

59C-1.033 Pediatric Open Heart Surgery Program.

(1) Agency Intent. This rule specifies the requirements for the establishment of a pediatric open heart surgery program, including minimum requirements for staffing and equipment; and it specifies a methodology for determining the numeric need for additional programs. A Certificate of Need for the establishment of a pediatric open heart surgery program shall not normally be approved unless the applicant meets the applicable review criteria in Section 408.035, F.S., and the standards and need determination criteria set forth in this rule. Hospitals operating more than one hospital on separate premises under a single license shall obtain a separate Certificate of Need for the establishment of pediatric open heart surgery services in each facility.

(2) Definitions.

(a) "Agency." The Agency for Health Care Administration.

(b) "Approved pediatric open heart surgery program." A pediatric open heart surgery program, approved by the Agency but not operational as defined by this rule, that had received a Certificate of Need or a statement of intent to award a Certificate of Need on or before the most recent published deadline for Agency initial decisions prior to publication of the fixed need pool (as specified in paragraph 59C-1.008(1)(g), F.A.C.).

(c) "District." A service District of the Agency defined in Section 408.032(5), F.S.

(d) "Fixed Need Pool." The numerical pediatric open heart surgery program need for the applicable planning horizon, as established by the Agency in accordance with this rule and subsection 59C-1.008(2), F.A.C.

(e) "Operational Pediatric Open Heart Surgery Program." A pediatric open heart surgery program approved by the Agency that has performed at least one open heart surgery operation as of 6 months prior to the beginning date of the quarter of the publication of the fixed need pool.

(f) "Pediatric Open Heart Surgery Operation." Surgical procedures that are used to treat conditions such as congenital heart defects, and heart and coronary artery diseases, including replacement of heart valves, cardiac vascularization, and cardiac trauma. One open heart surgery operation equals one patient admission to the operating room.

(g) "Pediatric Open Heart Surgery Program." A program established in a room or suite of rooms in a hospital, equipped for pediatric open heart surgery operations and staffed with qualified surgical teams and support staff.

(h) "Pediatric Open Heart Surgery Program Service Area." For the purpose of Certificate of Need review, the pediatric open heart surgery program service areas are:

1. Service area I includes Districts 1 and 2.
2. Service area II includes Districts 3 and 4.
3. Service area III includes Districts 5, 6 and 8.
4. Service area IV includes Districts 7 and 9.
5. Service area V includes Districts 10 and 11.

(i) "Pediatric patient" means a person under 15 years of age.

(j) "Planning Horizon." The projected date by which a proposed open heart surgery program would initiate service. For purposes of this rule, the planning horizon for applications submitted between January 1 and June 30 is July of the year 2 years subsequent to the year the application is submitted; the planning horizon for applications submitted between July 1 and December 31 is January of the year 2 years subsequent to the year which follows the year the application is submitted.

(3) Service Availability.

(a) Each pediatric open heart surgery program must have the capability to provide a full range of open heart surgery operations, including, at a minimum:

1. Repair or replacement of heart valves,
2. Repair of congenital heart defects,
3. Cardiac revascularization,
4. Repair or reconstruction of intrathoracic vessels; and,
5. Treatment of cardiac trauma.

Applicants for pediatric open heart surgery programs shall document the manner in which they will meet the requirements of this subparagraph.

(b) Each pediatric open heart surgery program must document its ability to implement and apply circulatory assist devices such as intra-aortic balloon assist and prolonged cardiopulmonary partial bypass.

(c) A health care facility with a pediatric open heart surgery program shall provide the following services:

1. Cardiology, hematology, nephrology, pulmonary medicine, and treatment of infectious diseases,
2. Pathology, including anatomical, clinical, blood bank, and coagulation laboratory services,
3. Anesthesiology, including respiratory therapy,
4. Radiology, including diagnostic nuclear medicine and magnetic resonance imaging studies,
5. Neurology,
6. Inpatient cardiac catheterization,
7. Non-invasive cardiographics, including electrocardiography, exercise stress testing, transthoracic and transesophageal echocardiography,
8. Intensive care,
9. Emergency care available 24 hours per day for cardiac emergencies; and,
10. Extra Corporeal Life Support (ECLS).

Notwithstanding any other sections in this rule to the contrary, approved pediatric open heart surgery providers may perform open heart surgery operations for or related to congenital heart defects regardless of the age of the patient.

(4) Service Accessibility.

(a) Hours of Operation. Pediatric open heart surgery programs shall be available for elective open heart operations 8 hours per day, 5 days a week. Each pediatric open heart surgery program shall possess the capability for rapid mobilization of the surgical and medical support teams for emergency cases 24 hours per day, 7 days a week. Applicants for pediatric open heart surgery programs shall document the manner in which they will meet this requirement.

(b) Open Heart Surgery Team Mobilization. Pediatric open heart surgery shall be available for emergency open heart surgery operations within a maximum waiting period of 2 hours.

(c) Underserved Population Groups. Pediatric open heart surgery shall be available to all persons in need. A patient's eligibility for pediatric open heart surgery shall be independent of his or her ability to pay. Applicants for pediatric open heart surgery programs shall document the manner in which they will meet this requirement. Pediatric open heart surgery shall be available in each District to Medicare, Medicaid, and indigent patients. Pediatric open and closed heart surgery shall be available in each pediatric open heart surgery program service area.

(5) Service Quality.

(a) Availability of Health Personnel. Any applicant proposing to establish a pediatric open heart surgery program must document that adequate numbers of properly trained personnel will be available to perform in the following capacities during open heart surgery:

1. A cardiovascular surgeon, board-certified by the American Board of Thoracic Surgery, or board-eligible,
2. A physician to assist the operating surgeon,
3. A board-certified or board-eligible anesthesiologist trained in open heart surgery,
4. A registered nurse or certified operating room technician trained to serve in open heart surgery operations and perform circulating duties; and,
5. A perfusionist to perform extracorporeal perfusion, or a physician or a specially trained nurse, technician, or physician assistant under the supervision of the operating surgeon to operate the heart-lung machine.

(b) Follow-up Care. Following pediatric a open heart surgery operation, patients shall be cared for in an intensive care unit that provides 24 hour nursing coverage with at least one registered nurse for every two patients during the first hours of post-operative care. There shall be at least one board certified or board eligible pediatric cardiac surgeon on the staff of a hospital with a pediatric open heart surgery program. A clinical cardiologist must be available for consultation to the surgical team and responsible for the medical management of patients as well as the selection of suitable candidates for surgery along with the cardiovascular surgical team. Backup personnel in cardiology, anesthesiology, pathology, thoracic surgery and radiology shall be on call in case of an emergency. Twenty-four hour per day coverage must be arranged for the operation of the cardiopulmonary bypass pump. All members of the team caring for cardiovascular surgical patients must be proficient in cardiopulmonary resuscitation.

(6) Patient Charges. Charges for pediatric open heart surgery operations in a hospital shall be comparable with the charges established by similar institutions in the service area, when patient mix, reimbursement methods, cost accounting methods, labor market differences and other extenuating factors are taken into account.

(7) Pediatric Open Heart Surgery Program Need Determination. The need for pediatric open heart surgery programs shall be determined on a regional basis in accordance with the pediatric open heart surgery program service areas as defined in paragraph

(2)(j). A new pediatric open heart surgery program shall not normally be approved unless the total of resident live births in the pediatric open heart surgery program service area, for the most recent calendar year available from the Department of Health, Office of Vital Statistics at least 3 months prior to publication of the fixed need pool, minus the number of existing and approved pediatric open heart surgery programs multiplied by 30,000, is at or exceeds 30,000.

(8) Utilization Reports. Facilities operating a licensed pediatric open heart surgery program shall provide utilization reports to the Agency or its designee within 45 days after the end of each calendar quarter. Facilities shall provide a report of the number of pediatric procedures, for the purpose of open heart surgery, performed by the pediatric open heart surgery program each calendar quarter.

Rulemaking Authority 408.034(3), (8), 408.15(8) FS. Law Implemented 408.032(17), 408.033(3)(b), 408.034(3), 408.036(1)(f) FS. History—New 1-1-77, Amended 11-1-77, 6-5-79, 4-24-80, 2-1-81, 4-1-82, 11-9-82, 2-14-83, 4-7-83, 6-9-83, 6-10-83, 12-12-83, 3-5-84, 5-14-84, 7-16-84, 8-30-84, 10-15-84, 12-25-84, 4-9-85, Formerly 10-5.11, Amended 6-19-86, 11-24-86, 1-25-87, 3-2-87, 3-12-87, 8-11-87, 8-7-88, 8-28-88, 9-12-88, 4-19-89, 10-19-89, 5-30-90, 7-11-90, 8-6-90, 10-10-90, 12-23-90, Formerly 10-5.011(1)(f), Amended 1-26-92, Formerly 10-5.033, Amended 6-17-93, 8-24-93, 1-24-02, 7-30-17.