

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 Governmental Oversight and Accountability

BILL: CS/SB 62

INTRODUCER: Governmental Oversight and Accountability Committee and Senator Bean

SUBJECT: Pediatric Cardiac Care in the Children’s Medical Services Program

DATE: February 7, 2017 REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Lloyd</u>	<u>Stovall</u>	<u>HP</u>	Favorable
2.	<u>Kim</u>	<u>Ferrin</u>	<u>GO</u>	Fav/CS
3.	_____	_____	<u>AHS</u>	_____
4.	_____	_____	<u>AP</u>	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 62 creates the Pediatric Cardiac Care Advisory Council (council) within the Department of Health (department) for the purpose of advising the department on the delivery of cardiac services to children and adults with congenital heart disease. The bill specifies the duties and composition of the council.

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.

Beginning January 1, 2019, the bill 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 Surgeon General. The report must summarize 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 recommend policy and procedural changes.

The bill requires the department to adopt rules that meet or exceed current standards for pediatric cardiac facilities. The bill also grants the department discretion to make rules governing the council and Pediatric and Congenital Centers of Excellence.

The bill takes effect upon becoming law.

II. Present Situation:

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 Chapter 391 of the Florida Statutes and 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 shall include, but are not limited to:

- Recommending standards and credentialing requirements for health care providers in the CMS 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 CMS 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, Agency for Health Care Administration (AHCA), the Chief Financial Officer, the Florida Chapter of the American Academy of Pediatrics, an academic pediatric program, and the health insurance industry.¹ 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.² No meetings of the council are currently scheduled.

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 Children's Medical Services program. On October 21, 2013, then-State Surgeon General John Armstrong created the Children's Medical Services Cardiac Technical Advisory Panel

¹ Section 391.221(2), F.S.

² Section 391.221 (3), F.S.

(CTAP) to provide both programmatic and technical advice to the department and its CMS program.³ 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
- 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.⁴

The CTAP membership is appointed by the State Surgeon General, in consultation with the Deputy Secretary of Children's Medical Services and the Director of the Division of Children's Medical Services. 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.⁵

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.⁶ The panel last met on May 4, 2015, and no additional meetings are currently scheduled.⁷

Children's Medical Services Managed Care Plan Technical Advisory Panel

State Surgeon General Celeste Philip created the Children's Medical Services Managed Care Plan Technical Advisory Council under this same general authority to assist with the transition of the CMS membership from a direct services network to a managed care plan. The panel was

³ Florida Dep't of Health, *Creation of the Children's Medical Services Cardiac Technical Advisory Panel* (October 2013) available at <http://www.cmsctap.com/files/documents/CTAP-Creation.pdf> (last visited Jan. 19, 2017).

⁴ *Id.*

⁵ *Id.*

⁶ *Id.*

⁷ E-Mail from Brian Wendel, Florida Dep't of Health (Jan. 20, 2017) (on file with the Senate Committee on Health Policy).

created in September 2015, and includes representation by pediatricians, health care providers, parents of enrollees, CMS staff, and Medicaid managed care plan staff.⁸

Panel members are charged with the development of long range planning, quality improvement initiatives, health education and wellness and other recommendations for the CMS Managed Care Plan. The panel's purpose is to recommend activities and strategies that will maintain the plan's accreditation status and improve care coordination and service delivery in all CMS Plan provider sites.⁹

Meetings of this panel are upon the call of the Surgeon General, CMS Plan President, or CMS Plan Chief Executive Officer. Any recommendations made by the panel are forwarded to the State Surgeon General. The panel's last meeting was October 30, 2015.

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. 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).¹⁰

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, 2015.¹¹ 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 injury was shown, and because common good such as quality health care is not within the zone of interest.¹²

⁸ Florida Dep't of Health, *Creation of the Children's Medical Services Managed Care Plan Technical Advisory Panel* (September 2015) available at <http://www.floridahealth.gov/documents/cms-plan-tap.pdf> (last visited Jan. 19, 2017).

⁹ *Id.*

¹⁰ *W.D., C.V., K.E., and K.M., v. Dep't of Health*, Case No. 15-6009RP (Fla. DOAH 2015).

¹¹ *Id.*

¹² Vol. 43 Fla. Admin. Register 145 (Jan. 9, 2017).

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.¹³

Rule 64C-4.003, F.A.C., remains in effect. The department has taken no further action to repeal the rule.¹⁴

Cardiac Advisory Council

Prior to the 2001 Regular Session, a Cardiac Advisory Council in the Division of Children's Medical Services existed.¹⁵ 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.¹⁶

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.¹⁷ The department recommended the repeal of the Cardiac Advisory Council and indicated it would absorb the functions of the Cardiac Advisory Council in 2001.¹⁸

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.

¹³ *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 Jan. 30, 2017). *K.M. v. Dep't of Health*, Florida Third District Court of Appeal Case number 3D16-23, Online Docket http://jweb.flcourts.org/pls/ds/ds_docket (last viewed Jan. 30, 2017.)

¹⁴ *Florida Administrative Code and Florida Administrative Register*, <https://www.flrules.org/gateway/ruleno.asp?id=64C-4.003> (last viewed Feb. 2, 2017).

¹⁵ See s. 391.222, F.S. (2000).

¹⁶ *Id.*

¹⁷ Chapter 2001-89, s. 27, Laws of Fla.

¹⁸ 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 Jan. 19, 2017).

Advisory bodies, commissions and boards may only be created by statute in furtherance of a public purpose¹⁹ and meet a statutorily defined purpose.²⁰ 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.²¹ The Legislature and the public must be kept informed of the numbers, purposes, memberships, activities, and expenses of advisory bodies, commissions and boards.²² Members of such bodies are appointed for staggered, four-year terms and unless otherwise provided in the State Constitution,²³ serve without compensation, but are authorized to receive reimbursement for per diem and travel as provided in s. 112.061, F.S.²⁴

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.²⁵ 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.²⁶

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.²⁷

Technical advisory panels are not separately defined in statute.

Agency for Health Care Administration

AHCA is responsible for the licensure, certification, and regulation of 40 different types of health care providers, including hospitals, nursing homes, assisted living facilities, and home health agencies through its Division of Health Quality Assurance.²⁸ Under its Bureau of Health Facility Regulation, AHCA reviews applications for new facilities and specialty services at hospitals through the certificate of need (CON) process.²⁹ Currently, pediatric cardiac standards only exist in the CON process and there is no authority to maintain compliance with pediatric cardiology standards as a condition of licensure.³⁰ Also, the Bureau of Health Facility Regulation conducts periodic and complaint-based inspections of hospitals.

¹⁹ Section 20.052(1), F.S.

²⁰ Section 20.052(4)(a), F.S.

²¹ Section 20.052(2), F.S.

²² Section 20.052(3), F.S.

²³ Section 20.052(4)(c), F.S.

²⁴ Section 20.052(4)(d), F.S.

²⁵ Section 20.052(5)(a), F.S.

²⁶ Section 20.052(5)(b), F.S.

²⁷ Section 20.052(5)(c), F.S.

²⁸ See <http://ahca.myflorida.com/MCHQ/index.shtml> (last visited on Jan. 19, 2017).

²⁹ See http://ahca.myflorida.com/MCHQ/CON_FA/index.shtml (last visited on Jan. 19, 2017). Also, see Agency for Health Care Administration, *Certificate of Need Publications* http://ahca.myflorida.com/MCHQ/CON_FA/Publications/index.shtml

³⁰ Agency for Health Care Administration, *Senate Bill 62 Agency Analysis* (Nov. 30, 2016) (on file with the Senate Committee on Health Policy)

Rulemaking

Rulemaking is required by Florida's Administrative Procedure Act (APA) whenever a government agency has express authority to make rules.³¹ Rulemaking authority is construed to extend no further than the implementing or interpreting the specific powers and duties conferred by the enabling statute.³² Rulemaking is not discretionary under the APA.³³

III. Effect of Proposed Changes:

Section 1 creates s. 391.224, F.S., and council under the department for the purpose of continued coordination of pediatric cardiac care in this state. The department, its cardiac consultants and AHCA are directed to maintain their existing, long-standing inter-agency terms and agreements for the delivery of pediatric cardiac services.

The council shall be composed of no more than 15 voting members with expertise in cardiac medicine. Members will serve staggered four-year terms. Membership is comprised of the following:

- Ten members who are either pediatric cardiologists or pediatric cardiovascular surgeons who must be nominated by the chief executive officers of 10 designated health care systems with pediatric cardiac certificates of need and have met state and national standards as recommended by the council following an onsite visit and then appointed by the Surgeon General;
- One or two members who are pediatric cardiologists or pediatric cardiovascular surgeons nominated by the chief executive officers of hospitals with pediatric cardiac certificates of need and have met state and national standards as recommended by the council following an onsite visit and then appointed by the Surgeon General;
- Two members who are pediatric cardiologists or pediatric cardiovascular surgeons with expertise in congenital heart disease; who are not associated with a facility that is otherwise represented by a voting member of the council; and who are appointed by the Surgeon General in consultation with the Deputy Secretary for Children's Medical Services and the Director of Children's Medical Services; and
- One member who is a community physician with a special interest in treating children with heart disease and who is not associated with one of the facilities already represented; or who is a community-based internist who experience treating adults with congenital heart disease; and who will be appointed by the Surgeon General in consultation with the Deputy Secretary for Children's Medical Services and the Director of Children's Medical Services.

The State Surgeon General is also authorized to select additional non-voting, advisory members, with expertise in pediatric cardiology or adults with congenital heart disease who are not associated with one of the designated facilities in consultation with the Deputy Secretary for Children's Medical Services and the Director of Children's Medical Services. Advisory members may participate in discussions and subcommittees of the council, but do not vote.

³¹ Section 120.536(1), F.S.

³² *Id.*

³³ Section 120.54(1)(a), F.S.

The voting privilege of a voting member of the 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 to clients, and facilities that provide services to clients of the department and the program and for the diagnosis of cardiac conditions;
- Analyzing reports on the periodic review of cardiac personnel, facilities, and diagnoses to determine if established standards for the cardiac services are met;
- Making recommendations to the Director of Children's Medical Services as to whether reviewed cardiac care personnel, clinics, facilities, and diagnoses meet established state and national standards;
- Making recommendations to the Director of Children's Medical Services as to the intervals for re-inspection of approved personnel, clinics, facilities; and diagnoses meeting established state and national standards;
- Reviewing and inspecting hospitals upon the request of the hospital, the department, or AHCA to determine compliance with established state and national standards for cardiac services;
- Advising the department and the AHCA on all aspects of the provision of cardiac care under the program, including rulemaking, and all components of providing care to adults and children with congenital heart disease and children with acquired heart disease;
- Reviewing and analyzing compliance by cardiac care personnel, clinics, and facilities with 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 pediatric cardiac services; and
- Providing advisory opinions to AHCA before AHCA approves a certificate of need for pediatric cardiac services.

The bill also authorizes the creation of the "Pediatric and Congenital Centers of Excellence" designation. The designation shall be awarded to facilities by the Surgeon General at the recommendation of the council and the Director of Children's Medical Services 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.

Beginning in January 2019, 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. This report must summarize the council's activities for the preceding fiscal year and include data and performance measures on surgical morbidity and mortality for all pediatric cardiac facilities that participated in the program. 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, is required to develop rules related to pediatric cardiac facilities that participate in the program. These rules will establish standards relating to the training and credentialing of medical and surgical personnel, facility and physician minimum case volumes, and data reporting requirements for monitoring and enhancing quality assurance. The bill provides that the department must adopt rules that are the same or better than the standards for pediatric cardiac facilities which were adopted in October of 2012. The standards adopted in October of 2012, are currently codified in Rule 64C-4.003, F.A.C.

The bill gives the department discretion to adopt rules related to the establishment, operations, and authority of the council. In addition, the department has the discretion to adopt rules related to performance standards and evaluation tools for designating facilities as "Pediatric and Congenital Cardiovascular Centers of Excellence."

The bill takes effect upon becoming law.

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:

Individuals from the private sector with expertise in cardiac medicine are eligible to serve as members of the council. Members are selected by the State Surgeon General to serve staggered terms of four years and will have an opportunity to provide input on all aspects of CMS' cardiac programs, including rulemaking, address components of cardiac care for both adults and children, make recommendations for legislation and appropriations and provide advisory opinions before AHCA approves a certificate of need for children's cardiac services.

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.

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 may no longer be necessary.

The department estimated minimal costs for the council for conference calls at \$336 annually. The estimate was based on four calls per year, 40 persons per call for one hour at 3.5 cents per minute. A registered nurse consultant will cost an estimated \$94,104.³⁴ In addition, if the council conducts in person meetings, the estimated to cost for rulemaking will be \$12,834.³⁵ The department also notes that additional costs will be incurred if the Counsel travels to inspect a hospital.³⁶

To the extent that the bill seeks to recommend any standards on cardiac facilities and to make designations of "Pediatric and Congenital Cardiovascular Excellence" on those that meet those standards, the department's authority is limited to its ability to credential facilities and providers that participate in the Children's Medical Services program.³⁷ 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.

³⁴ Florida Dep't of Health, *2017 Agency Legislative Bill Analysis*, dated Jan. 17, 2017.

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Senate Bill 378 Legislative Analysis* (Sept. 29, 2015) at 5.

VII. Related Issues:

Because of ongoing litigation, it is unclear how long Rule 64C-4.003, F.A.C., will remain in place. This bill anticipates that the department successfully repealed Rule 64C-4.003, F.A.C., before the bill goes into effect.

The rulemaking provisions of this bill could be redundant if the department does not repeal the rule, however, this should not be problematic. In the event that the department does not repeal Rule 64C-4.003, F.A.C., the current rules should stay in place. The bill prevents the department from repealing the rule in the future and also prevents the department from making rules which lower the standard of care currently in place. To the extent that the department has argued that it lacks statutory authority to maintain Rule 64C-4.003, F.A.C.,³⁸ this bill provides express authorizing language for the department to keep Rule 64C-4.003, F.A.C., or make similar rules in the future.

VIII. Statutes Affected:

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 Governmental Oversight and Accountability on February 7, 2017:

The CS adds two members to the council and provides that the department is required to make rules that meet or exceed the standard of care for pediatric cardiac facilities that are currently in effect.

The CS also makes some technical formatting and numbering changes.

- B. **Amendments:**

None.

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

³⁸ *W.D., C.V., K.E. and K.M., v. Dep't of Health*, Case No. 15-6009RP, Final Order, p. 5., (Fla. DOAH 2015).