



# **Pediatric Cardiac Technical Advisory Panel**

**Full Panel Meeting  
Friday, September 20, 2019  
AHCA Headquarters  
Tallahassee, FL  
9:00 a.m. – 4:00 p.m.**

MEETING  
AGENDA

# Agenda

## Pediatric Cardiac Technical Advisory Panel (PCTAP)



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| <b>Meeting Date:</b> Friday, September 20, 2019  |
| <b>Time:</b> 9:00 A.M – 4:00 P.M EST   |
| <b>Location:</b> AHCA Headquarters, 2727 Mahan Drive, Tallahassee, FL, Conference A  |
| <b>Webinar Link:</b> <a href="https://attendee.gotowebinar.com/register/207213262553188099">https://attendee.gotowebinar.com/register/207213262553188099</a> |
| <b>Dial – In Number:</b> 1-877-309-2074  |
| <b>Public Access Code:</b> 236-826-493   |

| TIME  | ITEM  | PRESENTER          |
|---|---|--------------------|
| <b>Call to Order, Welcome and Roll Call</b> |   |                    |
| 9:00–9:10 AM                                | Call to Order, Welcome and Roll Call  | Dr. Nykanen, Chair |
| <b>Review &amp; Approve Minutes</b>         |   |                    |
| 9:10-9:20 AM                                | March 28, 2019 Full Panel Minutes & July 11, 2019 Public Reporting Subcommittee Minutes | Dr. Nykanen, Chair |
| <b>Previous Action Items</b>                |   |                    |
| 9:20-9:30 AM                                | Review and Status   | Dr. Nykanen, Chair |
| <b>PCTAP Rule Update &amp; Discussion</b>   |   |                    |
| 9:30-10:00 AM                               | Agency Update on PCTAP Rule   | AHCA Staff         |
| 10:00-11:00 AM                              | PCTAP Rule Discussion   | Dr. Nykanen, Chair |
| <b>PCTAP Administration and Operations</b>  |   |                    |
| 11:00-11:05 AM                              | PCTAP Member Term Limit Discussion  | Dr. Nykanen, Chair |
| 11:05-11:10 AM                              | PCTAP At-Large Alternates Discussion  |                    |
| 11:10-11:25 AM                              | PCTAP Budgetary Appropriations  |                    |
| <b>Voting Membership Status</b>             |   |                    |
| 11:25-11:35 AM                              | Voting Membership Status  | Dr. Nykanen, Chair |
| <b>Site Visits</b>                          |   |                    |
| 11:35-12:30 PM                              | Site Visit Discussion   | Dr. Nykanen, Chair |

# Agenda

## Pediatric Cardiac Technical Advisory Panel (PCTAP)



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|---|---|------------------------|
| <b>Lunch</b>  |   |                        |
| 12:30-1:00 PM   | Lunch Break   |                        |
| <b>STS &amp; Public Reporting Subcommittee Update</b> |   |                        |
| 1:00-1:30 PM  | Public Reporting Subcommittee STS Update  | Dr. Scholl, Vice-Chair |
| 1:30-3:00 PM  | Full Panel Vote on subcommittee recommendations: <ul style="list-style-type: none"><li>• Approval of the subcommittee recommended STS tables</li><li>• Hospitals required to submit full STS report to AHCA every six months</li><li>• AHCA provide an easily accessible link to the reports on the FloridaHealthFinder.gov website</li></ul> | Dr. Scholl, Vice-Chair |
| 3:00-3:20 PM  | Proposed Real Time Outcomes Subcommittee  | Dr. Scholl, Vice-Chair |
| <b>Public Comment</b>                                 |   |                        |
| 3:20-3:35 PM  | Public Comment  |                        |
| <b>Meeting Summary, Next Steps &amp; Adjourn</b>      |   |                        |
| 3:35-3:45 PM  | Action Items  | Dr. Nykanen, Chair     |
| 3:45-4:00 PM  | Future Meeting Schedule   |                        |
| 4:00 PM   | Adjourn   |                        |

*\*Public commentary may be submitted by email to: [PCTAP@ahca.myflorida.com](mailto:PCTAP@ahca.myflorida.com)*

# Review and Approve Minutes

March 28, 2019 PCTAP Full Panel Meeting

July 11, 2019 Public Reporting and Transparency  
Subcommittee Meeting

## **DRAFT MINUTES**

Agency for Health Care Administration (AHCA)

Pediatric Cardiac Technical Advisory Panel (PCTAP or Advisory Panel)

Date: March 28, 2019

Time: 5:30-6:30 P.M. EST

Location: Online Webinar

**Members Present:** Alfred Asante-Korang, MD; Eric Eason, MD; Jose Etedgui, MD; Joel Hardin, MD; Jorge McCormack, MD; David Nykanen, MD; Jeremy Ringewald, MD; Biagio Pietra, MD; Frank Pigula, MD; Frank Scholl, MD; Peter Wearden, MD

**Staff Present:** Molly McKinstry, Deputy Secretary; Jack Plagge, Manager Outpatient Services Unit; Nikole Helvey, AHCA Bureau Chief, Florida Center for Health Information and Transparency (Florida Center); Patricia Vidal, Data Dissemination and Communication Manager; Jess Hand and Adrienne Henderson, Florida Center.

**Interested Parties:** Bill Blanchard, MD; Jeffrey Jacobs, MD; Jennifer Lloyd; Gerold Schiebler, MD; Joni Silvestri.

**Call to Order, Welcome and Roll Call:** Dr. David Nykanen welcomed the members, called roll and called the meeting to order.

**Review and Approve February 07, 2019 PCTAP Meeting Minutes:** Dr. Gerold Schiebler submitted a list of edits and corrections to the minutes. Dr. Nykanen motioned to approve the minutes including Dr. Schiebler's edits. The motion was seconded and the minutes approved.

### **Review Status of Action Items:**

Dr. Blanchard Legislative Update: Dr. Bill Blanchard provided an update on the status of HB 1207. He noted that the bill was heard in the House Health Market Reform Subcommittee on Tuesday, March 26 2019. Dr. Blanchard noted that Representative Mike Beltran submitted a strike-all amendment cutting newly drafted PCTAP language from the bill and re-introducing a sunset clause for the PCTAP on September 30, 2019.

Dr. Frank Scholl asked the nature of the resistance to keeping all proposed language in the bill. Dr. Blanchard explained that the strike-all and the sunset clause may reflect the Health and Human Services subcommittee's preference that the Panel make standards and recommendations which are implemented by Agency staff during inspections (as opposed to members of the Panel during site visits).

Dr. Eason asked who handles complaints and probations for the Florida Board of Medicine. Dr. Blanchard noted the Florida Board of Medicine handles these matters. Members discussed the various nuances of the legislation and legislative process. Dr. Scholl asked how likely it is that the Panel will sunset in 2019. Dr. Blanchard responded that unless the Senate takes up the

same version of the bill currently in the House the 2019 sunset clause will not pass this year. Dr. Schiebler added that the Senate is unlikely to take up the bill. However, he noted there is concern the House version of the bill may be passed as an addendum near the close of session.

Dr. Scholl asked if, since site visits are the source of contention in the bill, there might be a way to separate the issue in order to preserve the Panel. Dr. Nykanen noted that without legislative authority there is no enforcement mechanism for site visits.

Dr. Schiebler asked what the Agency position is on the House and Senate bills and requested a meeting with the Secretary and a representative of the Panel. Dr. Nykanen added that he would like to understand how the Panel costs included in the fiscal note were calculated. Dr. Schiebler responded that the amount of the fiscal note has come down from 1.2 million to less than 300k. Deputy Secretary Molly McKinstry responded that the fiscal note in the original draft of the legislation was based upon the cost of out-of-state experts making site visits at Florida's ten pediatric cardiac surgery programs. After further conversations with Senator Gayle Harrell and Agency staff, those costs were reduced. Deputy Secretary McKinstry noted that because PCTAP is a public panel, two members cannot meet outside of a publicly noticed meeting to discuss matters that may come before the Panel (such as during site visits). Additionally, Ms. McKinstry noted that any details of the site visits share in public meetings may be problematic if patient confidentiality is compromised.

Status of rule: Deputy Secretary McKinstry stated that the Agency is including the recommendations of the Panel into rule reflecting current Agency legislative authority, for evaluation by the Agency legal department. Dr. Schiebler asked when the Agency will be able to share a draft of the rule. Deputy McKinstry responded that she could not provide a definite timeline but will share any information with the Panel as it becomes available. Dr. Scholl asked whether the Agency has the authority to designate a site visit team without legislative authority. Ms. McKinstry responded that various access standards may be an issue. Agency access to facilities may restrict whether non-Agency staff may enter such facilities. The Agency does not contract out the regulatory duties of the Agency to third parties (i.e. for inspections). Ms. McKinstry and Dr. Schiebler discussed the possibility of voluntary hospital involvement in site visits with non-governmental associations. Dr. Schiebler asked whether a meeting with Secretary Mayhew and Dr. Nykanen could be arranged and Ms. McKinstry agreed to arrange such a meeting.

**STS Data Components Mock Up:** Members discussed the Excel document submitted by Agency staff regarding the different types of available pediatric cardiac data. Dr. Nykanen proposed a working group to address issues of transparency. Dr. Frank Pigula noted that STS publicly reported data already includes measures such as mortality rates. Dr. Scholl added that in the short term, the existing STS Top-Ten Pediatric Cardiac Surgery Public Report (including mortality and length of stay) could be used (noting it is not risk-adjusted data). In the long term, Dr. Scholl suggested moving away from procedural databases and moving to diagnosis based reporting. Dr. Nykanen suggested that Dr. Scholl chair the subcommittee and requested that members interested in participating contact the Agency via the [pctap@ahca.myflorida.com](mailto:pctap@ahca.myflorida.com)

inbox. Ms. Helvey noted that this subcommittee could be a resurrection of the existing PCTAP Public Reporting & Transparency Subcommittee. Dr. Schiebler noted that the statutory mandate for the Agency to contract with STS for public reporting data be a priority for the subcommittee.

**Discussion of Neonatal Pulse Oximetry Screening Test Data:** Dr. Schiebler stated that pulse oximetry screening has been mandated since 2014. However, the reported data elements were limited and insufficient. Dr. Schiebler suggested he draft a letter to be sent by Agency staff to Paul Patel outlining what data is important for the screening test. Dr. Nykanen agreed to this plan.

**Public Comment:** There were no public comments.

**Member Summary:**

- Panel members will contact the Agency at [pctap@ahca.myflorida.com](mailto:pctap@ahca.myflorida.com) if they are interested in participating in the Public Reporting & Transparency Subcommittee.
- Dr. Nykanen requested that Dr. Scholl Chair the Subcommittee.
- Dr. Schiebler will draft a letter regarding Pulse Oximetry for circulation to Paul Patel.

**Agency Next Steps:**

- Agency staff will coordinate a meeting with Secretary Mayhew, Dr. Nykanen and Dr. Blanchard.
- Agency staff will coordinate with respondents interested in participating in the Public Reporting Subcommittee.
- Agency staff will circulate a doodle poll to plan the next meeting.

**Adjournment:** Dr. Nykanen adjourned the meeting at 6:40 PM.



## **DRAFT MINUTES**

Agency for Health Care Administration (AHCA)

Pediatric Cardiac Technical Advisory Panel (PCTAP or Advisory Panel) **PCTAP Public Reporting & Transparency Subcommittee**

Date: July 11, 2019

Time: 5:30 pm – 6:30 pm

Location: Webinar

**PCTAP Public Reporting & Transparency Subcommittee Members Present:** Mark Bleiweis, MD; Eric Eason, MD; Vice-Chair Frank Scholl, MD;

**PCTAP Members Present:** Alfred Asante-Korang, MD; Kak Chen Chan, MD; Jamie Decker, MD; Joel Hardin, MD; Biagio Pietra, MD;

**Staff Present:** Nikole Helvey, Bureau Chief, Florida Center; Patricia Vidal, Data Dissemination and Communication Manager, Florida Center; Jess Hand, Florida Center.

**Interested Parties Present:** Bill Blanchard, MD; Steve Dunn; Bob Hannan, MD; Gerold Schiebler, MD; Joni Silvestri; Rosie Tuzik

**Call to Order, Welcome and Roll Call:** Dr. Frank Scholl called roll, welcomed the members and called the meeting to order.

**Review and Approve Minutes:** Dr. Scholl reviewed the action items from the May 16, 2019 Meeting Minutes. Dr. Gerold Schiebler submitted edits to the minutes. Dr. Bill Blanchard motioned to accept the minutes with the inclusion of Dr. Schiebler's edits. Members seconded the motion.

Per the previous action items, Dr. Schiebler noted that he contacted Senator Gayle Harrell, and she supported his suggestion that all present members serve four-year terms beginning July 1, 2019. Going forward, he suggested that half the members serve two years and half serve four years so there is continuity. Dr. Scholl requested that Agency staff add a discussion of term limits as described by Dr. Schiebler to the next full Panel agenda. Additionally, Dr. Schiebler requested, and Dr. Scholl agreed, to add a discussion of Agency appointments of at large alternates to the next Full Panel meeting agenda.

Dr. Eric Eason requested a discussion of the Scalability of Real-Time Outcome Data as per the action items from the May 16, 2019 minutes. Dr. Scholl agreed to such a discussion. Dr. Scholl noted that while real-time outcomes remains a goal of the Panel, producing a public report in a timely fashion is the immediate priority. Dr. Eason asked whether an ad hoc group could be formed to evaluate the disparities in EHRs, which are barriers to obtaining uniform data. Dr. Bob Hannan noted that EHRs do not impede real time outcomes, but are added to real-time outcomes as an additional feature. Dr. Hannan stated that real time outcome data is drawn directly from CardioAccess, and as such, anyone who uses CardioAccess can have real time

outcomes instantaneously. Members discussed the best approach to achieving uniformity in data reporting. Dr. Eason asked Ms. Nikole Helvey whether conversations with non-PCTAP members fall under Sunshine law. Ms. Helvey responded that Sunshine law only applies to discussions between members of the Panel. Dr. Eason suggested that he speak with Dr. Hannan and another outside professional in order to form an ad-hoc group. Dr. Scholl urged anyone interested in participating in an ad-hoc Real Time Outcome Subcommittee (of the Public Reporting and Transparency Subcommittee) to contact Jess Hand through the [pctap@ahca.myflorida.com](mailto:pctap@ahca.myflorida.com) inbox. Dr. Scholl requested that this announcement be added to the agenda for the next full panel meeting.

Dr. Hannan discussed the accuracy of real-time outcomes, as well as the capacity to cheat on real-time outcomes, and stated his willingness to assist Agency staff in discerning the accuracy of such data.

**STS Data Discussion:** Dr. Scholl reviewed the updated STS Data Excel Document tabs circulated with the meeting materials. Dr. Hannan discussed the accuracy of data quality across different fields of STS data. Dr. Scholl reviewed Tab 2 of the STS Excel document showing data already publicly reported by STS for pediatric cardiac surgery programs in Florida. Dr. Scholl noted that Tab 3 shows aggregate and participant case specific mortality and post op length of stay four-year data (for ten major operations) for the pediatric cardiac surgery programs. Dr. Scholl noted the data in Tab 3 can be obtained from the STS in a short time period. Alternately, he suggested that STS reports could be sent to ACHA for compilation into tables. Dr. Scholl proposed moving ahead with an STS request for the data elements on Tabs 1, 2 and 3 while continuing (with the subcommittee) to consider how to obtain more granular data, including real time outcomes. Dr. Scholl emphasized the importance of focusing on the data fields already reported by pediatric cardiac surgery programs in order to have uniform data elements. Dr. Hannan suggested that programs submit their full STS report to AHCA for review. Dr. Scholl requested that the subcommittee recommend a vote at the next full panel on the following: the submission of full STS reports to AHCA, the availability on the AHCA website of the data on the STS Excel Tables and the full STS reports of each program. Dr. Hannan motioned for such a vote and Dr. Eason seconded the motion. There were no votes opposed.

Dr. Blanchard and members discussed the best way to display the STS data reports on the AHCA website. Dr. Hannan stated that the full reports should be available on the AHCA website, and reiterated his willingness to help AHCA staff understand the STS reports. Ms. Helvey asked about the format of the STS reports, and Dr. Scholl responded that the reports are in PDF format. Ms. Helvey asked if the data could be provided in an extractable format (such as Excel). Dr. Hannan responded that only the PDF format is available, and offered to send his hospital's PDF report to AHCA.

**Public Comment:** Dr. Schiebler stated that there is legislative concern regarding the slow pace of the PCTAP, and he urged a meeting of the full panel be a top priority. He stated the importance of a recurring appropriation for PCTAP in the AHCA budget, and the importance of finalizing the STS letter. Dr. Schiebler also noted that the PCTAP statute states that ACHA will

request from CMS information regarding neonatal pulse oximetry screenings. Dr. Schiebler offered to ask Dr. Mark Hudak to supply this information to AHCA staff in order to expedite the request. Dr. Schiebler also noted the rule might need a heart and heart-lung transplant section to be developed. Dr. Scholl affirmed that Dr. Schiebler should reach out to Dr. Mark Hudak, and agreed the next full panel agenda should include discussion of recurring budgetary appropriations and appointment of at large alternates.

Dr. Blanchard asked Ms. Helvey about the AHCA budget submission deadline, and she responded that it is usually due in August. Dr. Blanchard stated his concern that AHCA's budget include a request for recurring funds for PCTAP, and funding for full time staff dedicated to PCTAP. Dr. Blanchard also stated his interest in a face-to-face meeting with Secretary Mayhew and Dr. David Nykanen.

Dr. Scholl discussed the logistics of the STS data request and the submission of STS reports to AHCA. He noted the latter might necessitate dedicated funding for additional Agency staff to process the data reports. Dr. Hannan stated that he owns the intellectual property rights to Nicklaus and Miami Children's real time outcomes, and the Agency is welcome to freely utilize the program.

Dr. Asante-Korang stated that, regarding the previous meeting discussion concerning the status of Johns Hopkins All Children's heart program, standards and procedures should be established by the Panel to govern programs that may shift from member to non-member status. He noted that other programs in Florida have experienced challenges, and criteria for dealing with these situations should be addressed. Dr. Scholl recommended this topic be added to the agenda of the next meeting of the full panel.

Dr. Schiebler suggested the next full panel meeting be two hours long in order to accomplish all that is on the agenda. Dr. Scholl noted there might not be time to schedule a face-to-face meeting in time for the next meeting. Dr. Scholl requested, and members agreed, that PCTAP meetings should begin in time to be complete by five o'clock in the evening.

**Subcommittee Meeting Summary Action Items:**

- Dr. Eason will speak with Dr. Hannan and another outside professional in order to form an ad-hoc real-time outcomes group
- Anyone interested in participating in an ad-hoc Real Time Outcome Subcommittee (of the Public Reporting and Transparency Subcommittee) should contact Jess Hand through the [pctap@ahca.myflorida.com](mailto:pctap@ahca.myflorida.com) inbox
- Dr. Hannan will submit his hospital PDF report to AHCA for informational purposes.
- Dr. Schiebler will contact Dr. Mark Hudak regarding the provision of CMS neonatal pulse oximetry screening results to AHCA

**Agency Action Items:**

- The following items were recommended for the next Full Panel meeting agenda:
  - A discussion of term limits as described by Dr. Schiebler
  - Agency appointment of at large alternates
  - An announcement of a proposed ad hoc real-time outcomes subcommittee
  - A vote of the full panel on the following subcommittee recommendations:
    - Approval of the subcommittee recommended STS tables
    - Hospitals required to submit full STS report to AHCA every six months
    - AHCA provide an easily accessible link to the reports on the FloridaHealthFinder.gov website
  - Recurring budgetary appropriations for the PCTAP
  - Development of standards and procedures for programs no longer qualified to serve as voting members of the Panel;
- The following changes were requested for all future scheduled meetings of the subcommittees and the full panel:
  - The next Full Panel meeting run for at least two hours
  - All meetings going forward finish by five o'clock

**Adjourn:** Dr. Scholl adjourned the meeting at 6:35 PM.

# PCTAP DRAFT RULE



RON DESANTIS  
GOVERNOR

MARY C. MAYHEW  
SECRETARY

September 16, 2019

Pediatric Cardiology Technical Advisory Panel Members:

Re: Draft Pediatric Cardiac Services Rule 59A-3.248, F.A.C.

Please find attached a draft of the hospital licensure rules related to pediatric cardiac services based on the recommendations from the Panel. The attached draft rule and crosswalk are included for your review and discussion during the meeting Friday, September 20<sup>th</sup>. Administrative rules follow a format and layout different than the format of the Panel's recommendations, therefore the order and exact wording may look different in some areas; the crosswalk is designed to assist in this translation. Areas of statutory authority for rules include "quality of care, personnel, physical plant, equipment, emergency transportation, data reporting, and appropriate operating hours and timeframes for mobilization for emergency procedures", and former Certificate of Need rules and designations. The Agency's draft is intended to include all Panel recommendations with the following exceptions.

- Several of the Panel's rule recommendations are already addressed in the general licensing requirements for all hospitals, therefore are not repeated in the pediatric standards, including quality assurance, infection control, medical records, administrative actions, and the Florida Building Code.
- Specific accreditation authorities are not listed by name as current law defines acceptable accrediting bodies.
- Professional board certification is included for specific practitioners, excluding those practitioners ancillary to pediatric cardiac services – radiologists and other practitioners that may be consulted.
- The rule authority is limited to the development of standards for hospitals seeking licensure, therefore does not address the function of the Panel, the Agency, or Children's Medical Services.
- The Department of Health licensing boards address practitioner-specific services and functions pertaining to the practice of medicine, therefore are excluded from this hospital licensure rule.
- Volume requirements are included as recommended, with the addition of an annual volume of 100 pediatric cardiac surgical procedures.

Agency staff will join you Friday to provide additional information and assist with questions and discussion. The Agency would also appreciate input regarding potential ICD-10 codes to consider for the cardiac procedure requirements. Thank you for your commitment to this important program.

Sincerely,

Molly McKinstry  
Deputy Secretary for Health Quality Assurance



**59A-3.248 Pediatric Cardiac Programs**

(1) Licensure. A hospital authorized to provide pediatric cardiac catheterization and angioplasty, and pediatric open heart surgery prior to July 1, 2019, will be licensed to provide pediatric cardiac services, provided the requirements of this rule continue to be met.

(a) Initial. A hospital may be authorized to provide pediatric cardiac services by submission of a hospital licensure application as specified in rule 59A-3.066(2), F.A.C. By submitting a licensure application, the hospital's chief executive officer or designee attests that prior to receiving the license:

1. The hospital's operating rooms and cardiac catheterization laboratories to be used for pediatric cardiac services meet Florida Building Code as evidenced by approval from the Agency's Office of Plans and Construction pursuant to rule 59A-3.080, F.A.C; and

2. The hospital meets the requirements of this rule.

(b) Renewal. The hospital's chief executive officer or designee must attest as part of the biennial licensure renewal application as specified in rule 59A-3.066(2), F.A.C., that the requirements of this rule, including minimum volume requirements, continue to be met.

**(2) Quality of Care.**

(a) A hospital providing pediatric cardiac services must:

1. Ensure all staff participating as members of a catheterization team or cardiovascular surgery team, including physicians, nurses, and technical staff, participate in a 24 hours per day, 7 days per week call schedule capable of rapid mobilization of the team(s) within 30 minutes for emergency catheterization procedures and capable of cardiovascular surgery within 2 hours;

2. Develop a quality assurance and improvement program, including a risk adjustment surgical procedure protocol following the guidelines established by the Society of Thoracic Surgeons, to monitor processes and outcomes, analyze data, and identify system improvements for each component of pediatric cardiac services, and integrate the program into the hospital wide quality improvement program as required by rule 59A-3.271, F.A.C.;

3. Have written policies and procedures for the transition of care from pediatric to adult congenital

services, including providing information on recommendations on endocarditis prophylaxis, anticoagulation therapy, diet, weight control, contraception, pregnancy risk with referral to maternal-fetal medicine physicians as appropriate, and exercise limitations;

4. Provide female adult congenital patients pre-pregnancy counseling, and genetic counseling and fetal echocardiography studies, as appropriate; and

5. Participate in national registries as specified in subsection (7) of this rule.

(b) As a condition for biennial licensure renewal, a hospital providing pediatric cardiac services must meet or exceed minimum volume requirements for pediatric and adult congenital procedures. Hospitals authorized to perform adult cardiovascular services may include patients up to 21 years of age for the following:

1. At least 100 cardiac catheterization procedures annually, averaged over a 2-year period, of which 50 procedures must be interventional, excluding myocardial biopsies;

2. At least 30 electrophysiology procedures annually, averaged over a 2-year period, of which 18 are ablations;

3. At least 50 pediatric stress tests annually, averaged over a 2-year period; and

4. At least 100 pediatric cardiac surgical procedures, averaged over a 2-year period.

(c) Each hospital must have the capability to provide:

1. Immediate endocardiac catheter pacemaking in cases of cardiac arrest;

2. Pressure recording for monitoring and evaluation of valvular disease or heart failure;

3. Repair or replacement of heart valves;

4. Repair of congenital heart defects;

5. Cardiovascular revascularization;

6. Repair or reconstruction of intrathoracic vessels, and

7. Treatment of cardiac trauma.

(d) Ambulatory care clinics serving pediatric and adult congenital patients must be located on the hospital premises and must:



1. Meet the requirements for ambulatory care services as described in rule 59A-3.244(1), F.A.C.:
2. Provide arrhythmia (holter) monitoring, implanted electronic device monitoring, exercise and metabolic stress testing, imaging, and pulmonary function testing to meet the needs of pediatric and adult congenital patients;
3. Have a board certified pediatric cardiologist immediately available whenever a stress test is being performed;
4. Have a licensed APRN or PA to coordinate care for adult congenital patients;
5. Conduct stress testing with at least one staff who is Pediatric Advanced Life Support or Advanced Cardiac Life Support certified in the room at all times with the patient during the test; and
6. Have at least one Basic Life Support certified cardiology technologist or respiratory care practitioner immediately available whenever a stress test is being performed.

(e) Hospitals providing birthing services must have a neonatal screening program using pulse oximetry to detect critical congenital heart disease.

(f) Each hospital must have policies and procedures for accommodating a parent, relative or guardian of a pediatric patient to stay overnight with the patient.

**(3) Personnel.**

(a) Medical Director. Pediatric cardiac services must be under the direction of one or more physician members of the hospital's organized medical staff.

1. The pediatric cardiac catheterization laboratory and ambulatory care cardiac clinic must be under the direction of a physician board certified or eligible by the Sub-Board of Pediatric Cardiology of the American Board of Pediatrics.

2. Electrophysiology services must be under the direction of a pediatric electrophysiologist board certified by the Sub-Board of Pediatric Cardiology of the American Board of Pediatrics and by the International Board of Heart Rhythm Examiners.

3. Adult congenital services must be under the direction of a physician board certified by the Adult Congenital Heart Disease sub-board of the American Board of Internal Medicine.

(b). Medical Staff. The medical director(s) must ensure trained and qualified physician members of the organized medical staff are available at all times to meet the needs of the patients.

1. The physician in charge of a cardiac catheterization procedure must be board certified or eligible by the Sub-Board of Pediatric Cardiology of the American Board of Pediatrics.

2. The physician in charge of an electrophysiology procedure must be a pediatric electrophysiologist board certified by the Sub-Board of Pediatric Cardiology of the American Board of Pediatrics.

3. At least one pediatric cardiovascular surgeon must be board certified or eligible by the American Board of Thoracic Surgery, specialty certification in congenital cardiac surgery.

4. Board eligible physicians must be board certified within 5 years of becoming eligible.

5. A physician who is not board certified, or who is not eligible due to foreign training or similar circumstance may provide pediatric cardiac services upon documentation of education, training, or alternative certification acceptable to the medical director and hospital's governing board or designated credentialing committee.

6. A cardiovascular surgery team, including an anesthesiologist and thoracic surgeon must be immediately available during interventional and electrophysiology cardiac catheterizations.

7. The organized medical staff membership must contain a complement of physicians with training or experience with pediatric cardiac patients to be available for consultation as needed, including:

a. Pediatric cardiologists;

b. Pediatric sub-specialists with expertise in hematology, nephrology, neurology, infectious disease, critical care, genetics, gastroenterology and pulmonology;

c. Radiologists;

d. Anesthesiologists; and

e. Pathologists.

8. All physicians caring for adult congenital patients must be Advanced Cardiac Life Support certified.

(c) Nursing Staff. Each hospital unit in which pediatric cardiac services are provided must have a

number of registered nurses on duty at all times to ensure immediate availability to any patient when needed.

1. The cardiac catheterization, electrophysiology and cardiovascular surgical services must have registred nurses with special training in cardiovascular techniques in the care of pediatric and adult congenital heart patients and have skills in the pre and post procedure evaluations and provision of instruction to the patient and their family members.

2. Registred nurses providing care in the cardiac catheterization and electrophysiology laboratories must be trained in cardiovascular implantable electronic device management and be certified in Basic Life Support and Pediatric Advanced Life Support.

(d) Additional Staff. Each hospital providing pediatric cardiac services must have a number of perfusionists, cardiovascular technologists, respiratory therapists, radiologic technicians, clinical laboratory personnel, and social workers available at all times to meet the needs of any patient.

1. Cardiovascular technologists must be credentialed as a Registered Cardiovascular Invasive Specialist or Registered Cardiac Electrophysiology Specialist or must complete a hospital-based education and training program acceptable to the medical director.

2. Cardiovascular technologists serving as the cardiovascular recorder must have no other duties during a procedure.

**(4) Physical Plant Requirements.**

The Florida Building Code contains the physical plant requirements for cardiac catheterization laboratories and operating rooms for cardiac surgery operated by a licensed hospital.

**(5) Equipment.**

(a) Each hospital must have policies and procedures for the selection, procurement, use, and maintenance of age and size appropriate equipment used for pediatric cardiac services, and must document preventive and daily maintenance activities following manufacturer's directions.

(b) Each hospital unit in which pediatric cardiac services are provided must have:

1. A protocol for handling emergency conditions related to the breakdown of essential equipment,

including the immediate availability of personnel trained in equipment repair and maintenance.

2. A crash cart containing the necessary medication and age and size appropriate equipment for ventilatory support. A listing of all crash cart contents must be readily available. At the beginning of each shift, the crash cart must be checked for intact lock; the defibrillator and corresponding equipment must be checked for function and operational capacity. A log must be maintained indicating review.

3. A quality improvement program for radiographic imaging systems must include measures of image quality, dynamic range and modulation transfer function.

(c) Each hospital must have age and size appropriate equipment available for patients receiving pediatric cardiac services, including:

1. Multi-dimensional imaging equipment for magnetic resonance imaging/magnetic resonance angiography (MRI/MRA), computed tomography, echocardiography, and scintigraphy;

2. A special procedure x-ray room with diagnostic x-ray examination table;

3. X-ray equipment with the capability in cineangiocardiology, or equipment with similar capabilities;

4. An image intensifier;

5. An automatic injector;

6. An electrocardiograph;

7. A multi-channel electrophysiology recording system;

8. A cardiopulmonary monitoring system;

9. Emergency equipment, including temporary pacemaker units with catheters, ventilatory assistance devices, and a DC defibrillator;

10. Biplane angiography, with framing rates of 30-60 fps and injection rates of up to 40 mL/s; and

11. Extra Corporeal Membrane Oxygenation machine.

(d) Cardiac MRI scanners must:

1. Be accredited by a national accrediting organization that is approved by the Centers for Medicare and Medicaid Services for magnetic resonance imaging and advanced diagnostic imaging services;

2. Have field strength of > 1.5 Tesla and equipped with localized multichannel radiofrequency surface coil and ECG gating capable of prospective triggering, retrospective gating, and triggered retrogating;

3. Have an MRI-compatible power injector for performing myocardial perfusion MR imaging or any MR angiographic methods.

4. Be capable of fast 3-D gradient-echo imaging, steady-state imaging with free precession, phase-contrast flow quantification, fast multi-slice myocardial perfusion imaging, and late contrast-enhanced myocardial imaging. Parallel imaging and half-Fourier capabilities are desirable to permit shortened breath-hold requirements.

(e) In addition to the requirements in rule 59A-3.270, F.A.C., each hospital must maintain a complete database of patients with devices to include all device models and ID numbers, and Lead models and ID numbers.

**(6) Emergency Transportation.**

Each hospital must have policies and procedures to effectuate the rapid transport of pediatric and adult congenital patients

**(7) Data Reporting.**

(a) Each hospital must submit quarterly utilization data to the Agency as required by rules 59C-1.032 and 59C-1.033, F.A.C.

(b) Each hospital must submit data to the Society of Thoracic Surgeons Congenital Heart Surgery Database, including the Anesthesia Model in the manner set forth herein. Each hospital must be deemed to have certified that the data submitted for each time period is accurate, complete and verifiable. Data must be submitted in accordance with the timetables and procedures established by the Society of Thoracic Surgeons National Database, and:

1. All data must be reported using the specific data elements, definitions and transmission format as set forth by the Society of Thoracic Surgeons;

2. Maintain participation in the Society of Thoracic Surgeons National Database;

3. Release the data reported by the Society of Thoracic Surgeons National Database to the Agency

upon request:

4. Publish cardiac surgical outcomes to the public on the Society of Thoracic Surgeons website <https://publicreporting.sts.org> and maintain no less than a 2-star rating for congenital heart surgery as determined by the Society of Thoracic Surgeons;

5. Use the Society of Thoracic Surgeons National Database and use software approved by the Society of Thoracic Surgeons for data reporting;

6. Ensure that software formats are established and maintained in a manner that meets Society of Thoracic Surgeons transmission specifications and encryption requirements. If necessary, each hospital must contract with a vendor approved by the Society of Thoracic Surgeons National Database for software and hardware required for data collection and reporting;

7. Implement procedures to transmit data via a secure website or other means necessary to protect patient privacy. To the extent required by the Society of Thoracic Surgeons National Database;

8. Ensure that all appropriate data is submitted on every patient who receives medical care and is eligible for inclusion in the Society of Thoracic Surgeons National Database;

9. Maintain an updated and current institutional profile with the Society of Thoracic Surgeons National Database;

10. Ensure that data collection and reporting will only be performed by trained, competent staff and that such staff must adhere to Society of Thoracic Surgeons National Database standards;

11. Submit corrections to any data submitted to the Society of Thoracic Surgeons National Database as discovered by the hospital or by the Society of Thoracic Surgeons National Database. Such corrections must be submitted within thirty days of discovery of the need for a correction or within such other time frame as set forth by the Society of Thoracic Surgeons National Database. Data submitted must be at a level that the Society of Thoracic Surgeons National Database will include the data in national benchmark reporting;

12. Designate a Society of Thoracic Surgeons National Database site manager that will serve as a primary contact between the hospital and the Society of Thoracic Surgeons National Database with regard

to data reporting; and

13. The following quality assurance data must be compiled annually from their Society of Thoracic Surgeons Congenital Heart Surgery Database Report and available for Agency review upon request:

a. Number of patients/operations submitted and an analysis of operative mortality, and complexity information, by year;

b. Number of patient/operations in analysis, operative mortality, and complexity information, by age group;

c. Primary Procedure Operative Mortality;

d. Society of Thoracic Surgeons - European Association of Cardio-Thoracic Surgery Mortality Category Operative Mortality, by year;

e. Society of Thoracic Surgeons - European Association of Cardio-Thoracic Surgery Mortality Category Operative Mortality, by age group.

(c). Report to the American College of Cardiology IMPACT Data Registry in accordance with the timetables and procedures established by the Registry, and:

1. Submit reports using the specific data elements, definitions, timetables, transmission format, required software, and procedures established and in accordance with the Registry criteria;

2. Ensure that software formats are established and maintained in a manner that meets transmission specifications and encryption requirements necessary to protect patient privacy;

3. Maintain an updated and current institutional profile with the Registry; and

4. Maintain participation in the Registry.

(d) Each hospital must register with the Adult Congenital Heart Association and submit data as required by the Adult Congenital Heart Association in order to maintain a current registration.

(e) Each hospital must register with the Adult Congenital & Pediatric Cardiology Quality Network of the American College of Cardiology and participate in 2 or more quality metrics defined by the American College of Cardiology. Data submitted for each quality metric must be in a format provided by the Adult Congenital & Pediatric Cardiology Quality Network.

**(8) Enforcement.**

(a) Enforcement of these rules must follow procedures established in rule 59A-3.253, F.A.C.

(b) Unless in the view of the Agency there is a threat to the health, safety or welfare of patients, hospitals with pediatric cardiac services programs that fail to meet provisions of this rule must be given 15 days to develop a plan of correction that must be acceptable to the Agency.

(c) Failure of the hospital with a pediatric cardiac services program to make improvements specified in the plan of correction must result in the suspension or revocation of the program license. The hospital may offer evidence of mitigation and such evidence could result in a lesser sanction.

Rulemaking Authority 395.1055, 408.036, 408.0361 FS. Law Implemented 395.1055, 408.0361 FS. History—New \_\_\_\_\_.

DRAFT



# PCTAP RULE CROSSWALK

## Crosswalk PCTAP Recommendations to Proposed Rule 59A-3.248 2 (002).xlsx

| Pediatric and Congenital Cardiovascular Center Recommended Standards |  | Proposed Rule 59A-3.248  |
|--|--|--|
| 1  | Agency for Health Care Administration (AHCA) Pediatric and Congenital Cardiovascular Centers (PCCC) undergo a quality assurance process that ensures such PCCC meet established minimum standards deemed necessary for the provision of quality cardiac services to children with special health care needs.   | NOTE: refer to statutory authority s. 395.1055, F.S.   |
| 2  | AHCA supports the creation of policies to foster growth of Centers of Excellence.  | NOTE: not rule appropriate   |
| 3  | The Pediatric Cardiac Technical Advisory Panel (PCTAP) shall be consulted for Certificate of Need applications for new programs under the advisement of the Secretary of AHCA.   | NOTE: refer to statutory authority s. 395.1055, F.S.   |
| 4  | Site visits should occur at least once every three years for each pediatric cardiovascular centers in Florida. The site visit shall be conducted by a team that consists of multidisciplinary professionals licensed to practice within the state. At a minimum the survey team shall include one pediatric cardiac surgeon, one pediatric interventional cardiologist, one pediatric electrophysiologist and one pediatric non-invasive cardiologist. The multidisciplinary team shall be proposed by the Chair and/or vice chair of the PCTAP. Following a survey the written findings shall be reviewed by the PCTAP committee and recommendations forwarded to the AHCA Secretary for consideration. | NOTE: refer to statutory authority s. 395.1055, F.S.   |
| 5  | An AHCA PCCC must provide care for all PCCC enrolled individuals with congenital and acquired heart disease who require such expertise   | NOTE: Not rule appropriate. Refer to emergency services and care.  |
| 6  | PCCC in Florida shall maintain a 2 or 3- star rating or equivalent as determined by The Society of Thoracic Surgeons (STS) database. Programs who fail to meet this standard will be reviewed by the PCTAP committee and recommendations for corrective action will be made to the Agency.   | <b>(7)(b)4</b> Publish cardiac surgical outcomes to the public on the Society of Thoracic Surgeons website <a href="https://public.reporting.sts.org">https://public.reporting.sts.org</a> and maintain no less than a 2-star rating for congenital heart surgery as determined by the Society of Thoracic Surgeons; |

## Crosswalk PCTAP Recommendations to Proposed Rule 59A-3.248 2 (002).xlsx

| Pediatric and Congenital Cardiovascular Center Recommended Standards  | Proposed Rule 59A-3.248   |
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| <p>7 Minimum Cardiac Catheterization Laboratory volume standards shall be 100 cases of which 50 cases are interventional (except for myocardial biopsies); and an electrophysiology volume standard of 30 cases of which 18 are ablations. For volume standard purposes, "pediatric cardiac" cases include children with congenital and acquired heart disease under age 21 years and adults 21 years or older with congenital heart disease.</p>   | <p><b>(2)(b)</b> As a condition for biennial licensure renewal, a hospital providing pediatric cardiac services shall meet or exceed minimum volume requirements for pediatric and adult congenital procedures. Hospitals authorized to perform adult cardiovascular services may include patients up to 21 years of age for the following:</p> <ol style="list-style-type: none"> <li>1. At least 100 pediatric cardiac catheterization procedures annually, averaged over a 2-year period, of which 50 procedures must be interventional, excluding myocardial biopsies;</li> <li>2. At least 30 pediatric electrophysiology procedures annually, averaged over a 2-year period, of which 18 are ablations;</li> <li>3. At least 50 pediatric stress tests annually, averaged over a 2-year period; and</li> <li>4. At least 100 pediatric cardiac surgical procedures, averaged over a 2-year period.</li> </ol> <p>NOTE: Refer to definitions in rule 59A-3.065, FAC<br/> "Adult congenital patient" means a person age 18 years and over who previously received pediatric cardiac services for congenital heart disease, or who was referred for specialized procedures for congenital heart disease. A hospital authorized to provide pediatric cardiac services may provide the services to adult congenital patients regardless of the age of the patient.</p> <p>"Pediatric patient" means a person under the age of 18 years.</p> <p>"Pediatric cardiac services" means integrated hospital services providing age-appropriate diagnostic and interventional cardiac catheterization and cardiovascular surgical services on the premises of the hospital and available 24 hours per day, 7 days per week to pediatric and adult congenital patients. Hospitals providing pediatric cardiac services must have the capability to provide treatment of cardiac trauma, coronary angioplasty, valvuloplasty, echocardiography, cardiac electrophysiology, advanced cardiac imaging, post-operative intensive care, and outpatient cardiac clinic services. For the purpose of Rule 59A-3.248, F.A.C., cardiovascular surgical services does not include heart transplantation.</p> |
| <p>8 For the purposes of AHCA PCCC program evaluation, development and review, each distinct facility component will be surveyed individually within a multi-site PCCC. Each of its individual components must meet or exceed standards; that is, each hospital-based team must perform the minimum number of echocardiograms, catheterizations, electrophysiologic studies and surgeries specified herein. Each component in the AHCA PCCC shall be evaluated based on its own merits.</p> | <p>NOTE: refer to statutory authority s. 395.1055, F.S.</p>   |
| <p>9 All AHCA PCCC must:<br/> 1. Be located within a healthcare facility that maintains accreditation by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and/or the National Committee for Quality Assurance (NCQA).</p>  | <p>NOTE: Unclear. Accreditation (hospital-wide) is voluntary.</p>   |
| <p>10 2. Be HIPAA (Health Insurance Portability and Accountability Act) compliant.</p>  | <p>NOTE: Federal law. Crossover to patient's rights per s. 381 and 395, FS and rule 59A-3.254 FAC</p>   |

## Crosswalk PCTAP Recommendations to Proposed Rule 59A-3.248 2 (002).xlsx

| Pediatric and Congenital Cardiovascular Center Recommended Standards |  | Proposed Rule 59A-3.248  |
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| 11   | 3. Provide limited English proficiency services, in accordance with Federal guidelines.  | Federal LEP guidelines - civil rights, patient's rights  |
| 12   | 4. Have quality assurance and quality improvement processes in place that continuously enhance the clinical operation and patient satisfaction with services.  | <b>(2)(a)2</b> Develop a quality assurance and improvement program, including a risk adjustment surgical procedure protocol following the guidelines established by the Society of Thoracic Surgeons, to monitor processes and outcomes, analyze data, and identify system improvements for each component of pediatric cardiac services, and integrate the program into the hospital wide quality improvement program as required by rule 59A-3.271, F.A.C.   |
| 13   | 5. Actively participate in the STS Congenital Heart Surgery Database.<br>6. Participate in the STS Congenital Heart Surgery Database Anesthesia Module.  | <b>(2)(a)5</b> Participate in national registries as specified in subsection (7) of this rule.<br><br><b>(7)(b)</b> Each hospital must submit data to the Society of Thoracic Surgeons Congenital Heart Surgery Database, including the Anesthesia Model in the manner set forth herein. Each hospital shall be deemed to have certified that the data submitted for each time period is accurate, complete and verifiable. Data must be submitted in accordance with the timetables and procedures established by the Society of Thoracic Surgeons National Database,   |
| 14   | 7. Participate in the Improving Pediatric and Adult Congenital Treatments (IMPACT) databases.  | <b>(7)(c)</b> Report to the American College of Cardiology IMPACT Data Registry in accordance with the timetables and procedures established by the Registry, and:<br><b>1.</b> Submit reports using the specific data elements, definitions, timetables, transmission format, required software, and procedures established and in accordance with the Registry criteria;<br><b>2.</b> Ensure that software formats are established and maintained in a manner that meets transmission specifications and encryption requirements necessary to protect patient privacy;<br><b>3.</b> Maintain an updated and current institutional profile with the Registry; and<br><b>4.</b> Maintain participation in the Registry.  |
| 15   | 8. Collect and submit the following quality assurance data annually, from their annual STS Congenital Heart Surgery Database Report:<br>· Number of patients/operations submitted and an analysis of operative mortality, and complexity information, by year<br>· Number of patient/operations in analysis, operative mortality, and complexity information, by age group<br>· Primary Procedure Operative Mortality<br>· STS-EACTS (STAT) (European Association of Cardio-Thoracic Surgery) Mortality Category Operative Mortality, by year<br>· STS-EACTS (STAT) Mortality Category Operative Mortality, by age group | <b>(7)(b)13</b> The following quality assurance data must be compiled annually from their Society of Thoracic Surgeons Congenital Heart Surgery Database Report and available for Agency review upon request:<br><b>a.</b> Number of patients/operations submitted and an analysis of operative mortality, and complexity information, by year;<br><b>b.</b> Number of patient/operations in analysis, operative mortality, and complexity information, by age group;<br><b>c.</b> Primary Procedure Operative Mortality;<br><b>d.</b> Society of Thoracic Surgeons - European Association of Cardio-Thoracic Surgery Mortality Category Operative Mortality, by year;<br><b>e.</b> Society of Thoracic Surgeons - European Association of Cardio-Thoracic Surgery Mortality Category Operative Mortality, by age group. |

## Crosswalk PCTAP Recommendations to Proposed Rule 59A-3.248 2 (002).xlsx

| Pediatric and Congenital Cardiovascular Center Recommended Standards   | Proposed Rule 59A-3.248   |
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| <p>16 All AHCA PCCC with birthing centers must have a neonatal screening program using pulse oximetry to detect critical congenital heart disease. Data from such a screening program will be transmitted annually, by the involved institutions, to the AHCA. The Secretary of the AHCA shall request the Surgeon General/Secretary of the Department of Health to forward to the Agency, the annual findings of this screening program. This data shall be made available to the PCTAP for review.</p> | <p><b>(2)(e)</b> Hospitals providing birthing services shall have a neonatal screening program using pulse oximetry to detect critical congenital heart disease.</p>  |
| <p>17 A multidisciplinary cardiac team must include pediatric cardiology, cardiovascular surgery, cardiovascular anesthesia, nursing, ancillary and support staff associated with pre- operative patient selection and preparation, the surgical or catheterization procedure, and post-operative care and follow-up.</p>  | <p><b>(2)(a)</b> A hospital providing pediatric cardiac services shall:</p> <ol style="list-style-type: none"> <li>1. Ensure all staff participating as members of the catheterization team or cardiovascular surgery team, including physicians, nurses, and technical staff must participate in a 24 hours per day, 7 days per week call schedule capable of rapid mobilization of the team(s) within 30 minutes for emergency catheterization procedures and capable of cardiovascular surgery within 2 hours;</li> </ol>  |
| <p>18 All physicians and other licensed healthcare professionals that require credentialing through the Department of Health (DOH) or the Department of Business and Professional Regulation (DBPR) credentialing process and are providing care at an AHCA PCCC must be credentialed providers, as specified in rule 64C-4.001 Florida Administrative Code (F.A.C.).</p>  | <p>NOTE: Unclear. Seems to refer to Wellcare managed care plan.</p>   |
| <p>19 Facilities requesting to be involved as a AHCA PCCC must submit a formal request to the Secretary of AHCA or designee, following the established Certificate of Need (CON) process.</p>  | <p><b>(1)</b> Licensure. A hospital licensed to provide pediatric cardiac catheterization and angioplasty, and pediatric open heart surgery prior to July 1, 2019 shall be licensed to provide pediatric cardiac services effective July 1, 2019, provided the requirements of this rule continue to be met.</p> <p>(a) Initial. A hospital may be authorized to provide pediatric cardiac services by submission of a hospital licensure application as specified in subsection 59A-3.066(2), F.A.C. By submitting a licensure application, the hospital's chief executive officer or designee attests that prior to initiating the services:</p> <ol style="list-style-type: none"> <li>1. The hospital's operating rooms and cardiac catheterization laboratories to be used for pediatric cardiac services meet Florida Building Code as evidenced by approval from the Agency's Office of Plans and Construction pursuant to rule 59A-3.080, F.A.C; and</li> <li>2. The hospital shall meet the requirements of this rule as described in a program narrative.</li> </ol> <p><b>(b)</b> Renewal. The hospital's chief executive officer or designee must attest as part of the biennial licensure renewal application as specified in subsection 59A-3.066(2), F.A.C. that the requirements of this rule continue to be met.</p> |

## Crosswalk PCTAP Recommendations to Proposed Rule 59A-3.248 2 (002).xlsx

| Pediatric and Congenital Cardiovascular Center Recommended Standards  | Proposed Rule 59A-3.248   |
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| <p>20 The following standards are required for entering into, and continuing in, an agreement with AHCA as a PCCC. An AHCA PCCC will consist of the following co- located components:</p> <ul style="list-style-type: none"> <li>I. Pediatric and Congenital Cardiology Clinic</li> <li>II. Pediatric and Congenital Echocardiography Laboratory</li> <li>III. Pediatric and Congenital Cardiac Catheterization Laboratory</li> <li>IV. Pediatric and Congenital Cardiac Electrophysiology (EP) Program</li> <li>V. Advanced Congenital Cardiac Imaging</li> <li>VI. Pediatric and Congenital Cardiovascular Centers</li> </ul>   | <p>NOTE: Refer to definitions in rule 59A-3.065, FAC</p> <p>“Pediatric cardiac services” means integrated hospital services providing age-appropriate diagnostic and interventional cardiac catheterization and cardiovascular surgical services on the premises of the hospital and available 24 hours per day, 7 days per week to pediatric and adult congenital patients. Hospitals providing pediatric cardiac services must have the capability to provide treatment of cardiac trauma, coronary angioplasty, valvuloplasty, echocardiography, cardiac electrophysiology, advanced cardiac imaging, post-operative intensive care, and outpatient cardiac clinic services. For the purpose of Rule 59A-3.248, F.A.C., cardiovascular surgical services does not include heart transplantation.</p>   |
| <p>21 I. Pediatric and Congenital Cardiology Clinic</p> <p>A. Pediatric and Congenital Cardiology Clinic:</p> <p>1. Physicians – The physician in charge of a Pediatric Cardiology Clinic must be board-certified by the Sub-board of Pediatric Cardiology of the American Board of Pediatrics. Recertification or maintenance of competency (MOC) certificates or equivalent of such a physician will be an integral component of all future program evaluations and development reviews. Board eligibility as an equivalent for board certification will not be considered as a criterion for credentialing beyond 5 years of eligibility unless a specific exception is made by the Secretary of AHCA or designee, upon the recommendation of the PCTAP.</p> | <p><b>(3)(a)</b> Medical Director. Pediatric cardiac services shall be under the direction of one or more physician members of the hospital’s organized medical staff.</p> <p>1. The pediatric cardiac catheterization laboratory and outpatient cardiac clinic shall be under the direction of a physician board certified or eligible by the Sub-Board of Pediatric Cardiology of the American Board of Pediatrics.</p> <p><b>(3)(b)</b> 4. Board eligible physicians must be board certified within 5 years of becoming eligible.</p> <p>5. A physician who is not board certified, or who is not eligible due to foreign training or similar circumstance may provide pediatric cardiac services upon documentation of education, training, or alternative certification acceptable to the medical director and hospital’s governing board or designated credentialing committee.</p> <p>NOTE: Hospitals must meet ambulatory care requirements at 59A-3.244 and Florida Building Code, as appropriate.</p> |
| <p>22 B. Holter Monitoring Laboratory:</p>  | <p><b>(2)(d)</b> Ambulatory care clinics serving pediatric and adult congenital patients must be located on the hospital premises and shall:</p> <ul style="list-style-type: none"> <li>1. Meet the requirements for ambulatory care services as described in rule 59A-3.244(1), F.A.C.;</li> <li>2. Provide arrhythmia (holter) monitoring, implanted electronic device monitoring, exercise and metabolic stress testing, imaging, and pulmonary function testing to meet the needs of the pediatric and adult congenital patients;</li> </ul>  |
| <p>23 1. A physician who is board certified in pediatric cardiology.</p>  | <p><b>(2)(d)3</b> Have a board certified pediatric cardiologist immediately available whenever a stress test is being performed;</p>  |
| <p>24 2. Personnel must have medical record access to previous Holter monitor studies and full print out of arrhythmias for comparison.</p>   | <p>NOTE: see 59A-3.270, 59A-3.254</p>   |

## Crosswalk PCTAP Recommendations to Proposed Rule 59A-3.248 2 (002).xlsx

| Pediatric and Congenital Cardiovascular Center Recommended Standards   | Proposed Rule 59A-3.248  |
|--|--|
| <p>25 C. Exercise Treadmill Laboratory:</p> <ol style="list-style-type: none"> <li>1. A physician who is board certified in pediatric cardiology.</li> <li>2. A Basic Life Support (BLS) certified cardiology technologist or respiratory care practitioner immediately available.</li> <li>3. Pediatric Advanced Life Support (PALS) or ACLS trained personnel in close proximity when a pediatric study &lt;15 years of age is being performed.</li> </ol>   | <p><b>(2)(d)5</b> Conduct stress testing with at least one staff who is Pediatric Advanced Life Support or Advanced Cardiac Life Support certified in the room at all times with the patient during the test; and</p> <p><b>6.</b> Have at least one Basic Life Support certified cardiology technologist or respiratory care practitioner immediately available whenever a stress test is being performed.</p>  |
| <p>26 4. The exercise treadmill lab must include a remote “code” button and telephone.</p>   | <p>NOTE: Florida Building Code. Codes many vary depending on location and services within that location.</p>   |
| <p>27 5. Each center should have access to a metabolic exercise laboratory, in which oxygen utilization and the anaerobic threshold can be determined, as an adjunct to detecting early failing cardiopulmonary function.</p> <p>6. All licensed PCCC institutions should follow the guidelines set forth in the American Heart Association Scientific Statement on "Clinical Stress Testing in the Pediatric Age Group" (Circulation. 2006; 113:1905-1920).</p> <p>7. Specifically, licensure as a PCCC requires that involved institutions:</p> <ol style="list-style-type: none"> <li>a. Maintain an appropriate pediatric exercise physiology laboratory, including             <ol style="list-style-type: none"> <li>i. Age- and size-appropriate treadmill and/or cycle ergometer</li> <li>ii. Age- and size-appropriate blood pressure cuffs</li> <li>iii. Age- and size-appropriate oxygen saturation monitor</li> <li>iv. EKG recording equipment</li> <li>v. An emergency resuscitation cart that includes emergency drugs, a defibrillator, supplemental oxygen, and a portable suction unit</li> <li>vi. A log demonstrating periodic testing of the defibrillator and oxygen supply, and periodic inspection of emergency drug expiration dates</li> <li>vii. Conduct all stress tests with at least one person trained in PALS in the room at all times with the patient during the test</li> </ol> </li> </ol> | <p><b>(5)(a)</b> Each hospital shall have policies and procedures for the selection, procurement, use, and maintenance of age and size appropriate equipment used for pediatric cardiac services.</p> <p><b>(b)</b> Each hospital unit in which pediatric cardiac services are provided shall have:</p> <ol style="list-style-type: none"> <li>1. A protocol for handling emergency conditions related to the breakdown of essential equipment, including the immediate availability of personnel trained in equipment repair and maintenance.</li> <li>2. A crash cart containing the necessary medication and equipment for ventilatory support. A listing of all crash cart contents shall be readily available. At the beginning of each shift, the crash cart shall be checked for intact lock; the defibrillator and corresponding equipment shall be checked for function and operational capacity. A log shall be maintained indicating review.</li> </ol> <p><b>(2)(d)5</b> Conduct stress testing with at least one staff who is Pediatric Advanced Life Support or Advanced Cardiac Life Support certified in the room at all times with the patient during the test; and</p> <p><b>6.</b> Have at least one Basic Life Support certified cardiology technologist or respiratory care practitioner immediately available whenever a stress test is being performed.</p> |
| <p>28 b. Conduct all stress tests with a pediatric cardiologist immediately available (i.e. in the building)</p>   | <p><b>(2)(d)3</b> Have a board certified pediatric cardiologist immediately available whenever a stress test is being performed;</p>   |
| <p>29 c. Perform a minimum of 50 pediatric exercise stress tests per year</p>  | <p><b>(2)(b)3</b> At least 50 pediatric stress tests annually, averaged over a 2-year period.</p>  |
| <p>30 d. Obtain meaningful written consent for the stress test (which may be a hospital-wide standard consent form filled out specifically for stress testing)</p>   | <p>NOTE: 59A-3.270</p>   |
| <p>31 8. Licensed PCCC institutions are recommended to:</p> <ol style="list-style-type: none"> <li>a. Have oversight of the laboratory and testing procedures provided by a physician trained in exercise testing and exercise physiology</li> </ol>   | <p>NOTE: 59A-3.275</p>   |
| <p>32</p> <ol style="list-style-type: none"> <li>b. Be able to perform spirometry/pulmonary function testing</li> <li>c. Be able to perform metabolic stress tests</li> <li>d. Be able to perform or refer patients for stress echocardiography</li> <li>e. Be able to perform or refer patients for pharmacologic stress testing</li> <li>f. Be able to perform or refer patients for nuclear myocardial blood flow imaging</li> </ol>  | <p><b>(2)(d)2</b> Provide arrhythmia (holter) monitoring, implanted electronic device monitoring, stress testing, imaging, and pulmonary function testing to meet the needs of the pediatric and adult congenital patients;</p>  |

## Crosswalk PCTAP Recommendations to Proposed Rule 59A-3.248 2 (002).xlsx

| Pediatric and Congenital Cardiovascular Center Recommended Standards |   | Proposed Rule 59A-3.248  |
|--|---|--|
| 33   | D. Serial monitoring and management of implanted electronic devices, such as pacemakers and defibrillators should be an integral component of any center.   | <b>(2)(d)2.</b> Provide arrhythmia (holter) monitoring, implanted electronic device monitoring, stress testing, imaging, and pulmonary function testing to meet the needs of the pediatric and adult congenital patients;<br><b>(3)(c)2.</b> Registered nurses providing care in the cardiac catheterization and electrophysiology laboratories must be trained and experienced with cardiovascular implantable electronic device management and be certified in Basic Life Support and Pediatric Advanced Life Support. |
| 34   | E. Adult Congenital Heart Programs:   | NOTE: integrated with pediatric - same requirements  |
| 35   | 1. All adults with congenital heart disease must have access to appropriate care. Pediatric cardiac programs must have a written policy detailing transition of care to an adult congenital program.  | <b>(2)(a)</b> A hospital providing pediatric cardiac services shall:<br><b>3.</b> Have written policies and procedures for the transition of care from pediatric to adult congenital services, including providing information on recommendations on endocarditis prophylaxis, anticoagulation therapy, diet, weight control, contraception, pregnancy risk with referral to maternal-fetal medicine physicians as appropriate, and exercise limitations;  |
| 36   | 2. Each PCCC must have as a goal to provide care in alignment with national standards, utilizing as guidelines those of the Adult Congenital Heart Association (ACHA). Each program, within 3 years, shall request a formal site visit by the staff of the AHCA.<br>3. AHCA accredited Comprehensive Adult Congenital Heart Programs and regionalization of expertise are encouraged.<br>4. Existing national and international guidelines, which outline the care provided in Adult Congenital Heart Programs, should be utilized.<br>5. All ACHD programs must be registered with the ACHA and submit required data at established intervals. | <b>(7)(d)</b> Each hospital must register with the Adult Congenital Heart Association and submit data as required by the Adult Congenital Heart Association in order to maintain a current registration.<br><br>NOTE: possible confusion with acromyns in PCTAP recommendation document.   |
| 37   | 6. Personnel<br>a. The program must be directed by a physician with special skills and training in caring for the adult patient with congenital heart disease.<br>b. ACHD program directors shall be board certified by the ABIM ACHD sub-Board.  | <b>(3)(a)3.</b> Adult congenital services shall be under the direction of a physician board certified by the Adult Congenital Heart Disease sub-board of the American Board of Internal Medicine.  |
| 38   | c. Congenital Heart Surgeon(s) with expertise in the unique surgical aspects and challenges of the adult congenital heart patient.  | NOTE: 59A-3.275  |
| 39   | d. Social Worker who is available to the adult patient to provide counseling and support services.  | <b>(3)(d)</b> Additional Staff. Each hospital providing pediatric cardiac services shall have a number of perfusionists, cardiovascular technologists, respiratory therapists, radiologic technicians, clinical laboratory personnel, and social workers available at all times to meet the needs of any patient.  |
| 40   | e. A health professional (ARNP or PA) whose role includes coordinating care for ACHD patients.  | <b>(2)(d)4.</b> Have a licensed APRN or PA to coordinate care for adult congenital patients; and   |
| 41   | f. Availability, defined by active medical staff or written policy, of Adult Medicine sub-specialty physicians to provide consultative care.  | NOTE: 59A-3.275  |
| 42   | g. All physicians caring for the ACHD patient must be ACLS certified.   | <b>(3)(b)8.</b> All physicians caring for adult congenital patients must be Advanced Cardiac Life Support certified.   |



## Crosswalk PCTAP Recommendations to Proposed Rule 59A-3.248 2 (002).xlsx

| Pediatric and Congenital Cardiovascular Center Recommended Standards   | Proposed Rule 59A-3.248   |
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| <p>43 h. All staff performing exercise testing on ACHD patient must be ACLS certified.</p>   | <p><b>(2)(d)5</b> Conduct stress testing with at least one staff who is Pediatric Advanced Life Support or Advanced Cardiac Life Support certified in the room at all times with the patient during the test; and<br/> <b>6.</b> Have at least one Basic Life Support certified cardiology technologist or respiratory care practitioner immediately available whenever a stress test is being performed.</p>   |
| <p>44 7. Clinic Physical Space</p> <ul style="list-style-type: none"> <li>a. The clinic space used for evaluation of adult patients must be in accordance with their specific needs.</li> <li>b. Facility must be accessible to handicapped Individuals.</li> <li>c. Availability of EKG, X-Rays, MRI studies, Echocardiography, and exercise/metabolic stress testing</li> <li>d. Availability of a conference room for multi-disciplinary meetings.</li> </ul>   | <p>NOTE: Florida Building Code and Life Safety Code</p>   |
| <p>45 8. Hospital and Inpatient Facilities</p> <ul style="list-style-type: none"> <li>a. The admitting facility must have expertise in the care of adults with congenital heart disease.</li> <li>b. The ACHD Program must have access to a fully equipped cardiac catheterization laboratory with appropriately trained personnel.</li> <li>c. The ACHD Program must meet national standards in all cardiac catheterization interventional and electrophysiology procedures.</li> <li>d. The ACHD Program must offer a comprehensive cardiovascular surgical program, with established commitment from cardiac intensivists, anesthesiologists, and other adult medical and surgical subspecialties.</li> </ul>   | <p>NOTE: Rules will set standards for OHS and Cardiac Cath.</p>   |
| <p>46 9. Patient Care Characteristics Specific to an ACHD Program – Recommendations and Specific Requirements:</p> <ul style="list-style-type: none"> <li>a. Complete transition into the ACHD clinic should be individualized by the treating pediatric cardiologist, taking into account patient age, maturity, special psychosocial needs, and wishes of the parent(s).</li> <li>b. Adult female patients with congenital heart disease must have access to professional staff expert in the management of contraception and pre-pregnancy counseling. In addition, Genetic Counseling and Fetal Echocardiography studies must be available.</li> <li>c. Pregnant patients with moderate to high complexity congenital heart disease must be evaluated as a High-Risk Pregnancy and referred to Maternal-Fetal Medicine Physicians.</li> <li>d. Health maintenance programs for adolescents and adult patients with CHD should be initiated by providing each patient with information related to, but not limited, to recommendations on endocarditis prophylaxis, anticoagulation therapy, diet, weight control, contraception, pregnancy risk and exercise limitations.</li> </ul> | <p><b>(2)(a)</b> A hospital providing pediatric cardiac services shall:</p> <ul style="list-style-type: none"> <li><b>3.</b> Have written policies and procedures for the transition of care from pediatric to adult congenital services, including providing information on recommendations on endocarditis prophylaxis, anticoagulation therapy, diet, weight control, contraception, pregnancy risk with referral to maternal-fetal medicine physicians as appropriate and exercise limitations;</li> <li><b>4.</b> Provide female adult congenital patients pre-pregnancy counseling, and genetic counseling and fetal echocardiography studies, as appropriate;</li> </ul> |

## Crosswalk PCTAP Recommendations to Proposed Rule 59A-3.248 2 (002).xlsx

| Pediatric and Congenital Cardiovascular Center Recommended Standards |  | Proposed Rule 59A-3.248   |
|--|--|---|
| 47   | g. Annual updates on information submitted by each center to the ACHA regarding ACHD activities should be forwarded to the AHCA program staff within 30 days of such submission.   | NOTE: Unclear. Refer to (8)(d). Participation with ACHA will be verified at license renewal. Information is posted on the ACHA website.   |
| 48   | h. High Risk Obstetrical Cases with Fetal Cardiac Anomalies- Each PCCC must have an established protocol to address the needs of such patients, usually high-risk obstetrical cases having a cardiac fetal anomaly diagnosed by fetal echocardiography and/or ultrasound.  | <b>(2)(a)</b> A hospital providing pediatric cardiac services shall:<br><b>3.</b> Have written policies and procedures for the transition of care from pediatric to adult congenital services, including providing information on recommendations on endocarditis prophylaxis, anticoagulation therapy, diet, weight control, contraception, pregnancy risk with referral to maternal-fetal medicine physicians as appropriate and exercise limitations;<br><b>4.</b> Provide female adult congenital patients pre-pregnancy counseling, and genetic counseling and fetal echocardiography studies, as appropriate; |
| 49   | i. Each center shall submit at least 2 metrics to the American College of cardiology ACPC quality network on a quarterly basis, or frequency as designated by Qnet. Cardiac centers shall designate appropriate personnel for data collection and submission.  | <b>(7)(e)</b> Each hospital must register with the Adult Congenital & Pediatric Cardiology Quality Network of the American College of Cardiology and participate in 2 or more quality metrics defined by the American College of Cardiology. Data submitted for each quality metric shall be in a format provided by the Adult Congenital & Pediatric Cardiology Quality Network.   |
| 50   | 10. Physical Facility General Requirements for licensed and new PCCC outpatient clinics:<br>a. The area must be suitable for performance of a high quality cardiovascular examination.<br>b. Examination areas must be adequately lighted, have adjustable temperature, and offer privacy to patients.<br>c. A conference room must be available for discussing cases. | NOTE: FBC. Codes may vary depending on location and services within that location.  |
| 51   | 11. Equipment - All clinic equipment must be monitored and maintained in accordance with manufacturers' recommendations.   | <b>(5)(a)</b> Each hospital shall have policies and procedures for the selection, procurement, use, and maintenance of age and size appropriate equipment used for pediatric cardiac services.<br><b>(b)</b> Each hospital unit in which pediatric cardiac services are provided shall have:<br><b>1.</b> A protocol for handling emergency conditions related to the breakdown of essential equipment, including the immediate availability of personnel trained in equipment repair and maintenance.  |
| 52   | 12. Radiological equipment- Access to a Radiological facility at which chest x-rays and other indicated radiological studies can be expeditiously performed, including access to Magnetic Resonance Imaging (MRI) studies, particularly to evaluate the large vessels of the chest associated with the heart.  | NOTE: 59A-3.242   |

## Crosswalk PCTAP Recommendations to Proposed Rule 59A-3.248 2 (002).xlsx

| Pediatric and Congenital Cardiovascular Center Recommended Standards |  | Proposed Rule 59A-3.248   |
|--|--|---|
| 53   | <p>13. Records:</p> <p>a. Permanent record of real time study must include, at a minimum, video, disk, chart, or digital or electronic medical records.</p> <p>b. Permanent record of real time study of Holter Monitoring studies must include one or more of the following: cassette tape, disk, printed paper, or digital or electronic medical records.</p> <p>c. Permanent record of real time study of exercise treadmill testing must include EKG and blood pressure recordings.</p> <p>d. Permanent record of real time study of serial pacemaker testing must be available.</p> <p>e. Interpretation and final approval of study reports must be performed by a physician who is board certified in pediatric cardiology.</p> <p>f. Medical records must be retained for a period of no less than seven (7) years in a locked area.</p> | NOTE: 59A-3.270   |
| 54   | <p>14. Initial Evaluation</p> <p>a. Program evaluation and development review: If a request is received for involvement as a PCCC co-located Pediatric Cardiology Clinic, along with attestation of compliance with these standards, a program evaluation and development review may be requested by the Secretary of AHCA and performed by members or designees of the PCTAP. A request for involvement shall not be deemed complete until the Secretary of AHCA or designee receives the recommendation of the PCTAP.</p>  | <p><b>(1)</b> Licensure. A hospital licensed to provide pediatric cardiac catheterization and angioplasty, and pediatric open heart surgery prior to July 1, 2019 shall be licensed to provide pediatric cardiac services effective July 1, 2019, provided the requirements of this rule continue to be met.</p> <p><b>(a)</b> Initial. A hospital may be authorized to provide pediatric cardiac services by submission of a hospital licensure application as specified in subsection 59A-3.066(2), F.A.C. By submitting a licensure application, the hospital's chief executive officer or designee attests that prior to initiating the services:</p> <ol style="list-style-type: none"> <li>1. The hospital's operating rooms and cardiac catheterization laboratories to be used for pediatric cardiac services meet Florida Building Code as evidenced by approval from the Agency's Office of Plans and Construction pursuant to rule 59A-3.080, F.A.C; and</li> <li>2. The hospital shall meet the requirements of this rule as described in a program narrative.</li> </ol> |
| 55   | <p>b. The Secretary of AHCA or designee shall consider new facilities upon the completion of CON approval and requirements and the advisory recommendation of the PCTAP and the criteria established above. The Secretary of AHCA or designee shall make the final decision on whether a facility may participate by entering into an agreement with the Agency.</p>   | AHCA licensing protocol   |
| 56   | <p>15. Re-evaluation of licensed PCCC</p> <p>a. IAC Accreditation: By the initial or subsequent program evaluation and development review, all echocardiography laboratories, Transthoracic Echoes (TTE), Trans Esophageal Echoes (TEE) and Fetal Echoes (FE) must be accredited by the IAC, whether within the center or "off-site".</p>  | Multiple radiology accreditation organizations exist besides IAC: ACR, TJC, Radsite.  |
| 57   | <p>16. The Secretary of AHCA or designee considers existing facilities for continuing involvement upon the recommendation of the PCTAP and the criteria established above. The Secretary of AHCA or designee shall make the final decision on whether or not a facility may continue such an agreement with the Agency.</p>  | AHCA licensing protocol   |

## Crosswalk PCTAP Recommendations to Proposed Rule 59A-3.248 2 (002).xlsx

| Pediatric and Congenital Cardiovascular Center Recommended Standards  | Proposed Rule 59A-3.248  |
|---|--|
| <p>58 II. Pediatric and Congenital Echocardiography Laboratory<br/>                     A. Congenital Echocardiographic Imaging Laboratory<br/>                     1. Echocardiographic Imaging is a vital tool often relied upon by all of the other components of a Pediatric Cardiovascular Centers. A Congenital Echocardiographic Imaging Laboratory must be accredited (and reaccredited when accreditation expires) for Pediatric Echocardiography by the Intersocietal Accreditation Commission (IAC) in order to perform Transthoracic Echoes (TTE), Trans Esophageal Echoes (TEE) and Fetal Echoes (FE). The IAC accreditation process is a rigorous process that is constantly being improved and revised by national experts in this field. The IAC standards and guidelines spell out responsibilities for Echo Lab Medical Director, Technical Director, Medical Staff, Technical Staff, and for Support services. As well the IAC spells out standards and guidelines for the Echo Lab Facility, Echo examination reports and records, and Echo Lab safety. The IAC also mandates the facility must have a written Quality Improvement (QI) program for all imaging procedures. The IAC makes some accommodations for its standards and guidelines that may be a challenge for smaller Pediatric Cardiovascular Centers. The IAC standards and guidelines will not be separately listed here, details can be found at <a href="http://www.intersocietal.org">www.intersocietal.org</a>.</p> | <p>Multiple radiology accreditation organizations exist besides IAC: American College of Radiology, The Joint Commission, Radsite.<br/>                     IAC estimated costs, annualized - \$750</p>  |
| <p>59 III. Pediatric Cardiac Catheterization Laboratory Component<br/>                     A. The Pediatric Cardiac Catheterization Laboratory must be co-located within a facility completely equipped to accommodate all aspects of the medical and surgical care of the patient.<br/>                     2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update. J Am College Cardiology. 2012; Vol. 59 No. 24 221-2305.</p>  | <p>NOTE: All hospital inpatient services must be provided within a licensed facility.</p>  |
| <p>60 B. Cardiac Team<br/>                     1. Physician in Charge<br/>                     a. The physician in charge of the procedure must be board- certified by the Sub-Board of Pediatric Cardiology of the American Board of Pediatrics. Pediatric cardiologists either trained in other countries or for any reason not eligible for certification by the Sub-Board of Pediatric Cardiology of the American Board of Pediatrics and have completed additional 12 months fellowship in interventional pediatric cardiology may be credentialed as a DOH physician by the Surgeon General/Secretary of the Department of Health or designee, as a special situation after a review and in-depth evaluation by the PCTAP, which recommended such approval.</p>   | <p><b>(3)(b)1.</b> The physician in charge of a cardiac catheterization procedure shall be board certified or eligible by the Sub-Board of Pediatric Cardiology of the American Board of Pediatrics.</p> |

## Crosswalk PCTAP Recommendations to Proposed Rule 59A-3.248 2 (002).xlsx

| Pediatric and Congenital Cardiovascular Center Recommended Standards |  | Proposed Rule 59A-3.248   |
|--|--|---|
| 61   | <p>2. Consulting Physicians</p> <p>a. In addition to the physician listed above, in interventional cardiac catheterizations, an anesthesiologist and a thoracic surgeon, each with advanced training in the cardiovascular aspects of their specialty, must be immediately available within the facility or in close proximity for consultation, assistance, emergency and elective surgical procedures and peri-operative care.</p> | <p><b>(3)(b)7.</b> The organized medical staff membership shall contain a complement of physicians with training or experience with pediatric cardiac patients to be available for consultation as needed, including:</p> <p><b>a.</b> Pediatric cardiologists;</p> <p><b>b.</b> Pediatric sub-specialists with expertise in hematology, nephrology, neurology, infectious disease, critical care, genetics, gastroenterology and pulmonology;</p> <p><b>c.</b> Radiologists;</p> <p><b>d.</b> Anesthesiologists; and</p> <p><b>e.</b> Pathologists.</p>  |
| 62   | <p>3. Nurse</p> <p>a. Each laboratory must have a registered nurse, with special training in cardiovascular techniques and in the care of children, as a full time member of the team. This nurse must have special skills in pre-catheterization evaluation and instruction of the patient and family, care of the patient post-catheterization, and discharge teaching for the patient and family.</p>                             | <p><b>(3)(c)</b> Nursing Staff. Each hospital unit in which pediatric cardiac services are provided shall have a number of registered nurses on duty at all times to ensure immediate availability to any patient when needed. There must be at least one registered nurse for every two patients during the first hours of post-operative care.</p> <p><b>1.</b> The cardiac catheterization, electrophysiology and cardiovascular surgical services unit must have registered nurses with special training in cardiovascular techniques in the care of pediatric and adult congenital heart patients and have skills in the pre and post procedure evaluations and provision of instruction to the patient and their family members.</p> <p><b>2.</b> Registered nurses providing care in the cardiac catheterization and electrophysiology laboratories must be trained and experienced with cardiovascular implantable electronic device management and be certified in Basic Life Support and Pediatric Advanced Life Support.</p> |
| 63   | <p>4. Cardiovascular Technologist</p> <p>a. Each laboratory must have a cardiovascular technologist with special training in cardiac catheterization laboratory techniques.</p>  | <p><b>(3)(d)1.</b> Cardiovascular technologists shall be credentialed as Registered Cardiovascular Invasive Specialist or Registered Cardiac Electrophysiology Specialist or shall complete a hospital-based education and training program acceptable to the medical director. This training program shall include a minimum of 500 hours proctored clinical experience, including participation in a minimum of 120 interventional cardiology procedures and didactic education components of hemodynamics, pharmacology, arrhythmia recognition, radiation safety, and interventional equipment.</p>   |
| 64   | <p>5. Dedicated Trained Cardiovascular Recorder</p> <p>a. Each laboratory must have a dedicated trained cardiovascular recorder who has no other responsibilities during procedures.</p>   | <p><b>(3)(d)2.</b> Cardiovascular technologists serving as the cardiovascular recorder shall have no other duties during a procedure.</p>   |
| 65   | <p>6. Each laboratory must have immediate access to personnel trained in equipment repair and maintenance.</p>   | <p><b>(5)(b)1.</b> A protocol for handling emergency conditions related to the breakdown of essential equipment, including the immediate availability of personnel trained in equipment repair and maintenance.</p>   |

## Crosswalk PCTAP Recommendations to Proposed Rule 59A-3.248 2 (002).xlsx

| Pediatric and Congenital Cardiovascular Center Recommended Standards   | Proposed Rule 59A-3.248   |
|--|---|
| <p>66 7. Although the above required functions are well defined, it is not necessary for one person to fulfill each separate job category. Well defined adequate cross training for other personnel classifications permits 24-hour coverage of essential team functions.</p> <p>8. All technologists in a cardiovascular laboratory must be certified by the Cardiovascular Credentialing Institute as a Registered Cardiovascular Technologist (RCVT) and licensed by the State of Florida under the Clinical Laboratory law, when applicable.</p>   | <p><b>(3)(d)1.</b> Cardiovascular technologists shall be credentialed as Registered Cardiovascular Invasive Specialist or Registered Cardiac Electrophysiology Specialist or shall complete a hospital-based education and training program acceptable to the medical director.</p>   |
| <p>67 9. Equipment: Radiological, electronic, and computer-based systems are integral components of the equipment in a catheterization laboratory.</p> <p>These systems all require a program of rigorous maintenance and troubleshooting. For pediatric patients, biplane angiography, higher frame rates (30-60 fps), and higher injection rates (up to 40 mL/s) are required to help define abnormal intra-cardiac anatomy. The catheterization laboratory must be able to perform procedures in a patient supported by extracorporeal membrane oxygenation (ECMO). 2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update. J Am College Cardiology. 2012; Vol. 59 No. 24 221-2305.</p> | <p><b>(5)(a)</b> Each hospital shall have policies and procedures for the selection, procurement, use, and maintenance of age and size appropriate equipment used for pediatric cardiac services.</p> <p><b>(b)</b> Each hospital unit in which pediatric cardiac services are provided shall have:</p> <p>1. A protocol for handling emergency conditions related to the breakdown of essential equipment, including the immediate availability of personnel trained in equipment repair and maintenance.</p> <p><b>(5)(c)10.</b> Biplane angiography, with framing rates of 30-60 fps and injection rates of up to 40 mL/s;</p> |
| <p>68 10. Electrical Safety and Radiation Protection</p> <p>a. Electrical safety and radiation protection shall be followed in accordance with the manufacturer's recommendations and applicable State and Federal regulations.</p>  | <p>NOTE: FBC and LSC</p>  |
| <p>69 11. Records</p> <p>a. Permanent record of real time study must include, at a minimum, video, disk, chart, or digital / electronic recordings.</p> <p>b. Interpretation and final approval of study reports must be performed by a physician who is board certified in pediatric cardiology.</p> <p>c. Medical records must be retained for a period of no less than seven (7) years in a secure locked area.</p>   | <p>NOTE: Hospital wide requirements per 59A-3.270</p>   |
| <p>70 IV. Pediatric and Congenital Cardiac Electrophysiology (EP) Program</p> <p>A Pediatric Cardiac Electrophysiology (EP) Program is an integral part of an AHCA PCCC. The EP program has two main components: (1) An Interventional program in a Pediatric Cardiac Electrophysiology Laboratory and (2) A non-invasive inpatient and outpatient arrhythmia evaluation and management service. All AHCA designated centers must participate in the outpatient arrhythmia evaluation, management, and consultation services.</p>  | <p><b>(2)(d)</b> Ambulatory care clinics serving pediatric and adult congenital patients may be located on the hospital premises or at an off-site location included on the hospital license pursuant to rule 59A-3.066, F.A.C., and shall:</p> <p>1. Meet the requirements for ambulatory care services as described in rule 59A-3.244(1), F.A.C.;</p> <p>2. Provide arrhythmia (holter) monitoring, implanted electronic device monitoring, stress testing, imaging, and pulmonary function testing to meet the needs of the pediatric and adult congenital patients;</p>   |

## Crosswalk PCTAP Recommendations to Proposed Rule 59A-3.248 2 (002).xlsx

| Pediatric and Congenital Cardiovascular Center Recommended Standards  | Proposed Rule 59A-3.248  |
|---|--|
| <p>71 A. Laboratory Component: The Pediatric Cardiac Electrophysiology Laboratory must be co-located within a facility completely equipped to accommodate all aspects of the medical and surgical care of the pediatric patient.</p> <p>B. Cardiac Team Physician in Charge: The physician in charge of the laboratory must be board-certified by the Sub-Board of Pediatric Cardiology of the American Board of Pediatrics and must be a pediatric electrophysiologist as defined below:</p> <ol style="list-style-type: none"> <li>1. Pediatric Electrophysiologist is a Pediatric Cardiology Board Certified physician, whose primary clinical practice is dedicated to pediatric electrophysiology activities.</li> <li>2. All pediatric electrophysiologists must be certified by the International Board of Heart Rhythm Examiners (IBHRE within 5 years of being board eligible).</li> </ol> | <p><b>(3)(a)2.</b> Electrophysiology services shall be under the direction of a pediatric electrophysiologist board certified by the Sub-Board of Pediatric Cardiology of the American Board of Pediatrics and by the International Board of Heart Rhythm Examiners.</p> <p><b>(3)(b)2</b> The physician in charge of an electrophysiology procedure must be a pediatric electrophysiologist board certified by the Sub-Board of Pediatric Cardiology of the American Board of Pediatrics.</p> <p><b>(3)(b)4</b> Board eligible physicians must be board certified within 5 years of becoming eligible.</p>  |
| <p>72 C. Consulting Physicians: In addition to the physician listed above, during interventional EP cardiac catheterizations, an anesthesiologist and a thoracic surgeon, each with advanced training in the cardiovascular aspects of their specialty, must be immediately available within the facility, or in close proximity, for consultation, assistance, emergency and elective surgical procedures and peri-operative care.</p>   | <p><b>(3)(b)7.</b> The organized medical staff membership shall contain a complement of physicians with training or experience with pediatric cardiac patients to be available for consultation as needed, including:</p> <ol style="list-style-type: none"> <li>a. Pediatric cardiologists;</li> <li>b. Pediatric sub-specialists with expertise in hematology, nephrology, neurology, infectious disease, critical care, genetics, gastroenterology and pulmonology;</li> <li>c. Radiologists;</li> <li>d. Anesthesiologists; and</li> <li>e. Pathologists.</li> </ol>   |
| <p>73 D. Nurse: Each laboratory must have a registered nurse, with special training in cardiovascular techniques and in the care of children, as a full time member of the team. This nurse must have special skills in pre and post catheterization evaluation, and management. In addition, this individual must be skilled in the coordination of patient and family education and provision of instructions pre and post procedure.</p>   | <p><b>(3)(c)</b> Nursing Staff. Each hospital unit in which pediatric cardiac services are provided shall have a number of registered nurses on duty at all times to ensure immediate availability to any patient when needed.</p> <ol style="list-style-type: none"> <li>1. The cardiac catheterization, electrophysiology and cardiovascular surgical services unit must have registered nurses with special training in cardiovascular techniques in the care of pediatric and adult congenital heart patients and have skills in the pre and post procedure evaluations and provision of instruction to the patient and their family members.</li> <li>2. Registered nurses providing care in the cardiac catheterization and electrophysiology laboratories must be trained in cardiovascular implantable electronic device management and be certified in Basic Life Support and Pediatric Advanced Life Support.</li> </ol> |

# Crosswalk PCTAP Recommendations to Proposed Rule 59A-3.248 2 (002).xlsx

| Pediatric and Congenital Cardiovascular Center Recommended Standards  | Proposed Rule 59A-3.248   |
|---|---|
| <p>74 E. Cardiovascular EP Technologist: Each laboratory must have a cardiovascular EP technologist with special training in cardiac EP laboratory techniques.</p> <ol style="list-style-type: none"> <li>1. Dedicated Trained Cardiovascular EP Recorder               <ol style="list-style-type: none"> <li>a. Each laboratory must have a dedicated trained cardiovascular EP recorder who has no other responsibilities during such procedures.</li> <li>b. Each laboratory must have immediate access to personnel trained in equipment repair and maintenance.</li> <li>c. Although the above-required functions are well defined, it is not necessary for one person to fulfill each separate job category. Adequate cross training for other personnel classifications permits 24-hour coverage of essential team functions.</li> </ol> </li> <li>2. All technologists in a cardiovascular laboratory must be certified by the Cardiovascular Credentialing Institute as a Registered Cardiovascular Technologist (RCVT) and licensed by the State of Florida under the Clinical Laboratory law, when applicable.</li> </ol> | <p><b>(3)(d)</b> Additional Staff. Each hospital providing pediatric cardiac services shall have a number of perfusionists, cardiovascular technologists, respiratory therapists, radiologic technicians and clinical laboratory personnel available at all times to meet the needs of any patient.</p> <ol style="list-style-type: none"> <li>1. Cardiovascular technologists shall be credentialed as Registered Cardiovascular Invasive Specialist or Registered Cardiac Electrophysiology Specialist or shall complete a hospital-based education and training program acceptable to the medical director. This training program shall include a minimum of 500 hours proctored clinical experience, including participation in a minimum of 120 interventional cardiology procedures and didactic education components of hemodynamics, pharmacology, arrhythmia recognition, radiation safety, and interventional equipment.</li> <li>2. Cardiovascular technologists serving as the cardiovascular recorder shall have no other duties during a procedure.</li> </ol> <p><b>(5)(b)</b> Each hospital unit in which pediatric cardiac services are provided shall have:</p> <ol style="list-style-type: none"> <li>1. A protocol for handling emergency conditions related to the breakdown of essential equipment, including the immediate availability of personnel trained in equipment repair and maintenance.</li> </ol> |
| <p>75 F. Equipment:</p> <ol style="list-style-type: none"> <li>1. Radiological, electronic, and computer-based systems are integral components of the equipment in a catheterization laboratory. These systems all require a program of rigorous maintenance and troubleshooting. A pediatric electrophysiology laboratory must have:               <ol style="list-style-type: none"> <li>a. Multi Channel EP recording system</li> <li>b. External Defibrillation system</li> <li>c. Cardiopulmonary monitoring system</li> <li>d. Radiofrequency Energy Source</li> <li>e. It is strongly recommended that Pediatric Electrophysiology laboratories also have:</li> <li>f. 3 Dimensional Mapping System</li> <li>g. Cryo ablation System</li> </ol> </li> </ol>  | <p><b>(c)</b> Each hospital must have age and size appropriate equipment available for patients receiving pediatric cardiac services, including:</p> <ol style="list-style-type: none"> <li>1. Multi-dimensional imaging equipment for magnetic resonance imaging/magnetic resonance angiography, computed tomography, echocardiography, and scintigraphy;</li> <li>2. A special procedure x-ray room with diagnostic x-ray examination table;</li> <li>3. X-ray equipment with the capability in cineangiocardiology, or equipment with similar capabilities;</li> <li>4. An image intensifier;</li> <li>5. An automatic injector;</li> <li>6. An electrocardiograph;</li> <li>7. A multi-channel electrophysiology recording system;</li> <li>8. A cardiopulmonary monitoring system;</li> <li>9. Emergency equipment, including temporary pacemaker units with catheters, ventilatory assistance devices, and a DC defibrillator;</li> <li>10. Biplane angiography, with framing rates of 30-60 fps and injection rates of up to 40 mL/s; and</li> <li>11. Extra Corporeal Membrane Oxygenation machine.</li> </ol>  |
| <p>76 2. Electrical Safety and Radiation Protection: Electrical safety and radiation protection shall be followed in accordance with the manufacturer's recommendations and applicable State and Federal regulations.</p>   | <p>NOTE: FBC and LSC</p>  |



## Crosswalk PCTAP Recommendations to Proposed Rule 59A-3.248 2 (002).xlsx

| Pediatric and Congenital Cardiovascular Center Recommended Standards |  | Proposed Rule 59A-3.248   |
|--|--|---|
| 77   | <p>G. Records</p> <ol style="list-style-type: none"> <li>1. Permanent record of real time study must include, at a minimum, video, disk, chart, or digital / electronic recordings.</li> <li>2. Interpretation and final approval of such EP study reports must be performed by a physician who is board certified in pediatric cardiology and meets the standards to be qualified as a pediatric electrophysiologist, as defined previously.</li> <li>3. Medical records must be retained for a period of no less than seven (7) years in a secure locked area.</li> </ol>  | <p>NOTE: Hospital wide requirements per 59A-3.270</p>   |
| 78   | <p>H. Outpatient Clinic Component</p> <ol style="list-style-type: none"> <li>1. Facility Criteria: include all standards, as outlined in the outpatient clinic section. In addition, an outpatient electrophysiology program must have the following components:                             <ol style="list-style-type: none"> <li>a. Personnel:                                     <ol style="list-style-type: none"> <li>i. The physician in charge of this clinic is to be board eligible or board certified by the IBHRE and Basic Life Support and have special expertise in arrhythmias and device management. The physician must be IBHRE certified within 5 years of becoming Board eligible.</li> </ol> </li> </ol> </li> </ol> | <p><b>(3)(a)2.</b> Electrophysiology services shall be under the direction of a pediatric electrophysiologist board certified by the Sub-Board of Pediatric Cardiology of the American Board of Pediatrics and by the International Board of Heart Rhythm Examiners.</p> <p><b>(3)(b)2</b> The physician in charge of an electrophysiology procedure must be a pediatric electrophysiologist board certified by the Sub-Board of Pediatric Cardiology of the American Board of Pediatrics.</p> <p><b>(3)(b)4</b> Board eligible physicians must be board certified within 5 years of becoming eligible.</p>   |
| 79   | <ol style="list-style-type: none"> <li>ii. The involved nurse/technician is to have special expertise in CIED management and be certified in both Basic Life Support and Pediatric Advanced Life Support.</li> </ol>   | <p><b>(3)(c)1.</b> The cardiac catheterization, electrophysiology and cardiovascular surgical services must have registered nurses with special training in cardiovascular techniques in the care of pediatric and adult congenital heart patients and have skills in the pre and post procedure evaluations and provision of instruction to the patient and their family members.</p> <p><b>2.</b> Registered nurses providing care in the cardiac catheterization and electrophysiology laboratories must be trained and experienced with cardiovascular implantable electronic device management and be certified in Basic Life Support and Pediatric Advanced Life Support.</p> |
| 80   | <ol style="list-style-type: none"> <li>2. Device Management: Pacemaker, Implantable Cardioverter Defibrillator (ICD) and Cardiac Resynchronization Therapy (CRT) device monitoring may be performed by combining both in-clinic and remote (home) monitoring.</li> </ol>   | <p><b>(2)(d)2.</b> Provide arrhythmia (holter) monitoring, implanted electronic device monitoring, stress testing, imaging, and pulmonary function testing to meet the needs of the pediatric and adult congenital patients;</p>  |

## Crosswalk PCTAP Recommendations to Proposed Rule 59A-3.248 2 (002).xlsx

| Pediatric and Congenital Cardiovascular Center Recommended Standards  | Proposed Rule 59A-3.248   |
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| <p>81 3. Equipment</p> <p>a. For in-clinic monitoring – the following items must be available: Electrocardiographic (EKG) recording machine, external defibrillator, and proprietary CIED programmers from every company pertinent to the patients being seen.</p> <p>b. For remote monitoring, some form of surveillance must be available including traditional trans-telephonic monitoring (TTM).</p>  | <p><b>(5)(c)</b> Each hospital must have age and size appropriate equipment available for patients receiving pediatric cardiac services, including:</p> <ol style="list-style-type: none"> <li>1. Multi-dimensional imaging equipment for magnetic resonance imaging/magnetic resonance angiography, computed tomography, echocardiography, and scintigraphy;</li> <li>2. A special procedure x-ray room with diagnostic x-ray examination table;</li> <li>3. X-ray equipment with the capability in cineangiocardiology, or equipment with similar capabilities;</li> <li>4. An image intensifier;</li> <li>5. An automatic injector;</li> <li>6. An electrocardiograph;</li> <li>7. A multi-channel electrophysiology recording system;</li> <li>8. A cardiopulmonary monitoring system;</li> <li>9. Emergency equipmernt, including temprary pacemaker units with catheters, ventilatory assistance devices, and a DC defibrillator;</li> <li>10. Biplane angiography, with framing rates of 30-60 fps and injection rates of up to 40 mL/s; and</li> <li>11. Extra Corporeal Membrane Oxygenation machine.</li> </ol> |
| <p>82 4. Records: A complete database of patients with devices should be maintained and to include all device models and ID numbers, Lead models and ID numbers.</p> <p>a. Records generated from the pacemaker visits shall be maintained for a minimum of 7 years.</p>  | <p><b>(5)(e)</b> In addition to the requirements in rule 59A-3.270, each hospital shall maintain a complete database of patients with devices to include all device models and ID numbers, and Lead models and ID numbers.</p>  |
| <p>83 V. Advanced Congenital Cardiac Imaging</p> <p>A. Imaging modalities</p> <p>Advanced diagnostic imaging provides multi- dimensional imaging and quantitative data used to plan cardiac interventions. These modalities shall include, but are not limited to:</p> <ol style="list-style-type: none"> <li>1. Cardiac MRI, MRA with 3D reconstructions</li> <li>2. Cardiac Computed Tomography, CT angiography, 3D reconstructions, coronary CTA</li> <li>3. Pulmonary scintigraphy</li> </ol> | <p><b>(5)(c)</b> Each hospital must have age and size appropriate equipment available for patients receiving pediatric cardiac services, including:</p> <ol style="list-style-type: none"> <li>1. Multi-dimensional imaging equipment for magnetic resonance imaging/magnetic resonance angiography, computed tomography, echocardiography, and scintigraphy;</li> <li>2. A special procedure x-ray room with diagnostic x-ray examination table;</li> <li>3. X-ray equipment with the capability in cineangiocardiology, or equipment with similar capabilities;</li> <li>4. An image intensifier;</li> <li>5. An automatic injector;</li> <li>6. An electrocardiograph;</li> <li>7. A multi-channel electrophysiology recording system;</li> <li>8. A cardiopulmonary monitoring system;</li> <li>9. Emergency equipmernt, including temprary pacemaker units with catheters, ventilatory assistance devices, and a DC defibrillator;</li> <li>10. Biplane angiography, with framing rates of 30-60 fps and injection rates of up to 40 mL/s; and</li> <li>11. Extra Corporeal Membrane Oxygenation machine.</li> </ol> |

## Crosswalk PCTAP Recommendations to Proposed Rule 59A-3.248 2 (002).xlsx

### Pediatric and Congenital Cardiovascular Center Recommended Standards

### Proposed Rule 59A-3.248

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| 84 | <p><b>B. Team Members:</b></p> <ol style="list-style-type: none"> <li>1. Physicians                     <ol style="list-style-type: none"> <li>a. Physician in Charge: The physician in charge shall be a board certified radiologist or board certified pediatric trained cardiologist responsible for overseeing protocol development, adherence, staffing development, facility/equipment standards, and quality assurance processes for advanced imaging of congenital cardiac disease.</li> </ol> </li> <li>2. Physician Credentialing- Cardiac MRI, MRA                     <ol style="list-style-type: none"> <li>a. Radiology Track: Physician with board certification in radiology or within 2 years of radiology residency shall fulfill 2008 ACCF COCATS3 requirements for Level 2 training specific to congenital cardiac MRI.</li> <li>b. Cardiology Track: Physician with board certification in Pediatric Cardiology or within 2 years of training shall fulfill the 2008 ACCF COCATS3 requirements for Level 2 training in congenital cardiac MRI.</li> <li>c. MAINTENANCE: All physicians performing cardiac MRI examinations shall demonstrate evidence of continuing education and competence in the interpretation and reporting of MRI examinations.</li> </ol> </li> <li>3. Physician Experience Congenital Cardiac Computed Tomography                     <ol style="list-style-type: none"> <li>a. Education in cardiac anatomy, physiology, pathology, and cardiac CT imaging for a time equivalent to at least 30 hours of CME and including                             <ol style="list-style-type: none"> <li>b. Physician with board certification in radiology or within 2 years of radiology training shall fulfill 2008 ACCF COCATS3 requirements for Level 2 training specific to congenital cardiac CT.</li> </ol> </li> <li>c. MAINTENANCE: Physicians performing cardiac CT examinations shall demonstrate evidence of continuing education and competence in the interpretation and reporting of cMRI examinations</li> </ol> </li> </ol> |
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- (3)(b)7.** The organized medical staff membership shall contain a complement of physicians with training or experience with pediatric cardiac patients to be available for consultation as needed, including:
- a. Pediatric cardiologists;
  - b. Pediatric sub-specialists with expertise in hematology, nephrology, neurology, infectious disease, critical care, genetics, gastroenterology and pulmonology;
  - c. Radiologists;

NOTE: Hospital governing boards are responsible for the physician credentialing procedure per 59A-3.272

# Crosswalk PCTAP Recommendations to Proposed Rule 59A-3.248 2 (002).xlsx

| Pediatric and Congenital Cardiovascular Center Recommended Standards   | Proposed Rule 59A-3.248  |
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| <p>85 C. Facilities</p> <ol style="list-style-type: none"> <li>1. Testing environment                             <ol style="list-style-type: none"> <li>a. The imaging environment shall be conducive to patient safety, comfort, and cooperation.</li> </ol> </li> <li>2. Imaging equipment, software                             <ol style="list-style-type: none"> <li>a. Cardiac MRI scanners shall be ACR accredited with equipment performance monitoring in accordance with state, federal requirements.</li> <li>b. Cardiac MRI scanners shall have field strength of &gt; 1.5 Tesla and equipped with localized multichannel radiofrequency surface coil and ECG gating. ECG gating capabilities shall include prospective triggering, retrospective gating, and triggered retrogating.</li> <li>c. An MRI-compatible power injector is required for performing myocardial perfusion MR imaging or any MR angiographic methods.</li> <li>d. The MRI scanner shall be capable of fast 3-D gradient-echo imaging, steady-state imaging with free precession, phase-contrast flow quantification, fast multi-slice myocardial perfusion imaging, and late contrast-enhanced myocardial imaging. Parallel imaging and half-Fourier capabilities are desirable to permit shortened breath-hold requirements.</li> <li>e. Commercial FDA-approved software for processing data (calculation of ejection fractions, reformatting angiographic data) shall be available either as part of the MRI system or on a separate workstation. Post-processing shall be performed or supervised by the cardiac MRI physician.</li> </ol> </li> </ol> | <p><b>(5)(c)</b> Each hospital must have age and size appropriate equipment available for patients receiving pediatric cardiac services, including:</p> <ol style="list-style-type: none"> <li>1. Multi-dimensional imaging equipment for magnetic resonance imaging/magnetic resonance angiography, computed tomography, echocardiography, and scintigraphy;</li> <li>2. A special procedure x-ray room with diagnostic x-ray examination table;</li> <li>3. X-ray equipment with the capability in cineangiocardiology, or equipment with similar capabilities;</li> <li>4. An image intensifier;</li> <li>5. An automatic injector;</li> <li>6. An electrocardiograph;</li> <li>7. A multi-channel electrophysiology recording system;</li> <li>8. A cardiopulmonary monitoring system;</li> <li>9. Emergency equipment, including temporary pacemaker units with catheters, ventilatory assistance devices, and a DC defibrillator;</li> <li>10. Biplane angiography, with framing rates of 30-60 fps and injection rates of up to 40 mL/s; and</li> <li>11. Extra Corporeal Membrane Oxygenation machine.</li> </ol> <p><b>(d)</b> Cardiac MRI scanners shall:</p> <ol style="list-style-type: none"> <li>1. Be accredited by a national accrediting organization that is approved by the Centers for Medicare and Medicaid Services for magnetic resonance imaging and advanced diagnostic imaging services;</li> <li>2. Have field strength of &gt; 1.5 Tesla and equipped with localized multichannel radiofrequency surface coil and ECG gating capable of prospective triggering, retrospective gating, and triggered retrogating;</li> <li>3. Have an MRI-compatible power injector for performing myocardial perfusion MR imaging or any MR angiographic methods.</li> <li>4. Be capable of fast 3-D gradient-echo imaging, steady-state imaging with free precession, phase-contrast flow quantification, fast multi-slice myocardial perfusion imaging, and late contrast-enhanced myocardial imaging. Parallel imaging and half-Fourier capabilities are desirable to permit shortened breath-hold requirements.</li> </ol> |
| <p>86 3. Emergency equipment</p> <ol style="list-style-type: none"> <li>a. Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications.</li> <li>b. The equipment and medications shall be monitored for inventory and drug expiration dates on a regular basis. The equipment, medications, and other emergency support must be appropriate for the range of ages and sizes in the patient population.</li> </ol>   | <p><b>(5)(b)2.</b> A crash cart containing the necessary medication and age and size appropriate equipment for ventilatory support. A listing of all crash cart contents shall be readily available. At the beginning of each shift, the crash cart shall be checked for intact lock; the defibrillator and corresponding equipment shall be checked for function and operational capacity. A log shall be maintained indicating review.</p>   |
| <p>87 D. Records and archive requirements</p> <ol style="list-style-type: none"> <li>1. Reporting shall be available in the electronic medical records in accordance to facility reporting timelines.</li> </ol>   | <p>NOTE: Hospital wide requirements per 59A-3.270</p>  |

## Crosswalk PCTAP Recommendations to Proposed Rule 59A-3.248 2 (002).xlsx

| Pediatric and Congenital Cardiovascular Center Recommended Standards   | Proposed Rule 59A-3.248  |
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| 88 E. A quality improvement process shall be utilized to evaluate for completeness, correlation and accuracy.  | <b>(2)(a)2</b> Develop a quality assurance and improvement program, including a risk adjustment surgical procedure protocol following the guidelines established by the Society of Thoracic Surgeons, to monitor processes and outcomes, analyze data, and identify system improvements for each component of pediatric cardiac services, and integrate the program into the hospital wide quality improvement program as required by rule 59A-3.271, F.A.C.   |
| 89 VI. Pediatric and Congenital Cardiovascular Centers<br>The Secretary of AHCA or designee considers existing facilities for continuing involvement based upon the recommendation of the PCTAP and all the criteria established above. The Secretary of AHCA or designee shall make the final decision as to whether or not to continue such an agreement with the Agency.  | NOTE: AHCA licensure process.  |
| 90 A. Diagnosis and treatment are so closely related that an AHCA Pediatric and Congenital Cardiovascular Surgical Program, AHCA Pediatric Cardiac Catheterization Laboratory Component and an AHCA Pediatric Cardiology Clinic Component must be co-located on the same campus.<br>B. General pediatric coverage with sub-specialty capability twenty-four hours a day, seven days a week.<br>C. An effective system (with documentation) of rapid referral and transportation.   | <b>(2)(a)</b> A hospital providing pediatric cardiac services shall:<br>1. Ensure all staff participating as members of the catheterization team or cardiovascular surgery team, including physicians, nurses, and technical staff must participate in a 24 hours per day, 7 days per week call schedule capable of rapid mobilization of the team(s) within 30 minutes for emergency catheterization procedures and capable of cardiovascular surgery within 2 hours;<br><br><b>(2)(d)</b> Ambulatory care clinics serving pediatric and adult congenital patients must be located on the hospital premises   |
| 91 D. Cardiac Team – Pediatric and Congenital Cardiovascular Surgical Program must have accredited pediatric and general surgery training programs with house staff or must have other arrangements to provide 24-hour physician or house staff coverage.<br>1. DOH credentialed thoracic and cardiovascular surgeon with special training, interest and experience with pediatric cardiac patients and certification by the American Board of Thoracic Surgery. All such surgeons will have 5 years to become Board Certified after becoming eligible for such an examination.<br>2. DOH credentialed associate thoracic and cardiovascular surgeon with special training interest and experience with pediatric cardiac patients and certification by the American Board of Thoracic Surgery. Such an associate surgeon should be either “on-site”, available through an established agreement with another AHCA PCCC, or available by an established organizational format approved by the Secretary of AHCA or designee. | <b>(2)(a)</b> A hospital providing pediatric cardiac services shall:<br>1. Ensure all staff participating as members of the catheterization team or cardiovascular surgery team, including physicians, nurses, and technical staff must participate in a 24 hours per day, 7 days per week call schedule capable of rapid mobilization of the team(s) within 30 minutes for emergency catheterization procedures and capable of cardiovascular surgery within 2 hours;<br><br><b>(3)(b) 4.</b> Board eligible physicians must be board certified within 5 years of becoming eligible.<br><b>5.</b> A physician who is not board certified, or who is not eligible due to foreign training or similar circumstance may provide pediatric cardiac services upon documentation of education, training, or alternative certification acceptable to the medical director and hospital’s governing board or designated credentialing committee.<br><br>NOTE: Hospital governing boards are responsible for the physician credentialing procedure per 59A-3.272 |
| 92 3. In regards to the above thoracic and cardiovascular surgeons, since the new Sub-Board of PCCC under the American Board of Thoracic Surgery is now fully implemented, at least one surgeon who started such training after July 1, 2008 must be certified by this new Board within 5 years of becoming eligible.  | <b>(3)(b)3.</b> At least one pediatric cardiovascular surgeon shall be board certified or eligible by the American Board of Thoracic Surgery, specialty certification in congenital cardiac surgery.   |

## Crosswalk PCTAP Recommendations to Proposed Rule 59A-3.248 2 (002).xlsx

| Pediatric and Congenital Cardiovascular Center Recommended Standards   | Proposed Rule 59A-3.248   |
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| <p>93 4. Pediatric and congenital heart cardiac surgeons, either trained in other countries or for any other reason not eligible for certification by the American Board of Thoracic Surgery, or the new Sub-Board of Pediatric and Congenital Cardiovascular Surgery, may be credentialed as an DOH physician by the Surgeon General/Secretary of the Department of Health or designee as a special situation after a review and in-depth evaluation by the PCTAP, which recommended such approval.</p> | <p><b>(3)(b)5.</b> A physician who is not board certified, or who is not eligible due to foreign training or similar circumstance may provide pediatric cardiac services upon documentation of education, training, or alternative certification acceptable to the medical director and hospital's governing board or designated credentialing committee.</p>   |
| <p>94 5. Pediatric sub-specialists with expertise in hematology, nephrology, neurology, infectious disease, critical care, genetics, gastroenterology and pulmonology must be available for consultation and management of patients with heart disease.<br/>6. Radiologist trained in cardiopulmonary disease.<br/>7. Anesthesiologist with training and experience in open and closed heart pediatric anesthesia.</p>   | <p><b>(3)(b)7.</b> The organized medical staff membership shall contain a complement of physicians with training or experience with pediatric cardiac patients to be available for consultation as needed, including:<br/><b>a.</b> Pediatric cardiologists;<br/><b>b.</b> Pediatric sub-specialists with expertise in hematology, nephrology, neurology, infectious disease, critical care, genetics, gastroenterology and pulmonology;<br/><b>c.</b> Radiologists;<br/><b>d.</b> Anesthesiologists; and<br/><b>e.</b> Pathologists.</p> |
| <p>95 8. Respiratory Therapist with training and experience in short and long- term ventilatory support in infants and children.<br/>9. Technicians available 24 hours a day for laboratory and radiology procedures.</p>  | <p><b>(3)(d)</b> Additional Staff. Each hospital providing pediatric cardiac services shall have a number of perfusionists, cardiovascular technologists, respiratory therapists, radiologic technicians, clinical laboratory personnel, and social workers available at all times to meet the needs of any patient.</p>  |
| <p>96 10. Specially trained nurses for preoperative evaluation and instruction of the patient and family, intensive care, and convalescent care.</p>   | <p><b>(3)(c)1.</b> The cardiac catheterization, electrophysiology and cardiovascular surgical services unit must have registred nurses with special training in cardiovascular techniques in the care of pediatric and adult congenital heart patients and have skills in the pre and post procedure evaluations and provision of instruction to the patient and their family members.</p>  |
| <p>97 11. Pathologist with skills and training in cardiovascular pathology.</p>  | <p><b>(3)(b)7.</b> The organized medical staff membership shall contain a complement of physicians with training or experience with pediatric cardiac patients to be available for consultation as needed, including:<br/><b>a.</b> Pediatric cardiologists;<br/><b>b.</b> Pediatric sub-specialists with expertise in hematology, nephrology, neurology, infectious disease, critical care, genetics, gastroenterology and pulmonology;<br/><b>c.</b> Radiologists;<br/><b>d.</b> Anesthesiologists; and<br/><b>e.</b> Pathologists.</p> |
| <p>98 12. The facility must identify and utilize a core surgical team.<br/>13. Involved staff will make a priority of maintaining on-going communication throughout the patient's hospital course with the patient's primary care physician.<br/>14. Continuous availability of a team skilled in performing intra-operative TEE's to aid in the post-surgical assessment of operative procedures.</p>   | <p><b>(a)</b> A hospital providing pediatric cardiac services shall:<br/><b>1.</b> Ensure all staff participating as members of the catheterization team or cardiovascular surgery team, including physicians, nurses, and technical staff must participate in a 24 hours per day, 7 days per week call schedule capable of rapid mobilization of the team(s) within 30 minutes for emergency catheterization procedures and capable of cardiovascular surgery within 2 hours;</p>  |

## Crosswalk PCTAP Recommendations to Proposed Rule 59A-3.248 2 (002).xlsx

| Pediatric and Congenital Cardiovascular Center Recommended Standards |   | Proposed Rule 59A-3.248   |
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| 99   | 15. Availability of Extra Corporeal Membrane Oxygenation (ECMO)   | <b>(5)(c)11.</b> Extra Corporeal Membrane Oxygenation machine.  |
| 100  | <p>E. Pre-operative Preparation</p> <ol style="list-style-type: none"> <li>1. Dedicated pediatric patient rooms with provision for a parent, relative or guardian to remain overnight with hospitalized child.</li> <li>2. Clear instructions to parents and patient with pre-operative visits to catheterization laboratory, intensive care unit, and other sites as needed, consistent with their ability to comprehend.</li> <li>3. Care management conference between the pediatric cardiologist, pediatric and congenital heart cardiac surgeon, and other professional staff as necessary documented in the patient record.</li> </ol>  | <p><b>(2)(f)</b> Each hospital must have policies and procedures for accommodating a parent, relative or guardian of a pediatric patient to stay overnight with the patient.</p>  |
| 101  | <p>F. Post-operative Care</p> <ol style="list-style-type: none"> <li>1. All post-operative care must be under the direction of the involved DOH credentialed cardiovascular surgeons in constant (24/7) communication with, and in support of, the post-operative cardiovascular team composed of pediatric intensivists, cardiologists, neonatologists, anesthesiologists, and other personnel as needed. In certain cases, the involved pediatric and congenital heart cardiac surgeon may transfer primary responsibilities to another member of the team, such as cases with arrhythmias, or neonates on Extra Corporeal Membrane Oxygenation (ECMO) in the neonatal intensive care unit (NICU).</li> </ol> | <p><b>(3)(b)7.</b> The organized medical staff membership shall contain a complement of physicians with training or experience with pediatric cardiac patients to be available for consultation as needed, including:</p> <ol style="list-style-type: none"> <li>a. Pediatric cardiologists;</li> <li>b. Pediatric sub-specialists with expertise in hematology, nephrology, neurology, infectious disease, critical care, genetics, gastroenterology and pulmonology;</li> <li>c. Radiologists;</li> <li>d. Anesthesiologists; and</li> <li>e. Pathologists.</li> </ol>  |
| 102  | <p>2. Each AHCA Pediatric and Congenital Cardiovascular Surgical Facility must have a dedicated Pediatric and Congenital Cardiovascular Intensive Care Unit with personnel specially trained in Congenital Heart Disease, including physicians, nurses, respiratory specialists, and ancillary staff. Such a unit may be either a separate cardiac ICU or a dedicated component within a Pediatric Intensive Care Unit. <i>Guidelines for Pediatric Cardiovascular Centers: Pediatrics. 2002: Vol. 109 No. 3 544-549</i></p>  | <p>NOTE: Refer to definitions in rule 59A-3.065, FAC<br/> “Pediatric cardiac services” means integrated hospital services providing age-appropriate diagnostic and interventional cardiac catheterization and cardiovascular surgical services on the premises of the hospital and available 24 hours per day, 7 days per week to pediatric and adult congenital patients. Hospitals providing pediatric cardiac services must have the capability to provide treatment of cardiac trauma, coronary angioplasty, valvuloplasty, echocardiography, cardiac electrophysiology, advanced cardiac imaging, post-operative intensive care, and outpatient cardiac clinic services. For the purpose of Rule 59A-3.248, F.A.C., cardiovascular surgical services does not include heart transplantation.</p> |
| 103  | <p>3. The facility must be co-located with an AHCA Pediatric Cardiology Clinic Facility and an AHCA Pediatric Catheterization facility.</p>   | <p><b>(2)(d)</b> Ambulatory care clinics serving pediatric and adult congenital patients must be located on the hospital premises<br/> NOTE: All hospital inpatient services must be provided within a licensed facility.</p>   |

## Crosswalk PCTAP Recommendations to Proposed Rule 59A-3.248 2 (002).xlsx

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| <b>Pediatric and Congenital Cardiovascular Center Recommended Standards</b> |
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| <b>Proposed Rule 59A-3.248</b> |
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| 104 | <p>4. All AHCA PCCC must collect and submit the following quality assurance data to STS:</p> <ul style="list-style-type: none"> <li>a. Number of patients/ operations submitted and an analysis, operative mortality, and complexity information, by year</li> <li>b. Number of patients/operations in analysis, operative mortality, and complexity information, by age group</li> <li>c. Primary procedure outcomes, by anomaly</li> <li>d. STS-EACTS (STAT) Mortality Category Operative Mortality, by year</li> <li>e. STS-EACTS (STAT) Mortality Category Operative Mortality, by age group</li> </ul> |
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| <p><b>(7)(b) 13.</b> The following quality assurance data must be compiled annually from their Society of Thoracic Surgeons Congenital Heart Surgery Database Report and available for Agency review upon request:</p> <ul style="list-style-type: none"> <li>a. Number of patients/operations submitted and an analysis of operative mortality, and complexity information, by year;</li> <li>b. Number of patient/operations in analysis, operative mortality, and complexity information, by age group;</li> <li>c. Primary Procedure Operative Mortality;</li> <li>d. Society of Thoracic Surgeons - European Association of Cardio-Thoracic Surgery Mortality Category Operative Mortality, by year;</li> <li>e. Society of Thoracic Surgeons - European Association of Cardio-Thoracic Surgery Mortality Category Operative Mortality, by age group.</li> </ul> |
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# 2019 FLORIDA STATUTE

**395.1055 (10) – (15) Rules and enforcement.—**

(10) The agency shall establish a pediatric cardiac technical advisory panel, pursuant to s. 20.052, to develop procedures and standards for measuring outcomes of pediatric cardiac catheterization programs and pediatric cardiovascular surgery programs.

(a) Members of the panel must have technical expertise in pediatric cardiac medicine, shall serve without compensation, and may be reimbursed for per diem and travel expenses.

(b) Voting members of the panel shall include: 3 at-large members, and 3 alternate at-large members with different program affiliations, including 1 cardiologist who is board certified in caring for adults with congenital heart disease and 2 board-certified pediatric cardiologists, neither of whom may be employed by any of the hospitals specified in subparagraphs 1.-10. or their affiliates, each of whom is appointed by the Secretary of Health Care Administration, and 10 members, and an alternate for each member, each of whom is a pediatric cardiologist or a pediatric cardiovascular surgeon, each appointed by the chief executive officer of the following hospitals:

1. Johns Hopkins All Children's Hospital in St. Petersburg.
2. Arnold Palmer Hospital for Children in Orlando.
3. Joe DiMaggio Children's Hospital in Hollywood.
4. Nicklaus Children's Hospital in Miami.
5. St. Joseph's Children's Hospital in Tampa.
6. University of Florida Health Shands Hospital in Gainesville.
7. University of Miami Holtz Children's Hospital in Miami.
8. Wolfson Children's Hospital in Jacksonville.
9. Florida Hospital for Children in Orlando.
10. Nemours Children's Hospital in Orlando.

Appointments made under subparagraphs 1.-10. are contingent upon the hospital's compliance with this section and rules adopted thereunder, as determined by the Secretary of Health Care Administration. A member appointed under subparagraphs 1.-10. whose hospital fails to comply with such standards may serve only as a nonvoting member until the hospital complies with such standards. A voting member may serve a maximum of two 2-year terms and may be reappointed to the panel after being retired from the panel for a full 2-year term.

(c) The Secretary of Health Care Administration may appoint nonvoting members to the panel. Nonvoting members may include:

1. The Secretary of Health Care Administration.
2. The Surgeon General.
3. The Deputy Secretary of Children's Medical Services.
4. Any current or past Division Director of Children's Medical Services.

5. A parent of a child with congenital heart disease.
6. An adult with congenital heart disease.
7. A representative from each of the following organizations: the Florida Chapter of the American Academy of Pediatrics, the Florida Chapter of the American College of Cardiology, the Greater Southeast Affiliate of the American Heart Association, the Adult Congenital Heart Association, the March of Dimes, the Florida Association of Children's Hospitals, and the Florida Society of Thoracic and Cardiovascular Surgeons.

(d) The panel shall meet biannually, or more frequently upon the call of the Secretary of Health Care Administration. Such meetings may be conducted telephonically, or by other electronic means.

(e) The duties of the panel include recommending to the agency standards for quality of care, personnel, physical plant, equipment, emergency transportation, and data reporting for hospitals that provide pediatric cardiac services.

(f) Beginning on January 1, 2020, and annually thereafter, the panel shall submit a report to the Governor, the President of the Senate, the Speaker of the House of Representatives, the Secretary of Health Care Administration, and the State Surgeon General. The report must summarize the panel's activities during the preceding fiscal year and include data and performance measures on surgical morbidity and mortality for all pediatric cardiac programs.

(g) Panel members are agents of the state for purposes of s. 768.28 throughout the good faith performance of the duties assigned to them by the Secretary of Health Care Administration.

(11) The Secretary of Health Care Administration shall consult the pediatric cardiac technical advisory panel for an advisory recommendation on any certificate of need applications to establish pediatric cardiac surgical centers.

(12) Based on the recommendations of the pediatric cardiac technical advisory panel, the agency shall adopt rules for pediatric cardiac programs which, at a minimum, include:

(a) Standards for pediatric cardiac catheterization services and pediatric cardiovascular surgery including quality of care, personnel, physical plant, equipment, emergency transportation, data reporting, and appropriate operating hours and timeframes for mobilization for emergency procedures.

(b) Outcome standards consistent with nationally established levels of performance in pediatric cardiac programs.

(c) Specific steps to be taken by the agency and licensed facilities when the facilities do not meet the outcome standards within a specified time, including time required for detailed case reviews and the development and implementation of corrective action plans.

(13) A pediatric cardiac program shall:

(a) Have a pediatric cardiology clinic affiliated with a hospital licensed under this chapter.

(b) Have a pediatric cardiac catheterization laboratory and a pediatric cardiovascular surgical program located in the hospital.

(c) Have a risk adjustment surgical procedure protocol following the guidelines established by the Society of Thoracic Surgeons.

(d) Have quality assurance and quality improvement processes in place to enhance clinical operation and patient satisfaction with services.

(e) Participate in the clinical outcome reporting systems operated by the Society of Thoracic Surgeons and the American College of Cardiology.

(14)(a) The Secretary of Health Care Administration may request announced or unannounced site visits to any existing pediatric cardiac surgical center or facility seeking licensure as a pediatric cardiac surgical center through the certificate of need process, to ensure compliance with this section and rules adopted hereunder.

(b) At the request of the Secretary of Health Care Administration, the pediatric cardiac technical advisory panel shall recommend in-state physician experts to conduct an onsite visit. The Secretary may also appoint up to two out-of-state physician experts.

(c) A site visit team shall conduct an onsite inspection of the designated hospital's pediatric medical and surgical programs, and each member shall submit a written report of his or her findings to the panel. The panel shall discuss the written reports and present an advisory opinion to the Secretary of Health Care Administration which includes recommendations and any suggested actions for correction.

(d) Each onsite inspection must include all of the following:

1. An inspection of the program's physical facilities, clinics, and laboratories.
2. Interviews with support staff and hospital administrators.
3. A review of:
  - a. Randomly selected medical records and reports, including, but not limited to, advanced cardiac imaging, computed tomography, magnetic resonance imaging, cardiac ultrasound, cardiac catheterization, and surgical operative notes.
  - b. The program's clinical outcome data submitted to the Society of Thoracic Surgeons and the American College of Cardiology pursuant to s. 408.05(3)(k).
  - c. Mortality reports from cardiac-related deaths that occurred in the previous year.
  - d. Program volume data from the preceding year for interventional and electrophysiology catheterizations and surgical procedures.

(15) The Surgeon General shall provide quarterly reports to the Secretary of Health Care Administration consisting of data from the Children's Medical Services' critical congenital heart disease screening program for review by the advisory panel.

# SUNSHINE LAW REVIEW



## Sunshine Law

- The Sunshine Law is established by Article I, Section 24 of the Florida State Constitution and Chapter 286, Florida Statutes.

## SUNSHINE LAW

- A collegial body is subject to the Sunshine Law. Any gathering (this includes email communications) of two or more members of the collegial body to discuss some matter on which foreseeable action will be taken by the collegial body is considered a meeting subject to Sunshine Law requirements.

## Collegial Body

Examples:

- Commission or council
- Advisory board
- Ad hoc committee
- Task force

## Basic Requirements

- The Sunshine Law imposes three basic requirements:
  1. Meetings of the collegial body must be open to the public
  2. The collegial body must give "reasonable notice" of its meetings
  3. The collegial body must keep minutes of its meetings

## MEETINGS

- A "meeting" of a body subject to the Sunshine Law is broadly defined to include any gathering – formal or informal – during which two or more members of the body discuss the official business of the body. Accordingly, business-related discussions between members of the collegial body may only take place at open, properly-noticed meetings. Members may not discuss the business of the collegial body with each other through private phone conversations or e-mail discussions. Members may distribute documents to each other, but they may not discuss or exchange comments on those documents outside of a public meeting.



## MEETINGS

- In addition, members may discuss business with third parties (i.e., non-members of the body); provided the members do not use a third party as a liaison for business-related communication with other members.

## NOTICE

- "Reasonable notice" of public meetings is required. AHCA follows Section 120.525, Fla. Stat. in providing public meeting notice, which dictates the following:

## NOTICE

- Notice of public meetings, hearings, and workshops shall be by publication in the Florida Administrative Register not less than 7 days before the event. The notice shall include a statement of the general subject matter to be considered.

## NOTICE

- An agenda shall be prepared in time to ensure that a copy of the agenda may be received at least 7 days before the event by any person in the state who requests a copy and who pays the reasonable cost of the copy. The agenda shall contain the items to be considered in order of presentation. After the agenda has been made available, a change shall be made only for good cause, as determined by the person designated to preside, and stated in the record. Notification of such change shall be at the earliest practicable time.

## MINUTES

- Although the Sunshine Law requires the collegial body to record minutes of its meetings, such minutes need not be verbatim transcripts of the proceedings. A summary or notes of the meeting is sufficient. It is within the collegial body's discretion to determine who is responsible for creating the minutes of meetings.

## SUNSHINE LAW AND PUBLIC RECORDS

- As a general matter, any documents or other materials that are (1) created or received by collegial body members, (2) related to the collegial body's official business are "public records" which must be made available to the public for inspection and copying.

## EXAMPLES OF “PUBLIC RECORDS”

These are all considered “public records” if they are used to “perpetuate, communicate, or formalize knowledge.”

- Reports – circulated drafts of such reports
- Business related correspondence between collegial body members and AHCA, or any member of the public
- E-mail between collegial body members and AHCA, or any member of the public
- Personal notes of collegial body members

## CONFIDENTIAL INFORMATION

- It is possible that records created by the collegial body will include information that is considered confidential and exempt from the Public Records Law. For example, some information which could conceivably come before the collegial body, such as Medicaid recipient identifying information and medical records, is confidential and exempt. In the event that a collegial body document were to include confidential information, the relevant portions of that document would have to be redacted before the document could be released to the public. Collegial body members should also take care during the public meetings not to discuss information derived from such confidential records.

## Public participation

- S. 286.0114, Fla. Stat. requires that members of the public be given reasonable opportunity to be heard on a proposition that is before the Council.
- The opportunity to be heard does not apply to acts which are ministerial, for example, the approval of minutes.

## Public participation

- The Panel may develop guidelines for public participation such as providing time limits for speakers, having a single representative speak for a group, using "speakers' cards," or designating a specific time period for public comment.

## Penalties

- Knowing violations of the Sunshine Law are second degree misdemeanors, which carry a maximum sentence of 60 days and up to a \$500 fine.
- Public officers who violate the law have committed a non-criminal infraction, punishable by a fine of up to \$500.

### Broward Hospital Leaders Indicted On Sunshine Charges By THE NEWS SERVICE OF FLORIDA • DEC 13, 2017

Four current and former North Broward Hospital District commissioners and the district's general counsel have been indicted on misdemeanor charges that they violated the state's open-government law in the firing of former interim President and CEO Pauline Grant.

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The indictment alleges that in the two weeks leading up to Grant's dismissal, board commissioners "through conduits or intermediaries" met at a restaurant at the Westin Hotel or "through telephonic communications" and that "business or official acts were discussed on which foreseeable action was taken." The meetings, according to the grand jury indictment, were not publicly noticed as required by law. The indictment also alleges that the district did not properly notice the meeting where commissioners voted to terminate Grant and, therefore, the public was "denied a reasonable opportunity to be heard" regarding her dismissal.

STS REPORT MOCK UP  
(1 OF 2)

**The Society of Thoracic Surgeons - STS Public Reporting Online -  
Operative and Adjusted Operative Mortality, Last 4 Years (January 2015 - December 2018)**

[https://publicreporting.sts.org/chsd?title=&field\\_state\\_value=FL](https://publicreporting.sts.org/chsd?title=&field_state_value=FL)

| Hospital Name   | Population: Neonates,<br>Infants, Children & Adults | #  | Eligible | Observed | Expected | O/E Ratio (95% CI) | Adj. Rate (95% CI) | Overall Star<br>Rating |
|---|---|----|----------|----------|----------|--------------------|--------------------|------------------------|
| <a href="#">Arnold Palmer Medical Center</a>          | Overall   | 11 | 480      | 2.3%     | 3.6%     | 0.64 (0.32, 1.14)  | 1.8 (0.9, 3.2)     | ★★                     |
|   | STAT Mortality Category 1                           | 0  | 125      | 0%       | 0.4%     | 0 (0, 7)           | 0 (0, 2.7)         |                        |
|   | STAT Mortality Category 2                           | 2  | 183      | 1.1%     | 2.1%     | 0.53 (0.06, 1.88)  | 0.8 (0.1, 2.8)     |                        |
|   | STAT Mortality Category 3                           | 1  | 52       | 1.9%     | 3.1%     | 0.62 (0.02, 3.3)   | 1.3 (0, 7.1)       |                        |
|   | STAT Mortality Category 4                           | 5  | 88       | 5.7%     | 6.9%     | 0.82 (0.27, 1.84)  | 5.2 (1.7, 11.6)    |                        |
|   | STAT Mortality Category 5                           | 3  | 32       | 9.4%     | 16.1%    | 0.58 (0.12, 1.56)  | 8.1 (1.7, 21.7)    |                        |
| <a href="#">Florida Hospital for Children</a>         | Overall   | 15 | 477      | 3.1%     | 2.3%     | 1.39 (0.78, 2.27)  | 3.9 (2.2, 6.4)     | ★★                     |
|   | STAT Mortality Category 1                           | 0  | 139      | 0%       | 0.3%     | 0 (0, 7.68)        | 0 (0, 3)           |                        |
|   | STAT Mortality Category 2                           | 4  | 202      | 2%       | 1.3%     | 1.5 (0.41, 3.79)   | 2.3 (0.6, 5.7)     |                        |
|   | STAT Mortality Category 3                           | 3  | 42       | 7.1%     | 2.8%     | 2.51 (0.53, 6.84)  | 5.4 (1.1, 14.7)    |                        |
|   | STAT Mortality Category 4                           | 8  | 85       | 9.4%     | 6%       | 1.57 (0.69, 2.96)  | 9.9 (4.4, 18.6)    |                        |
|   | STAT Mortality Category 5                           | 0  | 9        | 0%       | 15.2%    | 0 (0, 2.21)        | 0 (0, 30.8)        |                        |
| <a href="#">Holtz Children's Hospital</a>             | Overall   | 11 | 328      | 3.4%     | 2%       | 1.66 (0.83, 2.93)  | 4.7 (2.3, 8.2)     | ★★                     |
|   | STAT Mortality Category 1                           | 1  | 119      | 0.8%     | 0.3%     | 2.69 (0.07, 14.73) | 1.1 (0, 5.8)       |                        |
|   | STAT Mortality Category 2                           | 2  | 114      | 1.8%     | 1.2%     | 1.47 (0.18, 5.19)  | 2.2 (0.3, 7.8)     |                        |
|   | STAT Mortality Category 3                           | 0  | 22       | 0%       | 1.5%     | 0 (0, 10.59)       | 0 (0, 22.7)        |                        |
|   | STAT Mortality Category 4                           | 6  | 61       | 9.8%     | 4%       | 2.45 (0.92, 5.03)  | 15.4 (5.8, 31.7)   |                        |
|   | STAT Mortality Category 5                           | 2  | 12       | 16.7%    | 17.7%    | 0.94 (0.12, 2.73)  | 13.1 (1.6, 38.1)   |                        |
| <a href="#">Joe DiMaggio Children's Hospital</a>      | Overall   | 21 | 620      | 3.4%     | 3.4%     | 1 (0.62, 1.51)     | 2.8 (1.7, 4.2)     | ★★                     |
|   | STAT Mortality Category 1                           | 0  | 183      | 0%       | 0.3%     | 0 (0, 6.44)        | 0 (0, 2.5)         |                        |
|   | STAT Mortality Category 2                           | 4  | 202      | 2%       | 1.4%     | 1.42 (0.39, 3.59)  | 2.1 (0.6, 5.4)     |                        |
|   | STAT Mortality Category 3                           | 2  | 62       | 3.2%     | 2.2%     | 1.46 (0.18, 5.05)  | 3.1 (0.4, 10.8)    |                        |
|   | STAT Mortality Category 4                           | 9  | 145      | 6.2%     | 8.1%     | 0.76 (0.35, 1.41)  | 4.8 (2.2, 8.9)     |                        |
|   | STAT Mortality Category 5                           | 6  | 28       | 21.4%    | 16.0%    | 1.34 (0.52, 2.56)  | 18.7 (7.2, 35.7)   |                        |
| <a href="#">Johns Hopkins All Children's Hospital</a> | Overall   | 21 | 515      | 4.1%     | 3.0%     | 1.36 (0.85, 2.06)  | 3.8 (2.4, 5.8)     | ★★                     |
|   | STAT Mortality Category 1                           | 0  | 121      | 0%       | 0.4%     | 0 (0, 7.28)        | 0 (0, 2.8)         |                        |
|   | STAT Mortality Category 2                           | 20 | 194      | 1%       | 1.3%     | 0.8 (0.1, 2.86)    | 1.2 (0.1, 4.3)     |                        |
|   | STAT Mortality Category 3                           | 3  | 55       | 5.5%     | 2.1%     | 2.58 (0.54, 7.15)  | 5.5 (1.2, 15.3)    |                        |
|   | STAT Mortality Category 4                           | 11 | 117      | 9.4%     | 6.5%     | 1.46 (0.74, 2.51)  | 9.2 (4.7, 15.8)    |                        |
|   | STAT Mortality Category 5                           | 5  | 28       | 17.9%    | 13.1%    | 1.36 (0.46, 2.81)  | 18.9 (6.4, 39.2)   |                        |



|  |                           |    |      |       |       |                   |                  |     |
|--|---------------------------|----|------|-------|-------|-------------------|------------------|-----|
| Nemours Children's Hospital  | Overall                   | 0  | 0    | 0.00% | 0%    | 0 (0,0)           | 0 (0,0)          |     |
|  | STAT Mortality Category 1 | 0  | 0    | 0.00% | 0%    | 0 (0,0)           | 0 (0,0)          |     |
|  | STAT Mortality Category 2 | 0  | 0    | 0.00% | 0%    | 0 (0,0)           | 0 (0,0)          |     |
|  | STAT Mortality Category 3 | 0  | 0    | 0.00% | 0%    | 0 (0,0)           | 0 (0,0)          |     |
|  | STAT Mortality Category 4 | 0  | 0    | 0.00% | 0%    | 0 (0,0)           | 0 (0,0)          |     |
|  | STAT Mortality Category 5 | 0  | 0    | 0.00% | 0%    | 0 (0,0)           | 0 (0,0)          |     |
| <a href="#">Nicklaus Children's Hospital</a>                           | Overall                   | 29 | 1005 | 2.9%  | 2.6%  | 1.1 (0.74, 1.57)  | 3.1 (2.1, 4.4)   |     |
|  | STAT Mortality Category 1 | 1  | 325  | 0.3%  | 0.4%  | 0.77 (0.02, 4.26) | 0.3 (0, 1.7)     |     |
|  | STAT Mortality Category 2 | 5  | 390  | 1.3%  | 1.5%  | 0.85 (0.28, 1.96) | 1.3 (0.4, 2.9)   | ★ ★ |
|  | STAT Mortality Category 3 | 0  | 79   | 0%    | 1.8%  | 0 (0, 2.54)       | 0 (0, 5.4)       |     |
|  | STAT Mortality Category 4 | 16 | 174  | 9.2%  | 6.7%  | 1.37 (0.79, 2.15) | 8.6 (5, 13.6)    |     |
|  | STAT Mortality Category 5 | 7  | 37   | 18.9% | 16.3% | 1.16 (0.49, 2.16) | 16.2 (6.8, 30.1) |     |
| <a href="#">St. Joseph's Children's Hospital BayCare Health System</a> | Overall                   | 13 | 641  | 2%    | 2.9%  | 0.7 (0.38, 1.19)  | 2 (1.1, 3.3)     |     |
|  | STAT Mortality Category 1 | 0  | 194  | 0%    | 0.3%  | 0 (0, 6.06)       | 0 (0, 2.4)       |     |
|  | STAT Mortality Category 2 | 2  | 231  | 0.9%  | 1.3%  | 0.66 (0.08, 2.37) | 1 (0.1, 3.6)     | ★ ★ |
|  | STAT Mortality Category 3 | 1  | 68   | 1.5%  | 2.4%  | 0.61 (0.02, 3.26) | 1.3 (0, 7)       |     |
|  | STAT Mortality Category 4 | 8  | 130  | 6.2%  | 7.7%  | 0.8 (0.35, 1.53)  | 5 (2.2, 9.6)     |     |
|  | STAT Mortality Category 5 | 2  | 18   | 11.1% | 17.8% | 0.62 (0.08, 1.95) | 8.7 (1.1, 27.1)  |     |
| <a href="#">UF Health Shands Children's Hospital</a>                   | Overall                   | 11 | 858  | 1.3%  | 2.2%  | 0.57 (0.29, 1.02) | 1.6 (0.8, 2.9)   |     |
|  | STAT Mortality Category 1 | 0  | 243  | 0%    | 0.4%  | 0 (0, 4.15)       | 0 (0, 1.6)       |     |
|  | STAT Mortality Category 2 | 6  | 292  | 2.1%  | 1.2%  | 1.75 (0.65, 3.77) | 2.6 (1, 5.7)     | ★ ★ |
|  | STAT Mortality Category 3 | 0  | 71   | 0%    | 1.7%  | 0 (0, 2.9)        | 0 (0, 6.2)       |     |
|  | STAT Mortality Category 4 | 4  | 222  | 1.8%  | 4.3%  | 0.42 (0.11, 1.06) | 2.6 (0.7, 6.7)   |     |
|  | STAT Mortality Category 5 | 1  | 30   | 3.3%  | 13.5% | 0.25 (0.01, 1.28) | 3.4 (0.1, 17.8)  |     |
| <a href="#">Wolfson Children's Hospital</a>                            | Overall                   | 13 | 525  | 2.5%  | 1.5%  | 1.6 (0.86, 2.72)  | 4.5 (2.4, 7.6)   |     |
|  | STAT Mortality Category 1 | 1  | 178  | 0.6%  | 0.3%  | 2.02 (0.05, 11.1) | 0.8 (0, 4.3)     |     |
|  | STAT Mortality Category 2 | 6  | 201  | 3%    | 1.3%  | 2.29 (0.85, 4.89) | 3.4 (1.3, 7.3)   | ★ ★ |
|  | STAT Mortality Category 3 | 3  | 68   | 4.4%  | 1.6%  | 2.74 (0.57, 7.67) | 5.9 (1.2, 16.5)  |     |
|  | STAT Mortality Category 4 | 2  | 67   | 3.0%  | 4.5%  | 0.66 (0.08, 2.29) | 4.2 (0.5, 14.5)  |     |
|  | STAT Mortality Category 5 | 1  | 11   | 9.1%  | 7.8%  | 1.16 (0.03, 5.28) | 16.2 (0.4, 73.7) |     |

STS REPORT MOCK UP  
(2 OF 2)









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