (last visited January 12, 2018).

Level II ACS Programs

Licensed Level II ACS programs provide diagnostic and therapeutic cardiac catheterization services on a routine and emergency basis, and also have on-site open-heart surgery capability.[31] For a hospital seeking a Level II program license, it must demonstrate that, for the most recent 12-month period as reported to AHCA, it has:

- Performed a minimum of 1,100 adult inpatient and outpatient cardiac catheterizations, of which at least 400 must be therapeutic catheterizations; or
- Discharged at least 800 patients with the principal diagnosis of ischemic heart disease.[32]

In addition to the licensure requirements for a Level I ACS program, Level II ACS programs must also comply with guidelines from the American College of Cardiology and the American Heart Association, which include standards regarding staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.[33]

Level II ACS programs must also document an ongoing quality improvement plan to ensure that their cardiac catheterization, PCI, and cardiac surgical programs meet or exceed national quality and outcome benchmarks reported by the American College of Cardiology-National Cardiovascular Data Registry and the Society of Thoracic Surgeons.[34] In addition to the reporting requirements for Level I ACS Programs, Level II ACS programs must meet the reporting requirements for the Society of Thoracic Surgeons National Database.[35]

As of November 1, 2017, there are 79 general acute care hospitals with a Level II ACS program in Florida.[36]

Effect of the Bill

The bill expands the type of patients that a hospital may count to meet the minimum volume threshold for a Level I ACS program. It amends the minimum volume threshold for treatment of ischemic heart disease to provide greater flexibility by counting experience treating any patients with ischemic heart disease, rather than only those treated as inpatients. Currently, there are no hospitals without a Level I ACS program that have fewer than 300 inpatient discharges as required by the current standard, that also have more than 300 total patient discharges as would be required under the bill.[37]

The bill also provides alternate volume thresholds for a hospital more than 100 miles from a Level II ACS program that is seeking to become a Level I ACS program. The allow such hospitals to qualify for the Level I ACS program designation if the hospital can demonstrate that it:

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[31] Rule 59A-3.2085(17)(a), F.A.C.
[32] S. 408.0361(3)(c), F.S.
[33] Rule 59A-3.2085(16)(a)5., F.A.C. A Level II ASC must comply with the ACC/AHA 2004 Guideline Update for Coronary Artery Bypass Graft Surgery: A Report of the ACC/AHA Task Force on Practice Guidelines (Committee to Update the 1999 Guidelines for Coronary Artery Bypass Graft Surgery) Developed in Collaboration With the American Association for Thoracic Surgery and the Society of Thoracic Surgeons.
[34] Id. Eligible professionals must satisfactorily report 50 percent performance on at least nine quality measures for the annual reporting period. The measures address topics such as preoperative screenings, length of postoperative intubation, and length of postoperative stay.
[35] Rule 59A-3.2085(16)(a)5., F.A.C. The data collection form is available at https://www.ncdr.com/WebNCDR/docs/default-source/tvt-public-page-documents/tvt-registry_2_0_tavr_data-collection-form.pdf (last visited January 12, 2018).
[36] Agency for Health Care Administration, *Hospital & Outpatient Services Unit: Reports,* available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/reports/Level_II_ACS_Listing.pdf (last visited January 12, 2018). 64 of these Level II ACS programs were licensed pursuant to the grandfathering provisions of Chapters 2004-382 and 2004-383, Laws of Fla.; Agency for Health Care Administration, *Agency Analysis of HB 119 2018 Legislative Session*, Sept. 5, 2017 (on file with Health and Human Services Committee staff).
[37] *Supra*, note 26.

- Provided a minimum of 100 adult inpatient and outpatient diagnostic cardiac catheterizations for the most recent 12-month period; or
- Discharged or transferred at least 300 patients with a principle diagnosis of ischemic heart disease for the most recent 12-month period.

The Lower Keys Medical Center in Key West is the only diagnostic cardiac catheterization that would qualify for the exemption under this bill to become a Level I ACS program.[38] Currently, there are only seven general hospitals out of 84, that are neither Level I or Level II ACS program, which are also more than 50 miles away from a Level II hospital, including the Lower Keys Medical Center; however, the Lower Keys Medical Center is the only hospital more than 100 miles away from a Level II ACS program.[39]

The Lower Keys Medical Center has provided a minimum of 100 adult inpatient and outpatient diagnostic cardiac catheterizations for the most recent 12-month period, and as a result will qualify as a Level I ACS program.[40]

The bill provides an effective date of July 1, 2018.

B. SECTION DIRECTORY:

Section 1: Amends s. 408.0361, F.S., relating to cardiovascular services and burn unit licensure.
Section 2: Provides an effective date of July 1, 2018.

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:

None.

D. FISCAL COMMENTS:

None.

[38] *Supra*, note 26.
[39] Id.
[40] Id. Lower Keys Medical Center has not discharged or transferred at least 300 patients with a principle diagnosis of ischemic heart disease for the most recent 12-month period; however, it is only necessary that it meet one of the two volume requirements, not both.

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:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES