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 Appropriations Subcommittee on Health and Human Services

BILL:	SB 408
INTRODUCER:	Senator Flores
SUBJECT:	Licensure of Cardiovascular Programs
DATE:	January 9, 2018
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Favorable**
2.	Kidd	Williams	AHS	**Pre-meeting**
3.			AP	

I. Summary:

SB 408 reduces the number of adult inpatient and outpatient diagnostic cardiac catheterizations, from 300 to 100, that a hospital located more than 100 road miles from the nearest hospital offering Level II adult cardiovascular services (ACS) must provide in a 12-month period in order to become licensed as a Level I ACS program. A Level I program performs adult percutaneous cardiac interventions without onsite cardiac surgery.[1]

Currently, only the Lower Keys Medical Center would qualify for this exemption.[2]

Additionally, the bill amends the requirements for the licensure of all Level I programs to include both inpatients and outpatients when determining the volume of patients that have been discharged or transferred with a principal diagnosis of ischemic heart disease.

The bill has no impact on state revenues or expenditures.

The bill takes effect on July 1, 2018.

II. Present Situation:

Hospitals are regulated by the Agency for Health Care Administration (AHCA) under ch. 395, F.S., and the general licensure provisions of part II of ch. 408, F.S. Hospitals are subject to the certificate of need (CON) provisions in part I of ch. 408, F.S. A CON is a written statement

[1] Percutaneous coronary intervention, also known as coronary angioplasty, is a nonsurgical technique for treating obstructive coronary artery disease, including unstable angina, acute myocardial infarction, and multivessel coronary artery disease. See Medscape: Percutaneous cardiac intervention, *available at* http://emedicine.medscape.com/article/161446-overview, (last visited Dec. 1, 2017).

[2] AHCA, *Senate Bill 408 Analysis* (Nov. 8, 2017) (on file with the Senate Committee on Health Policy).

issued by the AHCA evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility or health service.[3]

Adult cardiovascular services (ACS) were previously regulated through the CON program.[4] However, in 2004, the Legislature established a licensure process for adult interventional cardiology services (the predecessor terminology for ACS), dependent upon rulemaking, in lieu of the CON procedure.[5]

Among other things, that law required the rules to establish two hospital program licensure levels: a Level I program and a Level II program.[6]

A hospital with Level I ACS designation on its license provides diagnostic and therapeutic cardiac catheterization procedures on a routine and emergency basis. A Level I hospital does not have the capability to perform open heart surgery, and by rule can provide the same routine and emergency cardiac catheterization services as a Level II (with open heart surgery capability) hospital except for the higher risk trans septal punctures and lead extractions of implanted devices. A Level I hospital qualifies for the designation by confirming compliance with national guidelines established by the American College of Cardiology and the American Heart Association, and having a transfer agreement with a Level II hospital in which a patient needing the higher level of care can be transferred within 60 minutes.[7]

Currently, in order to be designated as a Level I hospital, the hospital must perform at least 300 diagnostic cardiac catheterization sessions during the most recent 12-month period, or transfer or discharge at least 300 inpatients with the principal diagnosis of ischemic heart disease. For these metrics, the diagnostic cardiac catheterization sessions may include inpatients and outpatients in the total count, but the patients with ischemic heart disease must be inpatients. The criteria cannot be met by combining the two volume options - either the sessions volume is met or the inpatient principal diagnosis volume is met. Once a hospital obtains the designation it does not need to verify volume thresholds to maintain the designation.[8] Subsection 408.0361(3), F.S., allows a hospital more than 100 road miles from the closest Level II hospital to qualify for Level I designation if all criteria is met except for the emergency transfer of patients within 60 minutes.

III. Effect of Proposed Changes:

SB 408 amends s. 408.0361, F.S., to exempt a hospital that is more than 100 road miles from the nearest hospital offering Level II ACS from patient or procedure volume requirements in order to be licensed as a Level I ACS provider. The hospital must still demonstrate, for the most recent 12-month period as reported to the AHCA, that:

[3] Section 408.032(3), F.S.
[4] *See* s. 408.036(3)(m) and (n), F.S., allowing for an exemption from the full review process for certain adult open-heart services and PCI services.
[5] Chapter 2004-383, s. 7, Laws of Fla.
[6] Level I and Level II ACS programs may also perform adult diagnostic cardiac catheterization in accordance with Rule 59A-3.2085(13), F.A.C. Adult diagnostic cardiac catheterization involves the insertion of a catheter into one or more heart chambers for the purpose of diagnosing cardiovascular diseases.
[7] Supra note 2
[8] Supra note 2

- It has provided a minimum of 100 adult inpatient and outpatient cardiac catheterizations rather than 300; or
- It has discharged or transferred at least 300 patients with the principal diagnosis of ischemic heart disease.

Currently, only the Lower Keys Medical Center would qualify for this exemption.[9]

Additionally, the bill amends the requirements for the licensure of all Level I programs to include both inpatients and outpatients when determining the volume of patients that have been discharged or transferred with a principal diagnosis of ischemic heart disease. This will allow patients who have been transferred prior to admission to the hospital as an inpatient to be included in the counts.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

SB 408 may have a positive fiscal impact on a hospital that is able to be licensed as a Level I program under the changes made in the bill.

C. Government Sector Impact:

The bill does not impact state revenues or expenditures.

VI. Technical Deficiencies:

None.

[9] Supra note 2

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 408.0361of 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.