

### **59C-1.032 Pediatric Cardiac Catheterization and Angioplasty Institutional Health Services.**

(1) Agency Intent. This rule defines the requirements for the establishment of pediatric inpatient cardiac catheterization services, including minimum requirements for staffing, equipment, and a numeric need methodology for pediatric cardiac catheterization programs. A Certificate of Need for the establishment of pediatric inpatient cardiac catheterization services 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. A cardiac catheterization program which is established and utilized for the purpose of serving outpatients exclusively is not regulated under this rule. A pediatric cardiac catheterization program which provides services to inpatients, regardless of the reason for their admission, including coronary angioplasty, valvuloplasty, or ablation of intracardiac bypass tracts requires a Certificate of Need. Hospitals operating more than one hospital facility under the same hospital license in the same District, shall obtain a separate Certificate of Need for the establishment of a pediatric cardiac catheterization program in each health care facility.

#### **(2) Definitions.**

(a) Approved Program. A proposed pediatric cardiac catheterization and angioplasty program that is not operational but for which a valid Certificate of Need, a letter of intent to grant a Certificate of Need, or a final order granting a Certificate of Need has been issued, consistent with the provisions of paragraph 59C-1.008(2)(b), F.A.C., on or before the most recently 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.

(b) Cardiac Catheterization. Cardiac catheterization is defined as a medical procedure requiring the passage of a catheter into one or more cardiac chambers of the left and right heart, with or without coronary arteriograms, for the purpose of diagnosing congenital or acquired cardiovascular diseases, or for determining measurement of blood pressure flow. Cardiac catheterization also includes the selective catheterization of the coronary ostia with injection of contrast medium into the coronary arteries.

(c) Coronary Angioplasty. Coronary angioplasty is defined as a hospital inpatient procedure requiring the dilation of narrowed segments of the coronary vessels, via a balloon-tipped catheter.

(d) Catheterization Program. A cardiac catheterization program is defined as an institutional health service which is provided by or on behalf of a health care facility and which consists of one or more laboratories which comprise a room or suite of rooms, and has the equipment and staff required to perform cardiac catheterization serving inpatients and outpatients. A cardiac catheterization program approved for angioplasty services, or other types of therapeutic cardiac procedures shall have the additional necessary equipment and staff to perform angioplasty procedures.

(e) Operational Program. A new pediatric cardiac catheterization and angioplasty program approved by the Agency that has performed at least one pediatric cardiac catheterization as of 3 months prior to the beginning date of the quarter of the publication of the fixed need pool.

(f) Pediatric Patient. A person under 15 year of age.

(g) Service Planning Area. The service planning area for pediatric cardiac catheterization services shall be done on a regionalized basis. Certificate of Need applications for pediatric cardiac catheterization services shall be competitively reviewed within each of the following five regions. The planning regions for pediatric cardiac catheterization services shall be:

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

#### **(3) Scope of Service.**

(a) Each pediatric cardiac catheterization program shall be capable of providing immediate endocardiac catheter pacemaking in cases of cardiac arrest, and pressure recording for monitoring and to evaluate valvular disease, or heart failure. Applicants for pediatric cardiac catheterization programs shall document the manner in which they will meet this requirement.

(b) A range of non-invasive cardiac or circulatory diagnostic services must be available within the health care facility itself, including:

1. Hematology studies or coagulation studies,
2. Electrocardiography,
3. Chest x-ray,
4. Blood gas studies; and,

5. Clinical pathology studies and blood chemistry analysis.

(c) At a minimum a pediatric cardiac catheterization program shall include:

1. A special procedure x-ray room,
2. A film storage and darkroom for proper processing of films,
3. X-ray equipment with the capability in cineangiocardiology, or equipment with similar capabilities,
4. An image intensifier,
5. An automatic injector,
6. A diagnostic x-ray examination table for special procedures,
7. An electrocardiograph,
8. A blood gas analyzer,
9. A multichannel polygraph,
10. Emergency equipment including but not limited to a temporary pacemaker unit with catheters, ventilatory assistance devices, and a DC defibrillator,
11. Biplane angiography, with framing rates of 30-60 fps and injection rates of up to 40 mL/s; and,
12. A crash cart containing the necessary medication and equipment for ventilatory support; a crash cart shall be located in each pediatric cardiac catheterization procedure room.

(4) Service Accessibility.

(a) Hours of Operation. Every pediatric cardiac catheterization program shall have the capability of rapid mobilization of the study team within 30 minutes for emergency procedures 24 hours a day, 7 days a week. Applicants for new pediatric cardiac catheterization programs shall document the manner in which they will meet this requirement.

(b) Underserved Population Groups. Applicants for a pediatric cardiac catheterization program shall indicate the projected number of medically indigent and Medicaid patients to be served annually. Applicants shall indicate their past provision of health care services to medically indigent and Medicaid patients.

(5) Service Quality.

(a) Quality of Care. Pediatric cardiac catheterization programs shall have a department, service or other similarly titled unit which shall be organized, directed, staffed and integrated with other units and departments of the hospital in a manner designed to assure the provision of quality of care. Applicants proposing to establish a new pediatric cardiac catheterization program shall demonstrate how they will meet this provision.

(b) Availability of Health Personnel. Any applicant proposing to establish a pediatric cardiac catheterization program must document that adequate numbers of properly trained personnel will be available. At a minimum, a team involved in pediatric cardiac catheterization consists of a physician, one nurse, and one or more technicians. An applicant for a new pediatric cardiac catheterization program shall document that the following staff are available:

1. The program director for programs performing pediatric cardiac catheterization shall be board-eligible or board-certified by the Sub-Board of Pediatric Cardiology of the American Board of Pediatrics or the American Osteopathic Association in the area of pediatric cardiology,
2. A physician, board-certified or board-eligible in cardiology, radiology, or with specialized training in cardiac catheterization and angiographic techniques who will perform the examination,
3. Support staff, specially trained in critical care of cardiac patients, with a knowledge of cardiovascular medication and an understanding of catheterization and angiographic equipment,
4. Support staff, highly skilled in conventional radiographic techniques and angiographic principles, knowledgeable in every aspect of catheterization and angiographic instrumentation, with a thorough knowledge of the anatomy and physiology of the circulatory system,
5. Support staff for patient observation, handling blood samples and performing blood gas evaluation calculations,
6. Support staff for monitoring physiologic data and alerting the physician of any changes,
7. Support staff to perform systematic tests and routine maintenance on cardiac catheterization equipment, who must be available immediately in the event of equipment failure during a procedure,
8. Support staff trained in photographic processing and in the operation of automatic processors used for both sheet and cine film; and,
9. A Medical Review Committee which reviews medical invasive procedures such as endoscopy and cardiac catheterization.

(6) Coordination of Services. Pediatric cardiac catheterization programs must be located in a hospital in which pediatric open heart surgery is being performed.

(7) Service Cost. Cost data for pediatric cardiac catheterization programs, among similar institutions, shall be comparable when patient mix, cost accounting methods, labor market differences and other extenuating factors are taken into account.

(8) Need Determination. In order to assure patient safety and staff efficiency and to achieve maximum economic use of existing resources, the following criteria shall be considered in the approval of Certificate of Need applications for new pediatric cardiac catheterization programs.

(a) Pediatric cardiac catheterization programs shall be established on a regional basis. A new pediatric cardiac catheterization program shall not normally be approved unless the number of live births in the service planning area, minus the number of existing and approved programs multiplied by 30,000, is at or exceeds 30,000.

(b) Applicants for a new pediatric cardiac catheterization program shall project a minimum service volume of 150 cardiac catheterizations per year within 2 years of the initial operation of the program.

(c) Actual inpatient and outpatient migration from one service planning area to another shall be considered in the review of Certificate of Need applications.

(9) Utilization Reports. Facilities providing licensed pediatric inpatient cardiac catheterization services 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 cardiac catheterization or angioplasty, performed by the pediatric cardiac catheterization 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), 408.035(1), 408.036(1)(f), 408.039(4)(a) 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)(e), Amended 11-11-91, 7-6-92, Formerly 10-5.032, Amended 8-24-93, 9-12-94, 6-19-95, 8-23-95, 7-30-17.*