

59A-3.248 Pediatric Cardiac Programs

(1) Licensure. No hospital may provide pediatric cardiac services without first obtaining a license pursuant to this rule.

Commented [PJ1]: Item 1. Continued authorization addressed in (a).
Item 2. Clarification added to rule. See Item 27.

(a) A hospital authorized 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 as of the effective date of this rule and must meet all provisions of this rule within one year from the effective date. ~~must meet the requirements of this rule.~~

Commented [PJ2]: Item 3. Reference 395.1055(8), FS.

(b) Initial. A hospital seeking to provide pediatric cardiac services must submit a hospital licensure application for Agency approval as specified in rule 59A-3.066(2), F.A.C. which includes:

1. Approval from the Agency’s Office of Plans and Construction pursuant to rule 59A-3.080, F.A.C., of that the hospital’s operating rooms and cardiac catheterization laboratories to be used for pediatric cardiac services; and
2. Affirmation that the hospital meets the requirements of this rule.

(c) 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.

Commented [PJ3]: Item 4. No change.

(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) such that all on-call team members are present in the facility and ready to provide services and care within one hour for emergency catheterization procedures or cardiovascular surgery;

Commented [PJ4]: Item 5. Rapid mobilization’ by itself is not sufficiently clear to describe response time.

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 a dedicated intensive care unit or component within a unit for pediatric acquired or congenital heart disease patients with personnel specially trained as provided in (3) of this rule;

4. Have a neonatal intensive care unit capable of providing comprehensive care for infants born less than 32

weeks gestation, weighing less than 1500 grams, or having a critical illness, including pre- and post-operative care of complex congenital or acquired conditions:

5. 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:

6. Provide adult congenital heart disease patients contraception, pre-pregnancy, and genetic counseling, and fetal echocardiography studies, as appropriate; and

7. 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 cardiac and adult congenital procedures. Hospitals providing pediatric cardiac services may include adult congenital heart disease patients to meet volume requirements.

1. At least 100 cardiac catheterization procedures annually, averaged over a 2-year period, of which 50 procedures must be interventional, excluding myocardial biopsies. Reportable cardiac catheterization procedures are defined as single sessions with a patient in the hospital's cardiac catheterization procedure room(s), irrespective of the number of specific procedures performed during the session.

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

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

4. At least 100 cardiac surgical procedures annually, averaged over a 2-year period. Reportable cardiac surgical procedures are index procedures, defined as single sessions with a patient in the hospital's cardiovascular operating suite(s), irrespective of the number of specific procedures performed during the session, and may include permanent epicardial lead placement.

(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 all cardiovascular parameters;

3. Repair or replacement of heart valves;

4. Repair of congenital heart defects;

5. Emergency intra-cardiac catheterization for interventions, including septostomy;

Commented [PJ5]: Item 6. No change.
Item 7. See (8) below.
Item 8. No change.

Commented [PJ6]: Item 9. Specify 'index' or 'impact' or add additional clarification.
Item 10. No change.

Commented [PJ7]: Item 11. Recommended edit

~~6. 5-~~ Repair or reconstruction of intrathoracic vessels, and

~~7. 6-~~ Treatment of ~~penetrating and blunt force cardiac injury trauma.~~

~~(d) Ambulatory care clinics serving pediatric cardiac conditions and adult congenital heart disease 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. Have an exercise physiology laboratory providing 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 heart disease 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 heart disease 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 reside 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 cardiac services must be under the direction of a physician board certified by the Adult

Commented [PJ8]: Item 12. Edited to remove 'trauma' to avoid confusion with trauma center designation.

Commented [PJ9]: Item 13. Recommended edit

Commented [PJ10]: Item 14. Add board-certified pediatric intensivist as medical director for the ICU to this paragraph as sub-paragraph 4. May conflict with 59A-3.249 (NICU), which requires the NICU director to be a neonatologist.

Commented [PJ11]: Item 15. Recommendation to strike IBHRE.

Congenital Heart Disease Sub-board of the American Board of Internal Medicine.

4. The pediatric and adult intensive care unit must be under the direction of a pediatric intensivist board certified by the American Board of Pediatrics, with subspecialty certification in Pediatric Critical Care 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 circumstances 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 and 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. Pediatric radiologists;

d. Pediatric anesthesiologists;

e. Pediatric intensivists; and

f. Pathologists with skills and training in cardiovascular pathology.

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

Commented [PJ12]: Item 16. Recommendation to add a response timeframe requiring such a person to be on call at all times. See also (2)(a)1.

Commented [PJ13]: Item 17. Recommendation to add a response timeframe.

Commented [PJ14]: Item 18. Recommendation to require cardiac training and on-site 24/7.

(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.

Commented [PJ15]: Item 19. Spelling corrected in 1. and 2. Recommendation to add details to special training and validated competencies.

1. 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 disease patients and have skills in the pre- and post-procedure evaluations and provision of instruction to the patient and their family members, including intensive care and convalescent care.

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.

3. Registered nurses providing care in the cardiac intensive care unit must have training with validated competencies in caring for congenital heart patients.

(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.

Commented [PJ16]: Item 20. No change. Recommendation to require certified ECMO specialists.

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 suites rooms for cardiac surgery operated by a licensed hospital. The addition or renovation of cardiac catheterization laboratories and operating suites are subject to the Florida Building Code applicable at the time of construction or renovation, and are reviewed by the Agency as required by section 395.0163, F.S.

Commented [PJ17]: Item 21. No change
Item 22. No change. Refer to section (2)(a)3

(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 an intact lock; the defibrillator and corresponding equipment must be checked for function and operational capacity. A log must be maintained indicating the 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;

Commented [PJ18]: Item 23. Spelling corrected.

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

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

4. An automatic injector;

5. An electrocardiograph;

6. A multi-channel electrophysiology recording system;

7. A cardiopulmonary monitoring system;

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

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

10. Extracorporeal Membrane Oxygenation machine;

Commented [PJ19]: Changed for consistency

11. Treadmill or cycle ergometer;

12. Blood pressure cuffs; and

13. Oxygen saturation monitors.

(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 not less than 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) Each hospital must have a pediatric echocardiography laboratory accredited by the Intersocietal Accreditation Commission for pediatric echocardiography in order to perform Transthoracic Echoes, Transesophageal Echoes, and Fetal Echoes.

(f) 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 heart disease patients. The policies and procedures must consider factors affecting inter- and intra- facility transport, including:

(a) Providing emergency transportation directly or by contract;

(b) Age and size of the patient;

(c) Ground or air transport;

(d) Weather conditions;

(e) Distance.

(7) Data Reporting.

(a) Each hospital must submit data to the Society of Thoracic Surgeons Congenital Heart Surgery Database (National 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:

Commented [PJ20]: Item 24. Requested clarification

Commented [PJ21]: Item 25. Recommendation to remove Anesthesia Model.

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. Except for programs with less than the requisite number of years of data for publication, publish Publish cardiac surgical outcomes to the public on the Society of Thoracic Surgeons website <https://publicreporting.sts.org> and maintain an overall risk-adjusted observed to expected operative mortality ratio whose lower limit of the 95% confidence interval is less than or equal to 1;

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 as 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;

12. Designate a Society of Thoracic Surgeons National Database site manager that will serve as the primary

Commented [PJ22]: Item 26. Requested clarification. Explanation of the displayed data is provided on the website. Clarification added to rule to exclude hospitals not meeting the STS criteria for publication.

contact between the hospital and the Society of Thoracic Surgeons National Database with regard to data reporting;
and

13. Compile quality assurance data annually from their Society of Thoracic Surgeons Congenital Heart Surgery Database Report and provide 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.

(b). 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.

(c) 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.

(d) Each hospital must participate in two or more quality metrics defined by the American College of Cardiology, Adult Congenital & Pediatric Cardiology Quality Network. 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 shall ~~must~~ follow procedures established in rule 59A-3.253, F.A.C., Chapters 408, Part II and 395, Part I, F.S., including suspension or revocation of the pediatric cardiac program license.

Commented [PJ23]: Item 27. Requested clarification.

(9) The Agency will review this rule five years from the effective date and re-promulgate, amend or repeal the rule as appropriate, in accordance with Section 120.54, F.S. and Chapter 1-1, Florida Administrative Code.

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

New _____.

DRAFT