

**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 144

INTRODUCER: Senator Grimsley

SUBJECT: Adult Cardiovascular Services

DATE: November 6, 2017

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

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

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**I. Summary:**

SB 144 requires the Agency for Health Care Administration (AHCA) to include in its rules for hospitals providing adult cardiovascular services that nursing and technical staff have demonstrated experience in handling acutely ill patients requiring intervention in dedicated cardiovascular interventional laboratories or surgical centers. Current AHCA rules require the experience to be acquired in a hospital providing percutaneous coronary intervention (PCI) with onsite cardiac surgery (licensure Level II). The bill allows the experience also to be acquired in a Level I hospital (providing PCI without onsite cardiac surgery) if, at the time the experience was acquired, the Level I dedicated cardiovascular interventional laboratory met specified minimum standards for volume, performance, and types of procedures performed.

The bill takes effect on July 1, 2018.

**II. Present Situation:**

Percutaneous coronary 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, available at <http://emedicine.medscape.com/article/161446-overview>, (last visited Oct. 30, 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 and Adult Cardiovascular Services 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 onsite cardiac surgery, and a Level II program authorizing the performance of PCI with onsite 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, available at <https://www.heartandstroke.ca/heart/treatments/surgery-and-other-procedures/percutaneous-coronary-intervention>, (last visited Oct. 30, 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> Fla. Admin. Code R. 59A-3.2085(16)

<sup>9</sup> Fla. Admin. Code R. 59A-3.2085(17)

<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 onsite cardiac surgery. It states:

The nursing and technical catheterization laboratory staff must be experienced in handling acutely ill patients and must be comfortable with 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 onsite surgery. Table IV in that report addresses personnel requirements for PCI programs without onsite 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 October 31, 2017, there are 56 Florida hospitals providing Level I ACS services and 79 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 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. Currently, pursuant to AHCA rules, the experience must have been acquired in a hospital with a surgical center. 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;

<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 Web Site, *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&usq=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&usq=AFQjCNF0t0334L9yMm_XLA5rl0pXoCvPDw) (last visited Oct. 30, 2017).

<sup>12</sup> Gregory J. Dehmer, et.al, *available at* <http://circ.ahajournals.org/content/129/24/2610.full.pdf+html> (last visited Oct. 30, 2017).

<sup>13</sup> See The AHCA FloridaHealthFinder.gov *available at* <http://www.floridahealthfinder.gov/facilitylocator/FacilitySearch.aspx>, (last visited Oct. 31, 2017).

- Achieved a demonstrated success rate of 95 percent or higher for PCI;
- Experienced a complication rate of less than 5 percent for PCI; and
- 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.

The bill also makes technical changes replacing the term “percutaneous cardiac intervention” with “percutaneous coronary intervention.”

The bill takes effect July 1, 2018.

#### **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 144 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:**

The bill's mandate to establish rules to require nursing and technical staff in hospitals performing adult cardiovascular services to have specified experience appears to apply to both hospitals providing Level I and Level II services, however, this is placed within a statutory paragraph only relating to a hospital seeking a Level I program license. As such, it is unclear whether the staff training requirement applies to both hospitals providing Level I and Level II services or only to hospitals providing Level I services. The bill may need to be amended to clearly indicate to which hospitals the requirement applies.

**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.