HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1269 Adult Cardiovascular Services
SPONSOR(S): Health Innovation Subcommittee, Pigman
TIED BILLS: **IDEN./SIM. BILLS:** SB 1518

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	13 Y, 0 N, As CS	Langston	Poche
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Hospitals are regulated by the Agency for Health Care Administration (AHCA) under chapter 395, F.S., and the general licensure provisions of part II, of chapter 408, F.S. Adult cardiovascular services (ACS) were previously regulated through AHCA's Certificate-of-Need (CON) program. CON review has been eliminated for adult cardiac catheterization and adult open-heart surgery services. Hospitals are now approved to provide these services by AHCA through the licensure process.

Licensed Level I ACS programs provide diagnostic and therapeutic cardiac catheterization services, including percutaneous coronary intervention (PCI), on a routine and emergency basis, but do not have on-site open heart surgery capability. Level I ACS programs must comply with national guidelines that apply to diagnostic cardiac catheterization services PCI. Additionally, they must comply with national reporting requirements and meet specified staffing requirements. For example, nursing and technical catheterization laboratory staff in a Level I ACS program must have 500 hours of experience in a dedicated cardiac interventional laboratory at a hospital with a Level II ACS program.

Licensed Level II ACS programs provide the same services as a Level I ACS program, but have on-site open heart surgery capability. In addition to Level I requirements, Level II programs must comply with additional guidelines regarding staffing, physician training and experience, operating procedures, equipment, physical plant, patient selection criteria, and reporting requirements.

HB 1269 authorizes hospitals with Level I ACS programs to provide the prerequisite 500 hours of training required for nursing and technical catheterization laboratory staff, if, throughout the training period, the program:

- Meets an annual volume of 200 or more PCIs;
- Achieves a demonstrated success rate of 95 percent or greater for PCIs;
- Experiences a complication rate of less than five percent for PCIs;
- Experiences required emergent coronary artery bypass grafting on less than two percent of the patients undergoing a PCI; and
- Performs diverse cardiac procedures.

The bill requires AHCA to include, at a minimum, specific requirements in the rules for establishing and maintaining Level I and Level II ACS programs. The rules must require hospitals seeking licensure of Level I or Level II ACS programs to meet specified staffing requirements, perform at least 36 PCIs annually, and implement a training program.

The bill deletes outdated and obsolete language providing an exemption from the CON program for ACS. ACS requirements are addressed in the rules for licensure of Level I and Level II ACS programs.

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

The bill provides an effective date of July 1, 2016.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Hospital Licensure

Hospitals are regulated by the Agency for Health Care Administration (AHCA) 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, or 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.

Regulation of Adult Cardiovascular Services

Adult cardiovascular services (ACS) were previously regulated through the Certificate-of-Need (CON)[4] program. In 2007, CON review was eliminated for adult cardiac catheterization and adult open-heart surgery services[5] 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;[6] however, those hospitals were required to meet licensure standards applicable to existing programs for every subsequent licensure period.[7]

[1] S. 395.002(12), F.S.
[2] Id.
[3] S. 395.1055(1), F.S.
[4] 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. In addition, the CON program requires a facility to 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, it must undergo a full comparative review or an expedited review.
[5] 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.
[6] 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.
[7] S. 408.0361(2), F.S.

Section 408.0361, F.S., establishes two levels of hospital program licensure for ACS:

- Level I: The program is authorized to perform adult percutaneous cardiac intervention (PCI) without onsite cardiac surgery.
- Level II: The program is authorized to perform PCI with onsite cardiac surgery.[8]

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,[9] for the purpose of diagnosing congenital or acquired cardiovascular diseases, or for determining measurement of blood pressure flow.[10] It also includes the selective catheterization of the coronary ostia[11] with injection of contrast medium into the coronary arteries.[12]

AHCA regulates the operation of adult inpatient diagnostic cardiac catheterization programs through licensure. This license permits the program to perform diagnostic procedures[13] only; the license does not allow for the performance of therapeutic procedures.[14] [15] 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.[16]

As of January 11, 2016, there are 21 general acute care hospitals with an adult diagnostic cardiac catheterization program in Florida.[17]

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.[18] 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;[19] and

---

[8] S. 408.0361(3)(a), F.S.
[9] An arteriogram is an imaging test that uses x-rays and a contrast dye to see inside the arteries of the heart.
[10] Rule 59A-3.2085(13)(b)1., F.A.C.
[11] 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.
[12] Rule 59A-3.2085(13)(b)1., F.A.C.
[13] 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.
[14] Examples of therapeutic procedures are PCI or stent insertion, intended to treat an identified condition or the administering of intra-coronary drugs, such as thrombolytic agents. Rule 59A-3.2085(13)(b)3., F.A.C.
[15] S. 408.0361(1)(b), F.S.
[16] 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 20, 2016). 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.
[17] 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 20, 2016).
[18] 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.
[19] Heart condition caused by narrowed heart arteries. This is also called “coronary artery disease” and “coronary heart disease.”

- A formalized, written transfer agreement with a hospital that has a Level II program.[20]

Licensed Level I ACS programs must comply with the guidelines that apply to diagnostic cardiac catheterization services[21] 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.[22] Additionally, they must comply with the reporting requirements of the American College of Cardiology-National Cardiovascular Data Registry.[23]

Level I ACS programs must meet the following staffing requirements:

- Each cardiologist shall be an experienced physician who has performed a minimum of 75 interventional cardiology procedures, exclusive of fellowship training, within the previous 12 months from the date of the Level I ACS application or renewal application.
- Physicians with less than 12 months experience shall fulfill applicable training requirements prior to being allowed to perform emergency PCI in a hospital that is not licensed for a Level II ACS program.
- Nursing and technical catheterization laboratory staff must:
  - 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 adult cardiovascular services program;
  - Be skilled in all aspects of interventional cardiology equipment; and
  - Participate in a 24-hour-per-day, 365 day-per-year call schedule.
- A member of the cardiac care nursing staff who is adept in hemodynamic monitoring and Intra-aortic Balloon Pump management shall be in the hospital at all times.[24]

As of January 11, 2016, there are 52 general acute care hospitals with a Level I ACS program in Florida.[25]

Level II ACS Programs

Licensed Level II ACS programs provide diagnostic and therapeutic cardiac catheterization services on a routine and emergency basis, but have on-site open heart surgery capability.[26] 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.[27]

---

[20] S. 408.0361(3)(b), F.S.
[21] Rule 59A-3.2085(16)(a)5., F.A.C.
[22] 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 21, 2016), 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.
[23] 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.
[24] Rule 59A-3.2085(16)(b), F.A.C.
[25] 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 20, 2016).
[26] Rule 59A-3.2085(17)(a), F.A.C.
[27] S. 408.0361(3)(c), F.S.

In addition to the licensure requirements for a Level I ACS program, Level II ACS programs must also comply with the ACC/AHA 2004 Guideline Update for Coronary Artery Bypass Graft Surgery: A Report of the American College of Cardiology/American Heart Association 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, which includes standards regarding staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.[28] 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.[29] 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.[30]

As of January 11, 2016, there are 77 general acute care hospitals[31] with a Level II ACS program in Florida.[32]

Effect of the Bill

Training for Nursing and Technical Staff

HB 1269 authorizes a hospital with a Level I ACS program to provide the prerequisite 500 hours of training required for nursing and technical staff to work in the cardiac interventional laboratory, if, throughout the training period, the ACS program:

- Meets an annual volume of 200 or more percutaneous coronary intervention procedures (PCI);
- Achieves a demonstrated success rate of 95 percent or greater for PCIs;
- Experiences a complication rate of less than 5 percent for PCIs;
- Experiences required emergent coronary artery bypass grafting on less than 2 percent of the patients undergoing a PCI; and
- Performs 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.

Under current law, nursing and technical catheterization laboratory staff in a Level I ACS program must acquire the necessary training and experience at a dedicated interventional laboratory at a hospital with a Level II ACS program. The bill will enable Level I ACS programs to train their nursing and technical catheterization laboratory staff at their facilities instead of requiring that their staff be trained in a Level II ACS program.

Licensure Requirements for ACS Programs

The bill requires AHCA to include, at minimum, specific program requirements in the rules for establishing Level I and Level II ACS programs. To obtain a license as a Level I or Level II ACS program, a hospital must:

[28] Rule 59A-3.2085(16)(a)5., F.A.C.
[29] 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.
[30] 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?sfvrsn=2 (last visited January 23, 2016).
[31] 64 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 2016 SB 1518*, Jan. 12, 2016 (on file with Health Innovation Subcommittee staff).
[32] 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 20, 2016).

- Provide a minimum of 36 primary interventions annually;
- Offer sufficient physician, nursing, and laboratory staff to provide the services 24 hours a day, seven days a week;
- Undertake a training program of three to six months, prior to implementing ACS, which includes:
  - Establishing standards and testing logistics
  - Creating quality assessment and error management practices; and
  - Formalizing patient-selection criteria.
- Certify that they will use at all times the patient-selection criteria for the performance of primary angioplasty at hospitals without adult open-heart-surgery programs issued by the American College of Cardiology and the American Heart Association.

Requirements Related to Physicians

The bill requires ACHA, in the minimum requirements for licensure, to require ACS programs to have a physician available to provide such services 24 hours a day, seven days a week, which expands the current minimum criteria. Current rules and guidelines require sufficient nursing and technical staff to be available 24 hours per day, seven days per week, 365 days per year; however, that regulation does not apply to physicians.

Additionally, the bill requires ACHA to require ACS program cardiologists to perform a minimum of 50 interventions annually, averaged over 2 years. This reduces the number of minimum interventions per year for physicians from 75 annually to 50 annually, which is recommended by the most recent update to the guidelines.[33] AHCA is currently in rule development to incorporate the reduction of annual interventions into rule.[34]

Requirements for Nursing and Technical Staff

The bill codifies the current minimum standards for ACS program nursing and technical staff in rule. Additionally, the bill requires ACHA to require, in the minimum requirements for licensure, those providing cardiac care nursing to be adept in the operation of temporary pacemakers, management of indwelling arterial and venous sheaths, and identifying potential complications.

Repeal of CON Exemptions and Rules

The bill deletes language from ss. 408.0361(2) and (4), F.S., regarding CON review requirements that expired July 1, 2008. Additionally, the bill repeals paragraphs (m) and (n) of s. 408.036(3), F.S., which contain obsolete language for exemption from CON review of ACS programs. ACS programs are addressed under an AHCA licensure structure in rules.

B. SECTION DIRECTORY:

Section 1: Amends s. 408.0361, F.S., relating to cardiovascular services and burn unit licensure.
Section 2: Repeals s. 408.036(3)(m) and (n), F.S., relating to projects subject to review; exemptions.
Section 3 Provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

[33] Dehmer GJ, Blankenship JC, Cilingiroglu M, et al., *SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup*, Journal of the American College of Cardiology, Vol. 63, No. 23, June 2014: 2624-2641, available at http://content.onlinejacc.org/data/Journals/JAC/930319/03002.pdf (last visited January 21, 2016).
[34] Supra, note 31.

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.

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

On January 25, 2016, the Health Innovation Subcommittee adopted an amendment that removed the requirement for hospitals with Level I or Level II ACS programs to submit a quarterly report to AHCA for all patients receiving emergency PCIs and relocated the licensure requirements to another paragraph of s. 408.0361(3), F.S. The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.