

3701-84-75 Pediatric cardiac catheterization service standards.

- (A) The provisions of rules 3701-84-75 to 3701-84-79 of the Administrative Code are applicable on the effective date of this rule to each provider of cardiac catheterization services performing procedures on patients less than twenty-two years of age, regardless of the date the service was initiated.
- (B) Except as provided in paragraph (C) of this rule, all pediatric cardiac catheterization services shall:
 - (1) Have on-site a pediatric cardiovascular surgery service immediately accessible from the pediatric cardiac catheterization laboratory by gurney; and
 - (2) Have an experienced pediatric cardiovascular surgical team available in less than sixty minutes on a twenty-four hour basis in the event that emergency open heart surgery is required.
- (C) Only those pediatric cardiac catheterization services appropriately implemented prior to March 1, 1997 may perform pediatric cardiac catheterization procedures without an on-site pediatric cardiovascular surgery service. Those pediatric cardiac catheterization services subject to the provisions of this paragraph may perform such procedures only if:
 - (1) A formal written agreement is maintained for emergency pediatric medical / surgical management with a registered hospital that provides pediatric cardiovascular surgery services, that can be reached expeditiously from the pediatric cardiac catheterization service by available emergency vehicle within a reasonable amount of time and that provides the greatest assurance for patient safety. The agreement shall include:
 - (a) Protocols addressing indications, contraindications, and other criteria for the emergency transfer of patients in a timely manner;
 - (b) Assurance of the initiation of appropriate medical / surgical management in a timely manner;
 - (c) Specification of mechanisms for continued substantive communication between the services that are a party to the agreement and between their medical directors and physicians;
 - (d) Provisions for a collaborative training program among staff of the services that are a party to the agreement;
 - (e) Provisions for the recommendation by the medical director of the receiving service, regarding the cardiac catheterization service's credentialing criteria; and
 - (f) Provisions for the recommendation by the medical director of the receiving service, regarding the pediatric cardiac catheterization service's protocols addressing patient monitoring, the recognition of indications for transfer and the care and management of patients identified as a candidate for transfer; and

- (2) There is an established written protocol that provides for the emergency transfer and care of patients who require emergency pediatric medical / surgical management during or immediately after cardiac catheterization.
 - (3) Outcome data will be considered by the director in determining whether a transfer agreement is with an appropriate receiving service. The pediatric cardiovascular surgery service that is a party to a transfer agreement is referred to as the receiving service.
- (D) The provider of a pediatric cardiac catheterization service shall have immediate access to services for hematology and coagulation disorders; electrocardiography; diagnostic radiology; clinical pathology; doppler-echocardiography; pulmonary function testing; and microbiology.
- (E) The provider of a pediatric cardiac catheterization service shall establish and maintain a method for reviewing the quality of all cardiac catheterization procedures. This review shall assess the following:
- (1) Appropriateness of cardiac catheterization studies and interventions;
 - (2) Technical quality of cardiac catheterization studies;
 - (3) Procedure result;
 - (4) Rate of therapeutic success; and
 - (5) Rate of procedural complications.
- (F) The provider of a pediatric cardiac catheterization service shall establish and maintain a database to support the review process detailed in paragraph (E) of this rule. The results of analyses and review shall be documented and used to guide periodic internal reviews of individual physicians with respect to maintaining their credentials to perform specific cardiac catheterization procedures.
- (G) A cardiac catheterization service for pediatric patients shall only be provided in a fully permanent setting within the permanent frame of the building of a registered hospital that is classified as a general hospital, a children's hospital or a special hospital - cardiac that primarily furnishes limited services to patients with cardiac conditions. The hospital shall:
- (1) Operate inpatient pediatric medical and surgical services in the same building and accessible by gurney from the pediatric cardiac catheterization laboratory;
 - (2) Operate a pediatric intensive / critical care unit with registered special care beds, that is reviewed and accredited or certified as such as part of the hospital's accreditation or certification program in the same building and accessible by gurney from the pediatric cardiac catheterization laboratory. The unit shall provide appropriate equipment and staff to care for pediatric cardiac patients and have twenty-four hour monitoring capability;
 - (3) Provide a setting in the same building as the pediatric cardiac catheterization laboratory in which ambulatory pediatric cardiac catheterization patients can be observed for at least four hours after the procedure; and
 - (4) Provide adequate physician coverage to manage postprocedure complications.

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Certification

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