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:	CS/SB 1518
INTRODUCER:	Health Policy Committee and Senator Grimsley
SUBJECT:	Cardiovascular Services
DATE:	February 11, 2016 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Stovall	HP	**Fav/CS**
2.			AHS	
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1518 authorizes nursing and technical cardiac interventional laboratory staff to earn the required hours of training experience in a dedicated cardiac interventional laboratory at a hospital that does not have an approved adult open-heart-surgery program (a Level I adult cardiovascular services (ACS) program) if, throughout the training period, the cardiac interventional laboratory meets certain volume and quality performance measures. Currently this training may only be provided in a Level II ACS program, which is one that provides onsite cardiac surgery.

The bill also creates the Pediatric Cardiac Advisory Council (council) within the Department of Health (department) for the purpose of advising the department on the delivery of cardiac services to children. The bill specifies the duties and composition of the council.

The department, in coordination with the Agency for Health Administration (AHCA), is authorized to develop rules related to pediatric cardiac facilities participating in the Children's Medical Services Network. The bill creates the "Pediatric and Congenital Centers of Excellence" designation for facilities that meet standards established by the council and approved by the Director of Children's Medical Services and the State Surgeon General utilizing state and national professional standards.

Additionally, the bill provides that rules relating to pediatric cardiac services and facilities in effect on October 1, 2015, are authorized and remain in effect until amended.

The bill further requires the council to submit an annual report to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the State Surgeon General summarizing the council's activities for the preceding fiscal year, including specified data and performance measures of cardiac facilities participating in the Children's Medical Services Network, and recommending policy and procedural changes.

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 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 AHCA 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 AHCA 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

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

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 patient quality and safety.[7]

The AHCA 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 experienced physician who has performed a minimum of 75 interventional cardiology procedures within the previous 12 months, or those physicians with less than 12 months experience, to fulfill specified training requirements.
- The nursing and technical catheterization laboratory staff must meet the following requirements:
  - 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;[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 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;
  - 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 AHCA's rulemaking is The American College of Cardiology/American Heart Association Task Force on Practice Guidelines' report:

[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.
[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.

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.

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.

As of February 7, 2016, there are 52 hospitals providing Level I ACS services and 77 hospitals providing Level II ACS services.[13]

Children's Medical Services

Children's Medical Services (CMS) is a group of programs that serve children with special health care needs under the supervision of the department. Within CMS, individual services or programs are designed to address specific conditions or family needs such as the newborn screening program, early intervention screenings, or its managed medical assistance plan. CMS is created under ch. 391, F.S., which is divided into three parts: Part I (General Provisions), Part II (Children's Medical Services Councils and Panels), and Part III (Developmental Evaluation and Intervention Programs).

Statewide Children's Medical Services Network Advisory Council

The State Surgeon General has the discretion under s. 391.221, F.S., to appoint a 12-member Statewide Children's Medical Services Network Advisory Council to serve as an advisory body to the department. The council's duties include, but are not limited to:

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[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).

[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] *See* The AHCA FloridaHealthFinder.gov *available at* http://www.floridahealthfinder.gov/facilitylocator/FacilitySearch.aspx, (last visited Feb. 2, 2016).

- Recommending standards and credentialing requirements for health care providers in the CMS Network (Network);
- Making recommendations to the director of CMS concerning the selection of CMS providers;
- Providing input to the CMS program on the policies governing the Network;
- Reviewing the financial reports and financial status of the Network and making recommendations concerning the methods of payment and costs controls for the Network;
- Reviewing and recommending the scope of benefits for the Network; and
- Reviewing Network performance measures and outcomes and making recommendations for improvements to the Network and its maintenance and collection of data and information.

Council members represent the private health care provider sector, families of children with special health care needs, AHCA, the Chief Financial Officer, the Florida Chapter of the American Academy of Pediatrics, an academic pediatric program, and the health insurance industry.[14] The four-year terms were initially staggered and no member can be appointed for more than two consecutive terms. Members do not receive any compensation for their appointment except they are reimbursed for per diem and travel in accordance with s. 112.061, F.S.[15]

The department does not currently have an appointed Statewide Children's Medical Services Network Advisory Council.

Cardiac Technical Advisory Panel

The State Surgeon General also has general authority under s. 391.223, F.S., to establish technical advisory panels to assist with the development of specific policies and procedures for the CMS program. On October 21, 2013, State Surgeon General John Armstrong created the Children's Medical Services Cardiac Technical Advisory Panel (CTAP) to provide both programmatic and technical advice to the department and its CMS program.[16] The enabling document provides several charges to the panel:

- Developing recommended standards for personnel and facilities rendering pediatric congenital cardiac services as well as heart disease;
- Developing recommendations for legislative initiatives, including appropriation items, related to the cardiac program and developing rules;
- Developing recommendations for statewide cardiac initiatives, including identifying panel members who will collaborate with other department councils or committees or state agencies;
- Assisting AHCA, or as requested by individual hospitals, or as outlined in their individual contract with CMS, with the ongoing evaluation and development of congenital cardiovascular programs;
- Making a priority weight control programs and their implementation in all pediatric cardiovascular centers and clinics; and

[14] Section 391.221(2), F.S.
[15] Section 391.221 (3), F.S.
[16] Florida Dep't of Health, *Creation of the Children's Medical Services Cardiac Technical Advisory Panel,* (October 2013) http://www.cmsctap.com/_files/documents/CTAP-Creation.pdf (Last visited Oct. 6, 2015).

- Developing recommendations to the department and AHCA for congenital heart disease quality improvement to improve patient care and health and decrease the cost of care.[17]

The CTAP membership is appointed by the State Surgeon General, in consultation with the Deputy Secretary of CMS and the Director of the Division of CMS. Eleven members are designated in the creation document. They represent pediatric cardiologists or cardiovascular surgeons from specific pediatric cardiovascular children's hospitals across the state and include two at-large physicians and a community physician who are not affiliated with one of the named facilities. Non-voting advisory members may also be named by the State Surgeon General who may deliberate, but not vote, with the panel. Alternate members for each representative of the cardiovascular children's hospitals must also be named.

Under the creation document, CTAP members select their Chairperson and Vice Chairperson through majority vote every two years. Meetings of the CMS CTAP are upon the call of the Chairperson, at the request of the State Surgeon General, the Deputy Secretary of CMS, the Director of the Division of CMS, or the majority of the voting members.[18]

Members are reimbursed for per diem and travel expenses for required attendance at in-person or video conference committee meetings or CMS site visits in accordance with s. 112.061, F.S.[19]

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 CMS pediatric cardiac facilities.

On October 12, 2015, the department held a rule hearing regarding the proposed repeal of the standards for pediatric cardiac facilities, Rule 64C-4.003, F.A.C., as the department determined there was no statutory authority for it to establish standards, inspect facilities, or prepare inspection reports for the technical advisory panel to review.[20] A Petition for Determination of Invalidity of Proposed Rule regarding the proposed repeal of Rule 64C-4.003, F.A.C., was filed with the Division of Administrative Hearings (DOAH). The DOAH judge issued a final order on December 16, 2015, ruling that Petitioners did not have standing to challenge the proposed rule, and therefore he was without jurisdiction to rule on the merits of the rule challenge.[21] An appeal to that order was filed in the First District Court of Appeal on December 31, 2015.

[17] *Id.*
[18] *Id.*
[19] *Id.*
[20] Fla. Department of Health, *2016 Agency Bill Analysis - SB 378*, p. 2,(Sept. 29, 2015) (on file with the Senate Committee on Health Policy)
[21] W.D., C.V., K.E. and K.M., vs. Department of Health, Florida Division of Administrative Hearing, Case no. 15-6009RP, available at: https://www.doah.state.fl.us/ROS/2015/15006009.pdf (last visited on Feb. 8, 2016).

Cardiac Advisory Council

Prior to the 2001 Regular Session, a Cardiac Advisory Council in the Division of CMS existed.[22] The 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 CMS cardiac program, including the rulemaking process.[23]

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.[24] The department recommended the repeal of the council and indicated it would absorb the functions of the council in 2001.[25]

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:

> 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 purpose[26] and meet a statutorily defined purpose.[27] 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.[28] The Legislature and the public must be kept informed of the numbers, purposes, memberships, activities, and expenses of advisory bodies, commissions and boards.[29] Members of such bodies are appointed for staggered, four-year terms and unless otherwise provided in the

[22] *See* s. 391.222, F.S. (2000).
[23] *Id.*
[24] Chapter 2001-89, s. 27, Laws of Fla.
[25] Senate Committee on Governmental Oversight and Productivity, *CS/SB 1410 Staff Analysis and Economic Impact Statement* (March 28, 2001) *p. 9*, http://archive.flsenate.gov/data/session/2001/Senate/bills/analysis/pdf/2001s1410.go.pdf (Last visited Oct. 6, 2015).
[26] Section 20.052(1), F.S.
[27] Section 20.052(4)(a), F.S.
[28] Section 20.052(2), F.S.
[29] Section 20.052(3), F.S.

State Constitution,[30] serve without compensation, but are authorized to receive reimbursement for per diem and travel as provided in s. 112.061, F.S.[31]

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.[32] 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.[33]

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.[34]

Technical advisory panels are not separately defined in statute.

Rulemaking

Rulemaking is required by Florida's Administrative Procedure Act (APA) whenever a government agency has express authority to make rules, and must resort to rulemaking in order to implement, interpret, or prescribe law, policy, or requirements,[35] including mandatory forms.[36] Rulemaking is not discretionary under the APA.[37]

III. Effect of Proposed Changes:

Section 1 creates s. 391.224, F.S., and the Pediatric Cardiac Advisory Council (council) under the Department of Health (department) for the purpose of coordinating pediatric cardiac care in this state and advising the department and the Agency for Health Care Administration (AHCA) on the delivery of cardiac services to children.

The advisory council will be composed of no more than 13 voting members with expertise in cardiac medicine appointed by the State Surgeon General, and members will serve staggered four-year terms. Eight of the members who are either pediatric cardiologists or pediatric cardiovascular surgeons must be nominated by the chief executive officers of designated health care systems with pediatric cardiac certificates of need. A hospital with a certificate of need for a pediatric cardiac program that meets state and national standards as determined by the council following an on-site visit by a panel from the council shall have one of its pediatric cardiologists or pediatric cardiovascular surgeons who has been nominated by its chief executive officer and approved by the State Surgeon General appointed to the council as a new voting member.

[30] Section 20.052(4)(c), F.S.
[31] Section 20.052(4)(d), F.S.
[32] Section 20.052(5)(a), F.S.
[33] Section 20.052(5)(b), F.S.
[34] Section 20.052(5)(c), F.S.

[36] *Dep't of Bus. Reg., Div. of Alcoholic Bev. & Tobacco v. Martin County Liquors, Inc.*, 574 So.2d 170 (Fla. 1st DCA 1991).
[37] Section 120.54(1)(a), F.S.

The State Surgeon General is also authorized to select additional at-large members, with expertise in pediatric cardiology or adults with congenital heart disease who are not associated with one of the designated facilities. Additional advisory, non-voting members may also be appointed to the council by the State Surgeon General, one of whom must be a representative from a pediatric health advocacy group.

The voting privilege of a voting member of the advisory council must be suspended if the facility he or she represents no longer meets state and national standards as adopted by the council. Such individual may remain a member of the council in an advisory capacity but shall relinquish voting privileges until his or her facility meets required standards.

The bill requires the Council to meet at least quarterly. Meetings may also be called by the Chair, two or more voting members, or the State Surgeon General. An employee of the department or a contracted consultant paid by the department is not eligible to serve as a member or ex-officio member and no member may serve more than two consecutive terms.

Council members do not receive compensation; however, they are entitled to reimbursement in accordance with s. 112.061, F.S., for per diem and travel. Council meetings must be conducted via teleconference where that capability is available.

The council's duties include, but are not limited to:

- Recommending standards for personnel and facilities rendering cardiac services;
- Analyzing reports on the periodic review of cardiac personnel and facilities to determine if established standards for the cardiac services are met;
- Making recommendations to the CMS Director as to the approval or disapproval of personnel and facilities;
- Making recommendations as to the intervals for re-inspection of approved personnel and facilities;
- Reviewing and inspecting hospitals upon the request of the hospital, the department, or AHCA to determine if established state and national standards for cardiac services are met;
- Providing input on all aspects of the state's Children's Medical Services cardiac programs, including rulemaking;
- Addressing all components of the care of adults and children with congenital heart disease and children with acquired heart disease, as indicated and appropriate;
- Abiding by the recognized state and national professional standards of care for children with heart disease;
- Making recommendations to the State Surgeon General for legislation and appropriations for children's cardiac services; and
- Providing advisory opinions to AHCA before AHCA approves a certificate of need for children's cardiac services.

The bill also authorizes the creation of the "Pediatric and Congenital Centers of Excellence" designation. The designation may be awarded to facilities at the recommendation of the council with the approval of the Director of Children's Medical Services and the State Surgeon General utilizing state and national professional standards approved by the council. The designation shall be withdrawn automatically if a facility no longer meets those standards.

The council shall also develop and recommend to the State Surgeon General evaluation tools for measuring the goals and performance standards for the facilities seeking and receiving the designation.

The council must submit an annual report to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the State Surgeon General by each January 1, beginning in 2017. This report must summarize the council's activities for the preceding fiscal year and include data and performance measures for all pediatric cardiac facilities that participate in the Network relating to surgical morbidity and mortality. The annual report must also recommend any policy or procedural changes that would increase the council's effectiveness in monitoring pediatric cardiovascular programs in the state.

The department, in coordination with AHCA, shall develop rules related to pediatric cardiac facilities that participate in the Network. These rules may establish standards relating to the training and credentialing of medical and surgical personnel, facility and physician minimum case volumes, and date reporting requirements for monitoring and enhancing quality assurance. Also, the department is authorized to develop rules related to the establishment, operations, and authority of the council, and the establishment, goals, performance standards, and evaluation tools for designating facilities as "Pediatric and Congenital Cardiovascular Centers of Excellence."

The bill ratifies rules relating to pediatric services and facilities in effect on October 1, 2015, by providing these rules are authorized and shall remain in effect until amended.[38]

Section 2 amends s. 408.0361(3)(b), to require the AHCA to adopt or update rules relating to nursing and technical staff experience in dedicated cardiac interventional laboratories or surgical centers. The bill specifies that if a nurse's or technical staff member's prior experience is in a dedicated cardiac interventional laboratory at a hospital that does not have an approved adult open-heart-surgery program (Level I hospital), the previous experience qualifies only if, while the staff member acquires his or her experience, the dedicated cardiac interventional laboratory:

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

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

[38] Rule 64C-4.003, F.A.C., Diagnostic and Treatment Facilities or Services – Specific incorporates by reference the CMS Pediatric Cardiac Facilities Standards, October 2012, and requires CMS approved pediatric cardiac facilities to collect and submit quality assurance data annually relating to pediatric cardiology clinic laboratory procedures, cardiac catheterization procedures, cardiac catheterization cases-primary cardiac diagnoses, and patients with fetal diagnosis of heart conditions. The rule also provides for the approval of regional and satellite cardiac clinics for the CMS Network on a statewide basis and requires these clinics to comply with the CMS cardiac regional and satellite clinic standards, October 2012.

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:

Facilities will have the opportunity to earn a designation as a "Pediatric and Congenital Center of Excellence." This designation may distinguish one facility over another in the marketplace for the quality of care in the delivery of cardiac services to children and may impact the number of services delivered in a particular facility.

Level I hospitals may find it easier 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:

The council is housed in the department and makes recommendations to the State Surgeon General and the Children's Medical Services program. Since October 2013, the department has been supporting a similar technical advisory panel, the Children's Medical Services Cardiac Technical Advisory Panel, and this bill includes similar duties and responsibilities of that technical advisory panel. With passage of this bill, the technical advisory panel will no longer be necessary.

The department estimates minimal costs for the council for conference calls at $336 annually. The estimate is based on four calls per year, 40 persons per call for one hour at 3.5 cents per minute.[39]

To the extent that the bill seeks to enforce any standards on cardiac facilities, the department's authority is limited to its ability to credential facilities and providers that

[39] *Supra* note 7, at 4.

participate in the Children's Medical Services program.[40] Enforcement of facility standards related to licensure resides in AHCA which is directed to work in coordination with the council under the bill.

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.

This bill creates section 391.224 of the Florida Statutes.

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 Health Policy on February 9, 2016:
The committee substitute:

- Creates the Pediatric Cardiac Advisory Council within the department and requires the council to submit an annual report summarizing the council's activities and data and performance measures for all pediatric cardiac facilities that participate in the Children's Medical Services Network;
- Requires the department, in coordination with the AHCA, to develop rules related to pediatric cardiac facilities that participate in the Children's Medical Services Network and provides that rules relating to pediatric cardiac services and facilities in effect on October 1, 2015, are authorized and remain in effect until amended;
- Authorizes the department to create the "Pediatric and Congenital Centers of Excellence" designation for facilities that meet certain standards; and
- Removes the repeal of CON provisions and only addresses rulemaking to authorize certain Level I dedicated interventional cardiac laboratories to provide the prerequisite experience for nursing and technical staff.

B. Amendments:

None.

[40] *Supra* note 7, at 5.