

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 378

INTRODUCER: Health Policy Committee and Senator Bean

SUBJECT: Pediatric Cardiac Advisory Council

DATE: November 16, 2015 REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	Fav/CS
2.	Peacock	McVaney	GO	Pre-meeting
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 378 creates the Pediatric Cardiac Advisory 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 Pediatric Cardiac Advisory Council.

The bill also authorizes the department, in coordination with the Agency for Health Administration (AHCA), to develop rules related to pediatric cardiac facilities. 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 the law is remedial and makes the rulemaking authority retroactive to preserve existing rules.

CS/SB 378 has a minimal annual fiscal impact.

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

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, 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

The department does not currently have an appointed Statewide Children's Medical Services 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 Children's Medical Services program. On October 21, 2013, State Surgeon General John Armstrong created the Children's Medical Services Cardiac Technical Advisory Panel (CTAP)

¹ Section 391.221(2), F.S.

² Section 391.221 (3), F.S.

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

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.

³ 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).

⁴ *Id.*

⁵ *Id.*

⁶ *Id.*

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.⁷ A Petition for Determination of Invalidity of Proposed Rule regarding the proposed repeal of Rule 64C-4.003, F.A.C., has been filed with the Division of Administrative Hearings (DOAH), and a hearing is scheduled for November 20 and 23, 2015, before an administrative law judge.⁸

Cardiac Advisory Council

Prior to the 2001 Regular Session, a Cardiac Advisory Council in the Division of Children's Medical Services existed.⁹ 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 Children's Medical Services cardiac program, including the rulemaking process.¹⁰

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.¹¹ The department recommended the repeal of the council and indicated it would absorb the functions of the council in 2001.¹²

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.

⁷ Fla. Department of Health, *2016 Agency Bill Analysis - SB 378*, p. 2, (Sept. 29, 2015) (on file with the Senate Health Policy Committee)

⁸ W.D., C.V., K.E., and K.M. v. Dep't of Health, Case No. 15-600RP (DOAH 2015); *Also, see* DOAH Docket at <https://www.doah.state.fl.us/ALJ/searchDOAH/docket.asp?T=11/12/2015 5:09:16 PM> (last visited on November 12, 2015).

⁹ *See* s. 391.222, F.S. (2000).

¹⁰ *Id.*

¹¹ Chapter 2001-89, s. 27, Laws of Fla.

¹² 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).

Advisory bodies, commissions and boards may only be created by statute in furtherance of a public purpose¹³ and meet a statutorily defined purpose.¹⁴ 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.¹⁵ The Legislature and the public must be kept informed of the numbers, purposes, memberships, activities, and expenses of advisory bodies, commissions and boards.¹⁶ Members of such bodies are appointed for staggered, four-year terms and unless otherwise provided in the State Constitution,¹⁷ serve without compensation, but are authorized to receive reimbursement for per diem and travel as provided in s. 112.061, F.S.¹⁸

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.¹⁹ 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.²⁰

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.²¹

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.²² 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.²³ Also, the Bureau of Health Facility Regulation conducts periodic and complaint-based inspections of hospitals.

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

¹³ Section 20.052(1), F.S.

¹⁴ Section 20.052(4)(a), F.S.

¹⁵ Section 20.052(2), F.S.

¹⁶ Section 20.052(3), F.S.

¹⁷ Section 20.052(4)(c), F.S.

¹⁸ Section 20.052(4)(d), F.S.

¹⁹ Section 20.052(5)(a), F.S.

²⁰ Section 20.052(5)(b), F.S.

²¹ Section 20.052(5)(c), F.S.

²² See <http://ahca.myflorida.com/MCHQ/index.shtml> (last visited on November 9, 2015).

²³ See http://ahca.myflorida.com/MCHQ/CON_FA/index.shtml (last visited on November 9, 2015). Also, see Agency for Health Care Administration, *Certificate of Need Publications*: http://ahca.myflorida.com/MCHQ/CON_FA/Publications/index.shtml (last visited on November 9, 2015).

to implement, interpret, or prescribe law, policy, or requirements,²⁴ including mandatory forms.²⁵ Rulemaking is not discretionary under the APA.²⁶

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.

An 11-member advisory council of individuals with expertise in cardiac medicine appointed by the State Surgeon General will serve staggered four-year terms. Eight of the members must be nominated by the chief executive officers of designated health care systems with pediatric cardiac certificates of need. 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.

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 Children's Medical Services Director as to the approval or disapproval of personnel and facilities. At the recommendation of the cardiac advisory council and Director's approval, the department's secretary shall designate facilities approved under this paragraph as "Pediatric and Congenital Cardiovascular Centers of Excellence." The designation is withdrawn automatically if a particular center no longer meets state and national professional standards of care for children with heart disease;
- Making recommendations as to the intervals for re-inspection of approved personnel and facilities;
- 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;

²⁵ *Dep't of Bus. Reg., Div. of Alcoholic Bev. & Tobacco v. Martin County Liquors, Inc.*, 574 So.2d 170 (Fla. 1st DCA 1991).

²⁶ Section 120.54(1)(a), F.S.

- 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 department, in coordination with AHCA, is authorized to develop rules related to pediatric cardiac care facilities, 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 states its intention to clarify existing law, be remedial in nature, and its applicability to apply retroactively to rules already in existence without regard to when such rules were adopted.

Section 2 provides an effective date of July 1, 2016.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. Other Constitutional Issues

This bill provides that it is remedial in nature, is intended to clarify existing law, and applies retroactively to rules already in existence without regard to the date such rules

were adopted. Retroactive application of a statute is generally unconstitutional if the statute impairs vested rights, creates new obligations, or imposes new penalties.²⁷

To determine whether a statute should be retroactively applied, courts apply two interrelated inquiries. First, courts determine whether there is clear evidence of legislative intent to apply the statute retrospectively. If so, then courts determine whether retroactive application is constitutionally permissible.²⁸

The second prong looks to see if a vested right is impaired. To be vested, a right must be more than a mere expectation based on an anticipation of the continuance of an existing law. It must be an immediate, fixed right of present or future enjoyment.²⁹ This bill contains a finding that it is remedial. “Remedial statutes or statutes relating to remedies or modes of procedure, which do not create new or take away vested rights, but only operate in furtherance of the remedy or confirmation of rights already existing, do not come within the legal conception of a retrospective law, or the general rule against retrospective operation of statutes.”³⁰

To the extent an existing rule sets forth standards for pediatric cardiac facilities, this law may be constitutionally permissible.

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.

²⁷ See *State Farm Mutual Automobile Insurance Company v. Laforet*, 658 So.2d 55, 61 (Fla. 1995).

²⁸ See *Florida Ins. Guar. Ass’n, Inc., v. Devon Neighborhood Ass’n, Inc.*, 67 So.3d 187, 194 (Fla. 2011); See, also *Metropolitan Dade County v. Chase Federal Housing Corp.*, 737 So.2d 494, 499 (Fla. 1999).

²⁹ See *R.A.M. of South Florida, Inc. v. WCI Communities, Inc.*, 869 So.2d 1210, 1218 (Fla. 2d DCA 2004).

³⁰ *City of Lakeland v. Catinella*, 129 So.2d 133, 136 (Fla. 1961).

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 CS/SB 378 includes similar duties and responsibilities of that technical advisory panel. With passage of CS/SB 378, the technical advisory panel will no longer be necessary.

The department estimates minimal costs for the council for conference calls at \$336.00 annually. The estimate is based on four calls per year, 40 persons per call for one hour at 3.5 cents per minute.³¹

To the extent that CS/SB 378 seeks to enforce any standards on cardiac facilities, the department's authority is limited to its ability to credential facilities and providers that participate in the Children's Medical Services program.³² 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 creates section 391.224 of the Florida Statutes.

IX. Additional Information:**A. Committee Substitute – Statement of Changes:**

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

CS by Health Policy Committee on October 20, 2015:**The CS:**

- Adds legislative intent and findings for the Pediatric Cardiac Advisory Council;
- Specifies the State Surgeon General as the nominating official, not the department for the council;
- Establishes the process for the election of the council chair and the frequency of council meetings shall be at least quarterly;
- Eight of the 11 council members are specifically designated as pediatric cardiologists or pediatric cardiovascular surgeons nominated by specific facilities with pediatric

³¹ *Supra*, note 7 at 4.

³² *Supra*, note 7, at 5.

certificates of need in addition to three other at large physicians with special expertise in dealing with children or adults with congenital heart disease;

- At the recommendation of the council and with the approval of the Director of Children’s Medical Services , the State Surgeon General shall designate facilities that meet state and national standards of care for children with heart disease as “Pediatric and Congenital Cardiovascular Centers of Excellence”;
- A Centers of Excellence designation may automatically be withdrawn if a facility no longer meets the established standards;
- The council is directed to develop and recommend to the State Surgeon General measurable performance standards, goals, and evaluation tools, for the designation;
- The Department in coordination with AHCA, shall develop rules related to pediatric cardiac facilities; the establishment operations, and authority of the council; and the establishment, goals, performance standards, and evaluation tools for the designation of facilities as Centers of Excellence; and
- Clarifies existing law, is remedial in nature, and shall apply retroactively to rules already in existence without regard to the date such rules were adopted.

B. Amendments:

None.