

## **111-2-2-.23 Specific Review Considerations for Pediatric Cardiac Catheterization and Open Heart Surgery.**

### **(1) Definitions.**

(a) "Authorized service" means a pediatric cardiac catheterization service or pediatric cardiac surgery service that is either existing or approved. An existing service is an authorized service that has become operational, and an approved service is an authorized service that has not become operational.

(b) "Capacity" means:

1. for a pediatric catheterization service:

(i) in considering applications for a new pediatric cardiac catheterization service, 750

procedures per year per authorized service regardless of the number of rooms used; or

(ii) in considering applications for expansion of an existing service, 750 pediatric cardiac catheterization procedures per dedicated room per year in the existing service (3 per day per room, 5 days per week, 50 weeks per year) and for each multipurpose room in the existing service, 750 procedures (special procedures and pediatric cardiac catheterization procedures) per year. If adult and pediatric cardiac catheterization are performed in the same room in a service seeking to expand, the capacity of the room shall be equivalent to 750 pediatric procedures with adult procedures performed in the room weighted in proportion to pediatric procedures as being 0.50 for each adult cardiac catheterization or special procedure, except for each adult coronary angioplasty, which shall be 0.75, in order to determine the service's use rate; or

2. for a pediatric cardiac surgery service, the number of pediatric cardiac surgery procedures which could be performed annually as reported by each hospital with an authorized service and based on survey and other reported data. In determining capacity, a hospital must consider factors such as available operating rooms which can be used for pediatric cardiac surgery, cardiac surgical intensive care beds and other pediatric intensive care beds available for pediatric patients, general bed capacity, and any other factors which impact the determination.

(c) "Cardiac catheterization" means a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in the patient; subsequently, the free end of the catheter is manipulated by the physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aids in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures on the heart or its vessels.

(d) "Closed heart surgery" means an operation performed directly on the heart or its associated veins or arteries that does not require use of a heart and lung bypass machine (extracorporeal pump) to perform the work of the heart and lungs. Such operations often require the bypass machine to be available on standby for use if the surgery needs to be changed to open heart with the machine then performing the work of the heart and lungs.

(e) "Official State Component Plan" means the document related to specialized cardiovascular services developed by the Department, established by the Health Strategies Council, and adopted by the Board of Community Health.

(f) "Open heart surgery" means surgery performed directly on the heart or its associated veins or arteries during which a heart and lung bypass machine (extracorporeal pump) is used to perform the work of the heart and lungs.

(g) "Pediatric" refers to children 14 years of age and under.

(h) "Pediatric cardiac catheterization service" means an organized program which serves pediatric patients of a hospital which has a room or suite of rooms with the equipment, staff, and all support services required to perform angiographic, physiologic, and, as appropriate, therapeutic cardiac catheterization procedures. The pediatric cardiac catheterization service shall be located in a pediatric tertiary hospital. Procedures may be performed in a room dedicated to cardiac catheterization and/or in a special procedures or multipurpose room not exclusively used for cardiac catheterization.

(i) "Pediatric cardiac surgery" means an operation performed directly on a pediatric patient's heart or its associated veins or arteries, including open heart and closed heart surgery procedures but excluding surgical procedures for the closure of neonatal patent ductus arteriosus.

(j) "Pediatric cardiac surgery service" means an organized surgical program which serves pediatric inpatients of a hospital which has a suitable operating room or suite of operating rooms, equipment, staff, and all support services required to perform closed heart and open heart operations for pediatric patients. The pediatric cardiac surgery service shall be located in a pediatric tertiary hospital.

(k) "Pediatric tertiary hospital" means a teaching center, specialty medical or large community hospital characterized by serving pediatric patients from a large region or the entire state with sophisticated technology and support services to provide highly specialized medical and surgical care for unusual and complex medical problems of pediatric patients.

(l) "Procedure" means a cardiac catheterization study or treatment or combination of studies and/or treatments performed in a single session on a single patient who appears for cardiac catheterization or a pediatric open or closed heart operation or combination of operations performed in a single session on a single patient who appears for pediatric cardiac surgery.

(m) "Service area," for pediatric cardiac catheterization and pediatric cardiac surgery means the State of Georgia.

(2) **Standards.**

(a) An applicant for new pediatric cardiac catheterization and pediatric cardiac surgery services must be a pediatric tertiary hospital. Due to the highly specialized nature of pediatric cardiac catheterization and pediatric cardiac surgery services, applicants for these services must propose to provide both pediatric cardiac catheterization and pediatric cardiac surgery. Only those projects that meet all applicable standards for both services will be approved.

(b) New pediatric cardiac catheterization services shall be approved in the state only if each and all of the following conditions are met:

1. the combined use rate for all existing and approved pediatric cardiac catheterization services in the state has been at or above 80 percent of capacity for the past two years as documented through surveys submitted to the Department;
2. an applicant must project that the proposed service will be operating at a minimum of 150 procedures per year within three years of initiation of the service in order to maintain

and strengthen skills. Such projection at a minimum shall include consideration of patient origin data and the use rate of existing services; and

3. an applicant must show that authorized pediatric cardiac catheterization services that would be impacted by the establishment of the new service are not predicted to perform less than the minimum quality level of 150 procedures annually as a result of the establishment of the new service.

(c) An application for expansion of an existing pediatric cardiac catheterization service which exceeds the capital expenditure threshold shall be approved in the state only if the applicant's existing service has operated at a use rate of at least 80 percent of capacity for each of the past two years and the applicant can project a minimum of 150 additional pediatric procedures per year within three years of initiation of the service expansion and the applicant demonstrates compliance with or documents a plan and agreement to comply with the applicable provisions of 111-2-2-.23(2)(f) through (o).

(d) New pediatric cardiac surgery services shall be approved in the state only if each and all of the following conditions are met:

1. the combined use rate of all authorized pediatric cardiac surgery services in the state has been at or above 80 percent of capacity for the past two years as documented through surveys submitted to the Department;

2. an applicant must project that the proposed service will be operating at a minimum of 100 pediatric cardiac surgery procedures per year, of which at least 50 are open heart operations, within three years of initiation of the service in order to maintain and strengthen skills. Such projections at a minimum shall include consideration of patient origin data and the use rate of existing services; and

3. an applicant must show that authorized pediatric cardiac surgery services which would be impacted by the establishment of the new services are not predicted to perform less than the minimum quality level of 100 procedures annually, of which at least 50 are open heart operations, as a result of the establishment of the new service.

(e) An application for expansion of an existing pediatric cardiac surgery service which exceeds the capital expenditure threshold shall be approved in the state only if the applicant's existing service has operated at a use rate of at least 80 percent of capacity for each of the past two years and the applicant can project a minimum of 100 additional pediatric cardiac surgery procedures, of which at least 50 are open heart operations, within three years of initiation of the service expansion and the applicant demonstrates compliance with or documents a plan and agreement to comply with the applicable provisions of 111-2-2-.23(2)(f) through (o).

(f) An applicant for a new or expanded pediatric cardiac catheterization service shall:

1. document that the applicant is a pediatric tertiary hospital, which serves pediatric patients from a large region or the entire state, with sophisticated technology and support services to provide highly specialized medical and surgical care for unusual and complex medical problems of pediatric patients; and

2. document that, in addition to the basic requirements described for adult cardiac catheterization services, the hospital shall have support services and equipment necessary for the diagnosis and treatment of infants and children as specified by the American College of Cardiology and the American Academy of Pediatrics.

(g) An applicant for a new or expanded pediatric cardiac surgery service shall:

1. document that the applicant is a pediatric tertiary hospital, which serves pediatric patients from a large region or the entire state, with sophisticated technology and support services to provide highly specialized medical and surgical care for unusual and complex medical problems of pediatric patients; and

2. document that, in addition to the basic requirements described for adult open heart surgery, the hospital shall have support services and equipment necessary for surgery on infants and children as specified by the American College of Cardiology and the American Academy of Pediatrics, Guidelines for Pediatric Cardiology Diagnostic and Treatment Centers. This includes a complete pediatric cardiology unit, a neonatal intensive care unit, a pediatric intensive care unit, and a general pediatric unit with pediatric sub-specialists in hematology, endocrinology, pulmonary neurology, and radiology.

(h) An applicant for a new or expanded pediatric cardiac catheterization service or for a new or expanded pediatric cardiac surgery service shall document that the service shall be available for the performance of procedures as needed at least eight hours per day, five days per week, and shall document the capability to rapidly mobilize the surgical and medical support teams for emergency procedures 24 hours per day, seven days per week, including a plan for utilizing this capability when needed to perform emergency procedures.

(i) An applicant for a new or expanded pediatric cardiac catheterization service and/or pediatric cardiac surgery service shall:

1. submit a written plan to the Department which, when implemented, will ensure access to services for all segments of the population in the documented and proposed service area of the applicant. Such plan shall provide a detailed strategy to reach patients not currently served within the service area, ensure continuity of care for patients transferred between facilities and shall promote planning for a continuum of cardiac services within the service area; and

2. propose a heart disease prevention and clinical intervention program to be provided by the applicant or through formal referral agreements which, when implemented, shall include:

(i) A clinical intervention program for all patients that shall provide for the following in a comprehensive, systematic way:

(I) Assessment of risk factors including lipid disorders, hypertension, diabetes, obesity, cigarette smoking, and sedentary lifestyle;

(II) Assessment of risk factors and referral for appropriate care in first-degree relatives; and

(III) Assure risk management including modification of lipid disorders by diet/exercise/drugs, modification of blood pressure level by diet/exercise/drugs, control of blood glucose level by diet/exercise/drugs, dietary counseling aimed at reduced caloric and fat intake and appropriate weight management, smoking cessation, and exercise prescription. Patients should be referred to their primary care provider with documentation of treatments provided and actions recommended including preventive therapies.

(ii) The program shall provide for annual support and participation in at least three professional education programs targeted to community based health professionals,

related to heart disease risk assessment, diagnostic procedures, disease management in clinical settings, and case finding and referral strategies.

(iii) Community based heart health promotion:

(I) The program shall provide for organization of or participation in a consortium of community-based organizations to complete an assessment of heart disease risk factors in the community as well as resources available to provide programs and services. The objective of this consortium is to mobilize and coordinate resources to target at-risk populations in the community; and

(II) Organization of or participation in at least one major community-based campaign each year related to major heart disease risk factors.

3. propose a system of outcome monitoring and quality improvement and identify at least five clinical outcomes that the applicant proposes to monitor for performance on a regular basis.

(j) An applicant for new or expanded pediatric cardiac catheterization and pediatric cardiac surgery services shall foster an environment which assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing a written policy regarding the provision of any services provided by or on behalf of the applicant regardless of race, age, sex, creed, religion, disability or patient's ability to pay, and documentation or evidence that the applicant has a service history reflecting the principles of such a policy; and
2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent of annual, adjusted gross revenues for the pediatric cardiac catheterization and surgical services, or the applicant may request that the Department consider allowing the commitment for services to indigent and charity patients to be applied to the entire facility;
3. providing a written commitment to accept any patient within the facility's service area, without regard to the patient's ability to pay, unless such patient is clinically inappropriate;
4. providing a written commitment to participate in the Medicaid and PeachCare programs and to accept any Medicaid- and/or PeachCare-eligible patient for services unless such patient is clinically inappropriate;
5. providing a written commitment that the applicant, subject to good faith negotiations, will participate in any state health benefits insurance programs for which the service is deemed eligible; and
6. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients. The applicant's or its parent organization's failure to provide services at an acceptable level to Medicare, Medicaid and indigent and charity patients, and/or the failure to fulfill any previously made commitment to indigent and charity care may constitute sufficient justification to deny the application.

(k) An applicant for a new or expanded pediatric cardiac catheterization service shall:

1. demonstrate the intent to achieve the optimal standards established by the American Academy of Pediatrics, Guidelines for Pediatric Cardiology Diagnostic and Treatment Centers for evaluating the clinical and physical environments of cardiac catheterization

- services and covering professional qualifications and responsibilities, staffing requirements, supporting services, physical plant, and equipment; and
2. document the availability of, or shall present a plan for recruiting, a qualified service director who is a physician, board-certified in pediatrics, with subspecialty training and board eligibility in pediatric cardiology and who is competent to perform physiologic and angiographic procedures or both; and
  3. document a plan for obtaining a sufficient number of professional and technical staff for the size of the pediatric cardiac catheterization service proposed, including a pediatric nurse, radiologic technologist, cardiopulmonary technician, and darkroom technician and document that the staff required for most procedures shall be available, including two physicians, one nurse, and two technicians, with the nurse and technicians cross trained to cover technical responsibility of the monitoring and recording technicians.
- (l) An applicant for a new or expanded pediatric cardiac surgery service shall:
1. demonstrate the intent to achieve the optimal standards established by the Advisory Council for Cardiothoracic Surgery of the American College of Surgeons, and the American Academy of Pediatrics, Guidelines for Pediatric Cardiology Diagnostic and Treatment Centers for evaluating the clinical and physical environments of cardiac surgical services and covering professional qualifications and responsibilities, staffing requirements, supporting services, physical plant, and equipment; and
  2. document the availability of, or shall present a plan for recruiting, a qualified pediatric cardiac surgery director who is a pediatric cardiovascular surgeon, board-certified in thoracic surgery, with special emphasis and experience in surgery for congenital heart disease; and
  3. document a plan for obtaining a sufficient number of professional and technical staff, including pediatric cardiac intensive care nurses, for the size of the pediatric cardiac surgery service proposed, including at least two board-qualified cardiac surgeons on the staff of the hospital and a cardiovascular surgical team which includes a neonatologist, a pediatric anesthesiologist, a pediatric radiologist, a pediatric cardiologist, a nurse clinician, and backup of medical social services.
- (m) An applicant for new or expanded pediatric cardiac catheterization and pediatric cardiac surgery services shall provide documentation that the hospital is fully accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and also shall provide sufficient documentation that the hospital has no history of significant licensure deficiencies and no history of conditional level Medicare and Medicaid certification deficiencies in the past three years and has no outstanding licensure and Medicare and Medicaid certification deficiencies.
- (n) An applicant for new or expanded pediatric cardiac catheterization and pediatric cardiac surgery services shall demonstrate that the applicant's charges and/or reimbursement for pediatric cardiac catheterization and pediatric cardiac surgery services shall compare favorably with charges and/or reimbursement in existing pediatric cardiac catheterization and pediatric cardiac surgery services in the state, when adjusted for annual inflation.
- (o) An applicant for new or expanded pediatric cardiac catheterization and/or pediatric cardiac surgery services must agree in writing to the following conditions:

1. establishment and maintenance of a system of continuity of care and coordination of service, as evidenced by regular and ongoing planning and quality improvement sessions with community health providers and advocacy programs; and
2. participation in a data reporting, quality improvement, outcome monitoring, and peer review system within the applicant hospital as well as a national, state or multi-hospital system which benchmarks outcomes based on national norms and which shall be named in the application and which provides for peer review between and among professionals practicing in facilities and programs other than the applicant hospital;
3. development of procedures to ensure that any surgeon or cardiologists authorized to perform pediatric cardiac services for the hospital shall be required to accept Medicaid and PeachCare payment for services without discrimination;
4. commitment that charges for services shall be reasonable and comparable to other providers in the state and the service area;
5. provision of all required data and survey information to the Department as requested; and
6. commitment to act in good faith to fulfill all provisions and commitments documented in the application for a new or expanded service.

(p) The Department may revoke a Certificate of Need after notice to the holder of the certificate and a fair hearing pursuant to the Georgia Administrative Procedure Act for failure to comply with the defined scope, location, cost, service area, and person named in an application as approved by the Department and for the intentional provision of false information to the Department by an applicant in that applicant's application.

Authority O.C.G.A. Secs. 31-5A et seq., 31-6 et seq. **History.** Original Rule entitled "Specific Review Considerations for Pediatric Cardiac Catheterization and Open Heart Surgery" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.