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 Committee on Health Policy

BILL:	SB 1518
INTRODUCER:	Senator Grimsley
SUBJECT:	Adult Cardiovascular Services
DATE:	February 8, 2016
REVISED:	

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

I. Summary:

SB 1518 authorizes a Level I adult cardiovascular services (ACS) program to provide the 500 hours pre-requisite training required for nursing and technical cardiac interventional laboratory staff if, throughout the training period, the cardiac interventional laboratory meets certain volume and quality performance measures. A Level I ACS is a hospital that performs adult percutaneous cardiac intervention (PCI) but does not provide onsite cardiac surgery. Currently this training may only be provided in a Level II ACS program, which is one that provides onsite cardiac surgery.

Obsolete provisions relating to exemptions from certificate of need (CON) requirements for ACS are repealed because rules for licensure of Level I and Level II ACS programs now govern these services. Certain standards found in the CON exemption provisions are transferred to the licensure standards.

II. Present Situation:

Percutaneous cardiac intervention (PCI), also commonly known as coronary angioplasty or just angioplasty, is a nonsurgical technique for treating obstructive coronary artery disease, including unstable angina, acute myocardial infarction, and multivessel coronary artery disease.[1]

PCI uses a catheter (a thin flexible tube) to place a small structure called a stent to open up blood vessels in the heart that have been narrowed by plaque buildup, a condition known as atherosclerosis. A catheter is inserted into the blood vessels either in the groin or in the arm. Using a special type of X-ray called fluoroscopy, the catheter is threaded through the blood vessels into the heart where the coronary artery is narrowed. When the tip is in place, a balloon

[1] Medscape: Percutaneous cardiac intervention, http://emedicine.medscape.com/article/161446-overview, (last visited Feb. 4, 2016).

tip covered with a stent is inflated. The balloon tip compresses the plaque and expands the stent. Once the plaque is compressed and the stent is in place, the balloon is deflated and withdrawn. The stent stays in the artery, holding it open.[2]

Hospital Licensure and Regulation

Hospitals are regulated by the Agency for Health Care Administration (agency) under ch. 395, F.S., and the general licensure provisions of part II of ch. 408, F.S. Hospitals are subject to the CON provisions in part I of ch. 408, F.S. A CON is a written statement issued by the agency evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility or health service.[3]

Adult cardiovascular services (ACS), including PCI 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 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.[6] Additionally the rules must require compliance with the most recent guidelines of the American College of Cardiology and American Health Association guidelines for staffing, physician training and experience, operating procedures, equipment, physical plant, and patient-selection criteria to ensure patient quality and safety.[7]

The agency adopted rules for Level I ACS[8] and Level II ACS.[9] The staffing rules within a Level I ACS require:

- Each cardiologist to be an experience physician who has performed a minimum of 75 interventional cardiology procedures within the previous 12 months, or those physician with less than 12 months experience, to fulfill specified training requirements.
- The nursing and technical catheterization laboratory staff must meet the following requirements:
  - Be experience in handling acutely ill patients requiring intervention or balloon pump;

[2] Heart and Stroke Foundation, http://www.heartandstroke.com/site/c.ikIQLcMWJtE/b.3831925/k.4F32/Heart_disease__Percutaneous_coronary_intervention_PCI_or_angioplasty_with_stent.htm, (last visited February 4, 2016).
[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] Ch. 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] *See* s. 408.0361(3), F.S.
[8] Rule 59A-3.2085(16), F.A.C.
[9] Rule 59A-3.2085(17), F.A.C.

- Have at least 500 hours of previous experience in dedicated cardiac interventional laboratories at a hospital with a Level II ACS program;[10]
- Be skilled in all aspects of interventional cardiology equipment; and
- Participate in a 24-hour-per-day, 365 day-per-year call schedule.

- The hospital to ensure that a member of the cardiac care nursing staff who is adept in hemodynamic monitoring and Intra-aortic Balloon Pump (IABP) management be in the hospital at all times.

The staffing rules within a Level II ACS require:

- Each cardiac surgeon to be Board certified, new surgeons must be Board certified within four years after completion of their fellowship, and experienced surgeons with greater than 10 years of experience may document that their training and experience preceded the availability of Board certification, if applicable.
- Each cardiologist to be an experienced physician who has performed a minimum of 75 interventional cardiology procedures within the previous 12 months.
- The nursing and technical catheterization laboratory staff must meet the following requirements:
  - Be experience 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;
  - Be skilled in all aspects of interventional cardiology equipment; and
  - Participate in a 24-hour-per-day, 365 day-per-year call schedule.
- The hospital to ensure that a member of the cardiac care nursing staff who is adept in hemodynamic monitoring and Intra-aortic Balloon Pump (IABP) management be in the hospital at all times.

One of the authoritative sources referenced in the agency's rulemaking is The American College of Cardiology/American Heart Association Task Force on Practice Guidelines' report: ACC/AHA/SCAI 2005 Guideline Update for PCI.[11] 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.

[10] 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.
[11] 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&usg=AFQjCNF0t0334L9yMm_XLA5rl0pXoCvPDw (last visited February 7, 2016).

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.[12] 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.

With respect to interventional cardiologists, recommended standards include performing a minimum of 50 coronary interventional procedures per year, averaged over a 2-year period to maintain competency and that these procedures should be performed in institutions that perform more than 200 elective PCIs per year and more than 36 primary PCI procedures per year.[13]

As of February 7, 2016, there are 52 hospitals providing Level I ACS services and 77 hospitals providing Level II ACS services.[14]

III. Effect of Proposed Changes:

SB 1518 requires the agency to adopt or update rules relating to Level I ACS services for adult PCI. The rules must require:

- Cardiologists to be experienced interventionalists who have performed a minimum of 50 interventions annually, averaged over a two year period. In order for the intervention to count toward the minimum number of procedures, they must have been performed in an institution that performs more than 200 total intervention procedures and more than 36 primary intervention procedures, annually. This requirement updates the standards to reflect the 2014 consensus guidelines.
- The hospital must provide a minimum of 36 primary interventions annually. This requirement comports with the 2014 consensus guidelines, and was a standard in the CON exemption.
- The hospital must offer sufficient physician, nursing, and laboratory staff to provide the services 24 hours a day, 7 days a week. This provision specifically adds physicians to the staffing requirements to ensure adequate staffing for medical emergencies, and was a standard in the CON exemption.
- An opportunity for Level I ACS programs to provide the 500 hours of training and experience for nursing and technical staff, in addition to Level II ACS programs. In order for a Level I ACS program to qualify to provide the training, it must have, throughout the training period:
  - Had an annual volume of 200 or more PCI procedures;
  - Achieved a demonstrated PCI success rate of 95 percent or greater;
  - Less than 2 percent of the PCI patients required emergency coronary artery bypass grafting; and

[12] Gregory J. Dehmer, et.al, *available at* http://circ.ahajournals.org/content/129/24/2610.full.pdf+html (last visited Feb. 7, 2016).
[13] *Id.*
[14] *See* The AHCA FloridaHealthFinder.gov *available at* http://www.floridahealthfinder.gov/facilitylocator/FacilitySearch.aspx, (last visited Feb. 2, 2016).

  - Performed varied 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.
- Nursing staff to be adept in hemodynamic monitoring, operation of temporary pacemakers, intra-aortic balloon pump management, management of indwelling arterial and venous sheaths, and identifying potential complications. This requirement updates the standards to reflect the 2014 consensus guidelines.
- Hospitals newly implementing this program must first undertake a training program lasting three to six months, which was a requirement under the CON criteria.
- Hospitals to certify that it will use at all times the patient-selection criteria for the performance of primary angioplasty issued by the American College of Cardiology and the American Heart Association. This is a standard in the CON exemption.
- Hospitals to submit a quarterly report to the agency detailing patient characteristics, treatment and outcomes. This is a standard in the CON exemption, but may be duplicative to other reporting requirements.

The bill repeals obsolete language in s. 408.0361, F.S., relating to the conversion of the ACS from the CON process to regulation through licensure. The bill also repeals the two CON exemptions in s. 408.036, F.S., relating to adult open-heart services and PCI services in a hospital without an approved adult open-heart-surgery program as these exemptions have been replaced with licensure.

The effective date of the bill is July 1, 2016.

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:

It may be easier for Level I hospitals to maintain sufficient competent nursing and technical catheterization laboratory staff by allowing additional qualified programs to provide the pre-requisite training.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 408.0361 and 408.036.

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.