

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 Appropriations

BILL: CS/SB 58

INTRODUCER: Appropriations Committee and Senator Grimsley

SUBJECT: Cardiac Programs

DATE: February 27, 2017

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	Favorable
2.	Forbes	Williams	AHS	Recommend: Favorable
3.	Forbes	Hansen	AP	Fav/CS
4.			RC	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 58 requires the Agency for Health Care Administration (AHCA) to:

- Establish a technical advisory panel to develop procedures and standards for measuring outcomes of pediatric cardiac catheterization programs and pediatric open-heart surgery programs. The panel must consist of 11 members, ten of whom are pediatric cardiologists or pediatric cardiovascular surgeons appointed by the chief executive officer of various Florida hospitals and one member, who is an expert in pediatric and adult congenital heart disease and is appointed by the secretary of the AHCA. Based on the recommendations of the panel, the AHCA must develop and adopt rules related to outcome standards and risk adjustment procedures for pediatric cardiac catheterization programs and pediatric open-heart surgery programs.
- Include in its licensure rules for hospitals providing Level I adult cardiovascular services, 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. While current AHCA rules require nursing and technical staff to have experience at hospitals providing Level II adult cardiovascular services, the bill allows previous experience of nursing and technical staff if the staff member's experience was acquired in Level I facilities that met certain criteria at the time the staff member acquired such experience.

The bill appropriates \$95,620 from the Health Care Trust Fund for the AHCA to implement the technical advisory panel required by the bill.

The bill takes effect on July 1, 2017.

II. Present Situation:

Pediatric Cardiac Catheterization

Pediatric cardiac catheterization is a nonsurgical procedure that can be used in infants, children, and teens to determine if there is a problem with the heart or repair a problem. Catheterization in children is performed by inserting a thin plastic, flexible tube (called a “catheter”) into an artery and vein, usually in the groin, and threading it through the bloodstream into the heart and its large blood vessels. There, the cardiologist measures pressures and blood oxygen levels and takes special moving X-rays (called “cinegrams”) of the heart and blood vessels. The procedure can be performed in any age. Because pediatric cardiac catheterization requires a child to lie very still, and there is discomfort associated with insertion of the catheters, the procedure is done with sedation or anesthesia.¹

Department of Health’s Proposed Repeal of Rule 64C-4.003, F.A.C.

Rule 64C-4.003, F.A.C., establishes and incorporates by reference quality assurance standards and criteria for the approval and operation of Children’s Medical Services² (CMS) pediatric cardiac facilities.

On October 12, 2015, the Department of Health (department) held a rule hearing regarding the proposed repeal of the standards for pediatric cardiac facilities, Rule 64C-4.003, F.A.C. Following that hearing, the department determined it had no statutory authority to establish the standards, inspect facilities, or prepare inspection reports for the technical advisory panel to review. A group of CMS beneficiaries who require cardiac care services were concerned that repeal of Rule 64C-4.003, F.A.C., would reduce the quality of care that would be available to them within the CMS program and challenged the department’s actions through the Division of Administrative Hearings (DOAH).³

A final hearing was held on November 20 and 23, 2015, before an administrative law judge and a Final Order was issued on December 16, 2015.⁴ On January 9, 2017, the department published *A Notice of Disposition* in the *Florida Administrative Register* adopting the ruling in the DOAH Final Order. The notice stated that in the case of *W.D., C.V., K.E., and K.M., vs. Department of Health, Case No. 15-6009RP; Rule 64C-4.003*,

Petitioners lacked standing to challenge the proposed repeal of a rule that would deregulate certain cardiac facilities, because no real or immediate

¹ Cardiac Catheterization, <https://www.nemours.org/service/medical/delaware-valley-pediatric-cardiac-center/treatment-and-testing/cardiac-catheterization-in-children.html?location=naidhc>, (last visited on Feb. 23, 2017).

² CMS is a collection of programs within the Department of Health that serve children with special health care needs.

³ *W.D., C.V., K.E., and K.M., v. Dep’t of Health*, Case No. 15-6009RP (Fla. DOAH 2015).

⁴ *Id.*

injury was shown, and because common good such as quality health care is not within the zone of interest.⁵

The Petitioners appealed DOAH's Final Order in both the First and Third District Courts of Appeal. The case was voluntarily dismissed at the First District Court of Appeal on February 15, 2016, but is currently still on appeal at the Third District Court of Appeal.⁶

Rule 64C-4.003, F.A.C., remains in effect. The department has taken no further action to repeal the rule.⁷

Cardiac Advisory Council

Prior to the 2001 Regular Session, a Cardiac Advisory Council in the Division of Children's Medical Services existed.⁸ The Cardiac Advisory Council was appointed by the secretary of the department and included eight members with technical expertise in cardiac medicine who were charged with:

- Recommending standards for personnel and facilities rendering cardiac services;
- Receiving reports of the periodic review of cardiac personnel and facilities to determine if established standards for cardiac care are met;
- Making recommendations to the director as to the approval or disapproval of reviewed personnel and facilities; and
- Providing input on all aspects of the Children's Medical Services cardiac program, including the rulemaking process.⁹

The statute was repealed effective June 30, 2001, as part of an exhaustive review of more than three dozen boards, committees, commissions, and councils to determine whether to continue or abolish each entity.¹⁰ The department recommended the repeal of the Cardiac Advisory Council and indicated it would absorb the functions of the Cardiac Advisory Council in 2001.¹¹

Statutory Organization: Advisory Councils

Chapter 20, F.S., authorizes the creation of a number of different types of entities to assist state government in the efficient performance of its duties and functions. Under s. 20.03(7), F.S., a "council" or "advisory council" is defined as:

⁵ Vol. 43 Fla. Admin. Register 145 (Jan. 9, 2017).

⁶ *W.D., C.V., and K.E.*, v. Dep't of Health, First District Court of Appeal Case number 1D-15-5948 found on DOAH Online Docket for DOAH case number 15-6009RP, <https://www.doah.state.fl.us/DocDoc/2015/006009/15006009OOC-021516-09062506.PDF> (last viewed Feb. 23, 2017). *K.M. v. Dep't of Health*, Florida Third District Court of Appeal Case number 3D16-23.

⁷ *Florida Administrative Code and Florida Administrative Register*, <https://www.flrules.org/gateway/ruleno.asp?id=64C-4.003> (last viewed Feb. 2, 2017).

⁸ See s. 391.222, F.S. (2000).

⁹ *Id.*

¹⁰ Chapter 2001-89, s. 27, Laws of Fla.

¹¹ Senate Committee on Governmental Oversight and Productivity, *CS/SB 1410 Staff Analysis and Economic Impact*, p. 9 (Mar. 28, 2001) available at <http://archive.flsenate.gov/data/session/2001/Senate/bills/analysis/pdf/2001s1410.go.pdf> (last visited Feb. 23, 2017).

an advisory body created by specific statutory enactment and appointed to function on a continuing basis for the study of the problems arising in a specified functional or program area of state government and to provide recommendations and policy alternatives.

Advisory bodies, commissions and boards may only be created by statute in furtherance of a public purpose¹² and meet a statutorily defined purpose.¹³ Such advisory bodies, commissions and boards must be terminated by the Legislature once the body, commission or board notifies the Legislature when it is no longer necessary and beneficial to the furtherance of a public purpose.¹⁴ The Legislature and the public must be kept informed of the numbers, purposes, memberships, activities, and expenses of advisory bodies, commissions and boards.¹⁵ Members of such bodies are appointed for staggered, four-year terms and unless otherwise provided in the State Constitution,¹⁶ serve without compensation, but are authorized to receive reimbursement for per diem and travel as provided in s. 112.061, F.S.¹⁷

Private citizen appointees to an advisory body that is adjunct to an executive agency must be appointed by the Governor, the head of the department, the executive director of the department, or a Cabinet officer.¹⁸ Private citizen appointees to a board or commission that is adjunct to an executive agency must be appointed by the Governor, unless otherwise provided by law, confirmed by the Senate, and are subject to dual office holding provisions of s. 5(a), Art. II of the State Constitution.¹⁹

Unless exempted, all meetings of advisory bodies, boards and commissions are subject to public meetings requirements under s. 286.011, F.S., and minutes must be maintained for all meetings.²⁰

Technical advisory panels are not separately defined in statute.

Percutaneous Cardiac Intervention

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.²¹

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

¹² Section 20.052(1), F.S.

¹³ Section 20.052(4)(a), F.S.

¹⁴ Section 20.052(2), F.S.

¹⁵ Section 20.052(3), F.S.

¹⁶ Section 20.052(4)(c), F.S.

¹⁷ Section 20.052(4)(d), F.S.

¹⁸ Section 20.052(5)(a), F.S.

¹⁹ Section 20.052(5)(b), F.S.

²⁰ Section 20.052(5)(c), F.S.

²¹ Medscape: Percutaneous cardiac intervention, <http://emedicine.medscape.com/article/161446-overview>, (last visited Jan. 17, 2017).

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.²²

Hospital Licensure and Regulation

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 issued by the AHCA evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility or health service, or hospice.²³

Adult cardiovascular services (ACS), including PCI, were previously regulated through the CON program.²⁴ 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.²⁵ Among other things, the law requires 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.²⁶ 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.²⁷

The AHCA adopted rules for Level I ACS²⁸ and Level II ACS.²⁹ 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;³⁰
- 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:

²² Heart and Stroke Foundation, <https://www.heartandstroke.ca/heart/treatments/surgery-and-other-procedures/percutaneous-coronary-intervention>, (last visited Jan. 17, 2017).

²³ Section 408.032(3), F.S.

²⁴ 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.

²⁵ Ch. 2004-383, s. 7, Laws of Fla.

²⁶ 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.

²⁷ See s. 408.0361(3), F.S.

²⁸ Rule 59A-3.2085(16), F.A.C.

²⁹ Rule 59A-3.2085(17), F.A.C.

³⁰ 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.³¹ 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 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. They participate in a 24-hours-per-day, 365-days-per-year call schedule.

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.³² 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.³³

Currently, pediatric cardiac services are subject to CON review and approval prior to implementation of services pursuant to ss. 408.036(1) and 408.032(17), F.S. Licensure standards do not include pediatric cardiac service standards that only exist within the CON process. There is no authority to maintain compliance with pediatric cardiology standards as a condition of licensure.³⁴

III. Effect of Proposed Changes:

The bill requires the AHCA to establish a technical advisory panel to develop procedures and standards for measuring outcomes of pediatric catheterization programs and pediatric open-heart surgery programs. The panel must consist of 11 members, one member appointed by the secretary of the AHCA with expertise in pediatric and adult congenital heart disease, and 10 members who are pediatric cardiologists or pediatric cardiovascular surgeons and are appointed

³¹Smith 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 (last visited Jan. 17, 2017).

³² Gregory J. Dehmer, et.al, available at <http://circ.ahajournals.org/content/129/24/2610.full.pdf+html> (last visited Jan. 17, 2017).

³³ See The AHCA FloridaHealthFinder.gov available at <http://www.floridahealthfinder.gov/facilitylocator/FacilitySearch.aspx>, (last visited Jan. 17, 2017).

³⁴ AHCA bill analysis of SB 62, Nov. 30, 2016, on file with Senate Health Policy Committee staff.

by the chief executive officer of each of the listed hospitals.³⁵ Based on the recommendations from the panel, the bill requires the AHCA to develop and adopt rules for pediatric cardiac catheterization programs and pediatric open-heart surgery programs that, at a minimum, include:

- A risk adjustment procedure that accounts for the variations in severity and case mix found in hospitals in this state;
- Outcome standards specifying expected levels of performance in pediatric cardiac programs. Such standards may include, but are not limited to, in-hospital mortality, infection rates, nonfatal myocardial infarctions, length of postoperative bleeds, and returns to surgery; and
- Specific steps to be taken by the agency and licensed facilities that do not meet the outcome standards within a specified time, including time required for detailed case reviews and development and implementation of corrective action plans.

The bill appropriates \$95,620 from the Health Care Trust Fund for the AHCA to implement the technical advisory panel.

The bill also requires the AHCA licensure rules for hospitals providing Level I adult cardiovascular services 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. A staff member's previous experience in a dedicated cardiac interventional laboratory at a hospital that did not have an approved adult open-heart-surgery program will qualify if the laboratory met the specified criteria during the staff member's tenure. 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
- 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 effective date of the bill is July 1, 2017.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

³⁵ The hospitals are: Johns Hopkins All Children's Hospital in St. Petersburg, Arnold Palmer Hospital for Children in Orlando, Joe DiMaggio Children's Hospital in Hollywood, Nicklaus Children's Hospital in Miami, St. Joseph's Children's Hospital in Tampa, University of Florida Health Shands Hospital in Gainesville, University of Miami Holtz Children's Hospital in Miami, Wolfson Children's Hospital in Jacksonville, Florida Hospital for Children in Orlando, Nemours Children's Hospital in Orlando.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

CS/SB 58 appropriates \$95,620 from the Health Care Trust Fund for the Agency for Health Care Administration to implement the technical advisory panel required by the bill.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 395.1055 and 408.0361.

The bill creates one new unnumbered section of law.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Appropriations on February 23, 2017:

The committee substitute:

- Establishes a technical advisory panel to develop procedures and standards for measuring outcomes of pediatric cardiac catheterization and pediatric open-heart surgery programs.
- Provides for membership on the panel.
- Requires the AHCA to develop and adopt rules for pediatric cardiac catheterization and open-heart surgery programs, based on the recommendations of the panel.

- Provides for an appropriation of \$95,620 from the Health Care Trust Fund to the AHCA to implement the provisions authorizing the panel.

B. Amendments:

None.

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