

**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.)

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

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BILL: SB 58

INTRODUCER: Senator Grimsley

SUBJECT: Adult Cardiovascular Services

DATE: January 17, 2017

REVISED: \_\_\_\_\_

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	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	<b>Pre-meeting</b>
2.	_____	_____	AHS	_____
3.	_____	_____	AP	_____
4.	_____	_____	RC	_____

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**I. Summary:**

SB 58 amends s. 408.0361, F.S., to require that Agency for Healthcare Administration (AHCA) licensure rules for hospitals providing Level I adult cardiovascular services include, at a minimum, a requirement that nursing and technical staff have demonstrated experience in handling acutely ill patients in dedicated cardiac interventional laboratories or surgical centers. The bill also specifies performance requirements that must be met by a dedicated cardiac interventional laboratory at a hospital without an approved adult open-heart-surgery program in order for a staff member's work experience at that dedicated cardiac interventional laboratory to qualify.

The bill takes effect on July 1, 2017.

**II. Present Situation:**

Percutaneous cardiac 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.<sup>1</sup>

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 is 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

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<sup>1</sup> Medscape: *Percutaneous cardiac intervention* (Oct. 2016), <http://emedicine.medscape.com/article/161446-overview> (last visited Jan. 17, 2017).

is compressed and the stent is in place, the balloon is deflated and withdrawn. The stent stays in the artery, holding it open.<sup>2</sup>

### **Hospital Licensure and Regulation**

Hospitals are regulated by the 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 issued by the AHCA evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility or health service.<sup>3</sup>

Adult cardiovascular services (ACS), including PCI, were previously regulated through the CON program.<sup>4</sup> 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.<sup>5</sup> Among other things, that law required the rules to establish two hospital program licensure levels: a Level I program authorizing the performance of adult primary PCI for emergency patients without on-site cardiac surgery, and a Level II program authorizing the performance of PCI with on-site cardiac surgery.<sup>6</sup> Additionally the rules must require compliance with the most recent guidelines of the American College of Cardiology and American Heart Association guidelines for staffing, physician training and experience, operating procedures, equipment, physical plant, and patient-selection criteria to ensure quality and safety.<sup>7</sup>

The AHCA adopted rules for Level I ACS<sup>8</sup> and Level II ACS.<sup>9</sup> Staffing rules for both levels require the nursing and technical catheterization laboratory staff to meet the following:

- Be experienced in handling acutely ill patients requiring intervention or balloon pump;
- Have at least 500 hours of previous experience in dedicated cardiac interventional laboratories at a hospital with a Level II ACS program;<sup>10</sup>
- Be skilled in all aspects of interventional cardiology equipment; and
- Participate in a 24-hour-per-day, 365 day-per-year call schedule.

One of the authoritative sources referenced in the AHCA's rulemaking is The American College of Cardiology/American Heart Association Task Force on Practice Guidelines' report:

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<sup>2</sup> Heart and Stroke Foundation, <https://www.heartandstroke.ca/heart/treatments/surgery-and-other-procedures/percutaneous-coronary-intervention>, (last visited Jan. 17, 2017).

<sup>3</sup> Section 408.032(3), F.S.

<sup>4</sup> 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.

<sup>5</sup> Ch. 2004-383, s. 7, Laws of Fla.

<sup>6</sup> 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.

<sup>7</sup> See s. 408.0361(3), F.S.

<sup>8</sup> Rule 59A-3.2085(16), F.A.C.

<sup>9</sup> Rule 59A-3.2085(17), F.A.C.

<sup>10</sup> The standard in the CON exemption in s. 408.036(3)(n), F.S., for providing PCI in a hospital without an approved adult open-heart-surgery program required previous experience in dedicated interventional laboratories or surgical centers.

ACC/AHA/SCAI 2005 Guideline Update for PCI.<sup>11</sup> Table 15 in that report provides criteria for the performance of primary PCI at hospitals without on-site cardiac surgery. It states:

The nursing and technical catheterization laboratory staff must be experience in handling acutely ill patients and must be comfortable within interventional equipment. They must have acquired experience in dedicated interventional laboratories at a surgical center.

In 2014, the Society for Cardiovascular Angiography and Interventions, the American College of Cardiology Foundation, and the American Heart Association, Inc., issued the SCAI/ACC/AHA Expert Consensus Document: 2014 Update on PCI Without On-Site Surgical Backup.<sup>12</sup> That report acknowledged advances and best practices in PCI performed in hospitals without on-site surgery. Table IV in that report addresses personnel requirements for PCI programs without on-site surgery. It recommends the program have experienced nursing and technical laboratory staff with training in interventional laboratories. The report does not reference a requirement that the training or experience should occur in a dedicated interventional laboratory at a surgical center.

As of January 17, 2017, there are 54 Florida hospitals providing Level I ACS services and 77 Florida hospitals providing Level II ACS services.<sup>13</sup>

### III. Effect of Proposed Changes:

The bill expands the locations where nursing and technical staff may acquire experience handling acutely ill patients who require PCI.

The bill requires AHCA licensure rules for hospitals providing Level I ACS to include, at a minimum, a requirement that all nursing and technical staff have demonstrated experience in handling acutely ill patients requiring PCI in dedicated cardiac interventional laboratories or surgical centers. The bill states that, if a staff member's previous experience was in a dedicated cardiac interventional laboratory at a hospital that did not have an approved adult open-heart-surgery program, the laboratory must meet the following criteria in order for the staff member's experience to qualify. The laboratory must have:

- Had an annual volume of 500 or more PCI procedures;
- Achieved a demonstrated success rate of 95 percent or higher for PCI;
- Experienced a complication rate of less than 5 percent for PCI; and

<sup>11</sup> Smith SC Jr, Feldman TE, Hirshfeld JW Jr, Jacobs AK, Kern MJ, King SB III, Morrison DA, O'Neill WW, Schaff HV, Whitlow PL, Williams DO. *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)*. the Society for Cardiovascular Angiography and Interventions. available at [http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=3&ved=0ahUKEwizrYy2zubKAhUBfSYKHafZCiAQFggvMAI&url=http%3A%2F%2Fwww.scai.org%2Fasset.axd%3Fid%3Da1d96b40-b6c7-42e7-9b71-1090e581b58c%26t%3D634128854999430000&usg=AFQjCNF0t0334L9yMm\\_XLA5rl0pXoCvPDw](http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=3&ved=0ahUKEwizrYy2zubKAhUBfSYKHafZCiAQFggvMAI&url=http%3A%2F%2Fwww.scai.org%2Fasset.axd%3Fid%3Da1d96b40-b6c7-42e7-9b71-1090e581b58c%26t%3D634128854999430000&usg=AFQjCNF0t0334L9yMm_XLA5rl0pXoCvPDw) (last visited Jan. 17, 2017).

<sup>12</sup> Gregory J. Dehmer, et.al, available at <http://circ.ahajournals.org/content/129/24/2610.full.pdf+html> (last visited Jan. 17, 2017).

<sup>13</sup> See The AHCA FloridaHealthFinder.gov available at <http://www.floridahealthfinder.gov/facilitylocator/FacilitySearch.aspx>, (last visited Jan. 17, 2017).

- Performed diverse cardiac procedures, including, but not limited to, balloon angioplasty atheroma remodeling, and procedures relating to left ventricular support capability.

The bill creates an effective date of July 1, 2017.

**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 58 may have a positive fiscal impact on hospitals providing Level I ACS by expanding the number of programs where their nursing and technical staff may be trained as well as potentially allowing such hospitals to provide the required training at their own facilities.

C. Government Sector Impact:

None.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Statutes Affected:**

This bill substantially amends section 408.0361 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.

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

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