



CHILDREN'S MEDICAL SERVICES CARDIAC FACILITIES STANDARDS DECEMBER, 2005

Children's Medical Services (CMS) Pediatric Cardiac Facility Approval Process is a quality assurance process that ensures participating CMS Network cardiac facilities meet established minimum standards deemed necessary for the provision of quality cardiac services to children with special health care needs. CMS encourages the creation of policies to foster growth of centers of excellence.

The following standards are required for initial evaluation and approval as a Children's Medical Services (CMS) Pediatric Cardiac Facility and for re-evaluation of approved facilities. CMS evaluates and approves the following pediatric cardiac facility program components:

- Hospital Affiliated Pediatric Non-Invasive Cardiology Laboratory Component - must be affiliated with a CMS approved Pediatric Cardiac Catheterization Laboratory.
- Pediatric Cardiac Catheterization Laboratory Component –must be co-located with a CMS approved Cardiovascular Surgery Program.
- Pediatric Cardiovascular Surgery Program Component– must be co-located with a CMS approved Pediatric Cardiac Catheterization Laboratory and affiliated with a CMS approved Pediatric Non-Invasive Cardiology Laboratory.

Transition. Existing CMS approved pediatric cardiovascular facilities which have been approved as of the effective date of the Florida Administrative Code Rule that incorporate these standards shall be first surveyed for re-approval under the criteria set forth below for Initial Evaluations. Each such facility re-approval evaluation will be conducted no sooner than three (3) months after the effective date of these standards or three (3) years from the time of the facility's last evaluation and survey, whichever period is longer. If approved under the Initial Evaluation standards, subsequent re-approval evaluations and surveys shall be conducted under the criteria set forth below for Re-evaluation of Approved Facilities. CMS approved pediatric cardiovascular facilities that fail to meet re-evaluation standards in effect prior to the effective date of these standards, but whose disapproval is pending final agency action or a final agency order, shall be re-evaluated under the Initial Evaluation standards contained herein at any time after the effective date of these standards.

A Pediatric Cardiovascular Facility must provide care for all CMS enrolled individuals with congenital heart disease who require such expertise. For volume standard purposes, "pediatric cardiac" includes children under age 21 years and adults 21 years or older with congenital heart disease.

For the purposes of CMS cardiac facility review and approval, each distinct site or facility will be surveyed individually within a multi-site cardiac center. Each of its individual facilities must meet or exceed CMS standards; that is, each hospital-based team must perform the minimum number of echocardiograms, catheterizations and surgeries specified herein. Each facility shall receive its own approval based on its own merits.

All CMS approved cardiac facilities must be located within a healthcare facility that maintains accreditation by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the National Committee for Quality Assurance (NCQA).

All CMS approved cardiac facilities must have quality assurance and quality improvement processes in place that continuously enhance the clinical operation and patient satisfaction with services.

All CMS approved Pediatric Cardiac Facilities must collect and submit quality assurance data annually in accordance with the following CMS forms:

- Pediatric Non-Invasive Cardiology Laboratory Procedures (DH-CMS 2056, 8/05)

- Cardiac Catheterization Procedures (DH-CMS 2057, 4/05)
- Cardiac Catheterization Cases--Primary Cardiac Diagnoses (DH-CMS 2058, 3/05)
- Pediatric Cardiac Surgical Procedures--Closed Heart Procedures (DH 2059, 4/05); and
- Pediatric Cardiac Surgical Procedures--Open Heart Procedures (DH-CMS 2060, 4/05)

The above forms are hereby adopted and incorporated by reference. All forms adopted and incorporated by reference in these standards are available upon request from Children's Medical Services, Department of Health, 4052 Bald Cypress Way, Bin # A-06, Tallahassee, Florida 32399-1707.

All CMS cardiac facilities are required to provide limited English proficiency services, in accordance with Federal guidelines.

A multidisciplinary cardiac team must include pediatric cardiology, cardiovascular surgery, cardiovascular anesthesia, nursing, ancillary and support staff associated with pre-operative patient selection and preparation, the surgical or catheterization procedure, and post-operative care and follow-up.

All physicians providing care at a CMS cardiac facility must be CMS approved providers, as specified in rule 64C-4.001 Florida Administrative Code (F.A.C.).

All non-physician health care professionals providing care at a CMS cardiac facility must be CMS approved providers, as specified in rule 64C-4.001, F.A.C.

Facility approval requests must be submitted to the Deputy Secretary of Children's Medical Services at 4052 Bald Cypress Way, Bin # A-06, Tallahassee, Florida, 32399-1707.

I. Standards for CMS Hospital Affiliated Pediatric Non-Invasive Cardiology Laboratory Component

- A. The hospital affiliated pediatric non-invasive cardiology laboratory must be affiliated with a CMS approved Pediatric Cardiac Catheterization Laboratory.
- B. All echocardiography laboratories must be accredited by the Intersocietal Commission for the Accreditation of Echocardiography Laboratories (ICAEL) prior to their first three-year re-approval date.
- C. A pediatric non-invasive cardiology laboratory must be able to perform diagnostic evaluations including, but not limited to, echocardiographic recording, Holter monitoring, exercise testing, fetal echocardiography, and serial pacemaker monitoring.
- D. Echocardiograms performed by a physician outside the physical boundaries of an approved facility may be counted toward the required Facility Volume Standards so long as all of the following are met:
 - 1. The physician performing the echocardiogram is on the medical staff of the hospital facility and affiliated with the hospital's pediatric cardiology program;
 - 2. The physician performing the echocardiogram is designated as a CMS physician; and
 - 3. The program provides evidence that the physician maintains appropriate times of operation and protocols, including proper affiliate agreements to ensure availability and appropriate referrals in the event of emergencies.
- E. Pediatric Non-Invasive Cardiology Laboratory Teams
 - 1. Cardiac Clinic:
 - a) Physicians – The physician in charge of a Pediatric Cardiology Clinic must be eligible for, 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.

- b) Nurse - A registered nurse who has experience with cardiac problems in children must participate in each cardiac clinic.
- c) Social Worker or another individual capable of performing social service functions.
- 2. Echocardiography Lab:
 - a) A physician who is board certified or board eligible in pediatric cardiology
 - b) A sonographer – Registered Diagnostic Cardiac Sonographer (RDCS), American Registry of Diagnostic Medical Sonographers (ARMDS), or Registered Cardiovascular Technologist (RCVT) pediatric certified
- 3. Holter Monitoring Lab:
 - a) A physician who is board certified or board eligible in pediatric cardiology
 - b) A Basic Life Support (BLS) certified cardiology technologist or respiratory care practitioner
- 4. Exercise Treadmill Lab and Serial Pacemaker Monitoring:
 - a) A physician who is board certified or board eligible in pediatric cardiology
 - b) A BLS certified cardiology technologist or respiratory care practitioner
 - c) Pediatric Advanced Life Support (PALS) trained personnel available
- F. Physical Facility
 - 1. General requirements:
 - a) The area must be quiet enough to perform a high quality cardiovascular examination.
 - b) Examination areas must be adequately lighted, have adjustable temperature, and offer privacy to patients.
 - c) A conference room for discussing cases.
 - 2. Specific requirements:
 - a) The echocardiography lab workstation must include a study review area with dictation capabilities, and supplies necessary for compilation and analysis of echocardiography studies.
 - b) The exercise treadmill lab must include a remote “code” button and telephone.
- G. Equipment - All non-invasive laboratory equipment must be monitored and maintained in accordance with manufacturers’ recommendations.
- H. Records
 - 1. Permanent record of real time study must include, at a minimum, video, disk, or chart.
 - 2. Permanent record of real time study of Holter Monitoring studies must include one or more of the following: cassette tape, disk, printed paper.
 - 3. Permanent record of real time study of exercise treadmill testing must include EKG and blood pressure on paper.
 - 4. Permanent record of real time study of serial pacemaker testing must include printed paper.
 - 5. Interpretation and final approval of study reports must be performed by a physician who is board certified or board eligible in pediatric cardiology.
 - 6. Medical records must be retained for a period of no less than seven (7) years in a locked area.
- I. Initial Evaluation
 - 1. On-site Review: When an application requesting approval as a CMS Hospital Affiliated Pediatric Non-Invasive Cardiology Laboratory is submitted with documentation of compliance with these standards, an on-site review by representatives or designees of the CMS Cardiac Subcommittee will be scheduled. An application shall not be deemed complete until the Deputy Secretary for CMS receives the recommendation of the CMS Cardiac Subcommittee.
 - 2. Medical Record Review: A minimum of 25 consecutive pediatric cardiac cases within a specified time period must be available to warrant initial evaluation of any facility.
 - 3. Facility Volume Standards: An applicant facility must present documentation of the following minimum number of pediatric procedures: echocardiograms - 300 per year,

which include: transesophageal echocardiograms (TEE) – 50 per year; and fetal echocardiograms – 50 per year.

Intersocietal Commission for the Accreditation of Echocardiography Laboratory. 2001.

4. Practitioner Volume Standards:
 - a) Each member of the pediatric medical staff designated to interpret echocardiograms must interpret a minimum of 300 pediatric studies annually.
 - b) Each member of the pediatric technical staff must perform a minimum of 100 pediatric studies annually.
 - c) Each member of the medical staff who performs or interprets TEEs must perform a minimum of 25 studies annually.
 - d) Each member of the medical staff who performs or interprets fetal echocardiography must do a minimum of 25 studies annually.

Intersocietal Commission for the Accreditation of Echocardiography Laboratory. 2001.
 5. Facility Criteria: include all standards in the CMS Hospital Affiliated Pediatric Non-Invasive Cardiology Laboratory Component section.
 6. The CMS Deputy Secretary considers new facilities for approval upon the recommendation of the CMS Cardiac Subcommittee and the criteria established above. The Deputy Secretary shall make the final decision on whether to approve an application.
- J. Re-evaluation of Approved Facilities
1. On-site Review: Each Hospital Affiliated Pediatric Non-Invasive Cardiology Laboratory must be re-evaluated at a minimum of once every three (3) years on-site by representatives or designees, of the CMS Cardiac Subcommittee. Application for re-evaluation and approval is not complete until the Deputy Secretary for CMS receives the recommendation of the CMS Cardiac Subcommittee.
 2. Medical Record Review: A minimum of 25 consecutive pediatric cardiac cases within a specified time period must be available for review at the time of the re-evaluation.
 3. Facility and Practitioner Volume Standards: Meets requirements for Intersocietal Commission for the Accreditation of Echocardiography Laboratory (ICAEL) accreditation. *Intersocietal Commission for the Accreditation of Echocardiography Laboratory. 2001*
If the ICAEL requirements are not met, the facility shall be placed on probationary status for one year. Probationary status may be extended one (1) additional year if the facility documents a positive trend in meeting the volume standards. If the facility has not achieved the volume standards necessary for ICAEL accreditation at the end of a second year of probationary status, the facility shall be provided with a notice of intent to disapprove the facility as a CMS cardiovascular facility.
 4. ICAEL Accreditation: By the first three-year re-approval review, the echocardiography lab must be accredited by the ICAEL.
 5. Facility Criteria: include all standards in the CMS Hospital Affiliated Pediatric Non-Invasive Cardiology Laboratory Component section. If the facility criteria other than volume standards are not met, the facility must submit a corrective action plan for approval by the Deputy Secretary for CMS upon the recommendation of the CMS Cardiac Subcommittee. If the plan is approved, the facility shall be granted a one (1) year probationary status. Probationary status may be extended one additional year if the facility documents improvements toward achieving the facility criteria. If the facility is not in compliance with the facility criteria at the end of a second year of probationary status, the facility shall be provided with a notice of intent to disapprove the facility as a CMS cardiovascular facility. After the 90-day transition period, the facility will receive formal notice of disapproval.
 6. Data Submission: All CMS approved Pediatric Non-Invasive Cardiology Laboratories must collect and submit quality assurance data annually in accordance with the following CMS form:
 - Pediatric Non-Invasive Cardiology Laboratory Procedures (DH-CMS 2056, 8/05)
 7. In the event that a facility's participation with CMS is terminated by either the facility or CMS, 90 days notice shall be provided to the other party and to CMS patients receiving

active treatment at the facility. The 90-day notice is to assure adequate time to transfer care of the patient to another CMS cardiovascular facility.

8. The CMS Deputy Secretary considers existing facilities for re-approval upon the recommendation of the CMS Cardiac Subcommittee and the criteria established above. The Deputy Secretary shall make the final decision on whether to re-approve a facility.

II. Standards for CMS Pediatric Cardiac Catheterization Laboratory Component

- A. The Pediatric Cardiac Catheterization Laboratory must be co-located within a facility completely equipped to accommodate all aspects of the medical and surgical care of the patient.
Catheterization laboratory standards: a report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. J Am College Cardiology. 2001; 37:2170-2214.
- B. Cardiac Team
 1. Physician in Charge
The physician in charge of the procedure must be eligible for 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. Associate Physician
A second physician familiar with catheterization procedures must be immediately available either in the laboratory or in close proximity, in the event that additional help is needed or if a complication develops.
 3. Consulting Physicians
In addition to the two (2) physicians listed above, an anesthesiologist, and a thoracic surgeon, each with advanced training in the cardiovascular aspects of their specialty, must be immediately available within the facility or in close proximity for consultation, assistance, emergency and elective surgical procedures and peri-operative care.
 4. Nurse
Each laboratory must have a registered nurse, with special training in cardiovascular techniques and in the care of children, as a full time member of the team. This nurse must have special skills in pre-catheterization evaluation and instruction of the patient and family, care of the patient post-catheterization, and discharge teaching for the patient and family.
 5. Cardiovascular Technologist
Each lab must have a cardiovascular technologist with special training in cardiac catheterization lab techniques.
 6. Recording Cardiovascular Technologist
Each lab must have a recording cardiovascular technologist who has no other responsibilities during procedures.
 7. Each lab must have immediate access to personnel trained in equipment repair and maintenance.
 8. Although the required functions are well defined, it is not necessary for one person to fulfill each separate job category. Cross training for other personnel classifications permits 24-hour coverage of essential team functions.
 9. All technologists in a cardiovascular laboratory must be certified by the Cardiovascular Credentialing Institute as a Registered Cardiovascular Technologist (RCVT) and licensed by the State of Florida under the Clinical Laboratory law, when applicable.
- C. Equipment: Radiological, electronic, and computer-based systems are integral components of the equipment in a catheterization laboratory. These systems all require a program of rigorous maintenance and troubleshooting. For pediatric patients, biplane angiography, higher framing rates (30-60 fps), and higher injection rates (up to 40 mL/s) are required to help define abnormal intracardiac anatomy.

American College of Cardiology/Society for Cardiac Angiography and Interventions (ACC/SCA&I) Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards. J Am College of Cardiology. 2001; 37:2176 and 2185.

- D. Electrical Safety and Radiation Protection
Electrical safety and radiation protection shall be followed in accordance with the manufacturer's recommendations and applicable State and Federal regulations..
- E. Records
1. Permanent record of real time study must include, at a minimum, video, disk, or chart.
 2. Interpretation and final approval of study reports must be performed by a physician who is board certified or board eligible in pediatric cardiology.
 3. Medical records must be retained for a period of no less than seven (7) years in a locked area.
- F. Initial Evaluation
1. On-site Review: When an application requesting approval as a CMS Pediatric Cardiac Catheterization Laboratory facility is submitted with documentation of compliance with these standards, an on-site review by representatives or designees of the CMS Cardiac Subcommittee will be scheduled as the final component of the application process. An application shall not be deemed complete until the Deputy Secretary for CMS receives the recommendation of the CMS Cardiac Subcommittee.
 2. Medical Records Review: A minimum of 25 consecutive pediatric cardiac catheterization cases within a specified time period must be available to warrant initial inspection of any facility.
 3. Facility Volume Standards: The minimum annual number of pediatric cardiac catheterizations in an applicant facility is 100 per facility (a minimum of 50 interventional). *Catheterization laboratory standards: a report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. J Am College Cardiology. 2001; 37:2170-2214.*
 5. Practitioner Volume Standards: The minimum annual number of pediatric cardiac catheterizations performed by each practitioner in an applicant facility is 50 per year. Practitioners doing electrophysiological (E-P) procedures must do a minimum of 25 procedures per year. Practitioners doing interventional procedures must do a minimum of 25 procedures per year. *Catheterization laboratory standards: a report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. J Am College Cardiology. 2001; 37:2170-2214.*
 6. Facility Criteria: include all standards in the CMS Pediatric Cardiac Catheterization Laboratory Component section.
 7. The CMS Deputy Secretary considers new facilities for approval upon the recommendation of the CMS Cardiac Subcommittee and the criteria established above for pediatric cardiac catheterizations. The Deputy Secretary shall make the final decision on whether to approve an application.
- G. Re-evaluation of Approved Facilities
1. On-site Review: Each CMS approved Pediatric Cardiac Catheterization Laboratory Facility must be evaluated on-site by representatives or designees of the CMS Cardiac Subcommittee at a minimum of once every three (3) years. Application for re-evaluation and approval is not complete until the Deputy Secretary for CMS receives the recommendation of the CMS Cardiac Subcommittee.
 2. Medical Record Review: A minimum of 25 consecutive pediatric cardiac catheterization cases must be available within a specified time period for review at the time of the re-evaluation.
 3. Facility Volume Standards: The minimum annual number of cardiac catheterizations in an approved facility is 150 per facility (a minimum of 50 interventional).

If the annual facility volume drops below 100 for the twelve (12) month reporting period the facility shall be provided with a notice of intent to disapprove the facility as a CMS cardiovascular facility.

If the facility volume is below 150 but above 100 for the twelve (12) month reporting period, the facility shall be placed on probationary status for one year. Probationary status may be extended one (1) additional year if the facility documents a positive trend in meeting the volume standard. If the facility has not achieved the volume standard at the end of a second year of probationary status, the facility shall be provided with a notice of intent to disapprove the facility as a CMS cardiovascular facility.

4. **Practitioner Volume Standards:** By the first three-year re-approval review, the minimum number of cardiac catheterizations performed by each practitioner in an approved facility is 50 per year. Practitioners doing electrophysiological (E-P) procedures must do a minimum of 25 procedures per year. Practitioners doing interventional procedures must do a minimum of 25 procedures per year.
5. **Facility Criteria:** include all standards, other than facility volume standards, in the CMS Pediatric Cardiac Catheterization Laboratory Component section.
If the facility criteria other than the volume standards are not met, the facility must submit a corrective action plan for approval by the Deputy Secretary for CMS upon the recommendation of the CMS Cardiac Subcommittee. If the plan is approved, the facility shall be granted one-year probationary status. Probationary status may be extended one additional year if the facility documents improvements toward achieving the facility criteria. If the facility is not in compliance with the facility criteria at the end of a second year of probationary status, the facility shall be provided with a notice of intent to disapprove the facility as a CMS cardiovascular facility. After the 90-day transition period, the facility will receive formal notice of disapproval.
6. **Data Submission:** All CMS approved Pediatric Cardiac Catheterization Laboratories must collect and submit quality assurance data annually in accordance with the following CMS forms:
 - Cardiac Catheterization Procedures (DH-CMS 2057, 4/05); and
 - Cardiac Catheterization Cases--Primary Cardiac Diagnoses (DH-CMS 2058, 3/05).
7. In the event that a facility's participation with CMS is terminated by either the facility or CMS, 90 days notice shall be provided to the other party and to CMS patients receiving active treatment at the facility. The 90-day notice is to assure adequate time to transfer care of the patient to another CMS cardiovascular facility.
8. The CMS Deputy Secretary considers existing facilities for re-approval upon the recommendation of the CMS Cardiac Subcommittee and the criteria established above. The Deputy Secretary shall make the final decision on whether to approve a facility for re-approval.

III. Standards for CMS Pediatric Cardiovascular Surgery Program Component

- A. Diagnosis and treatment are so closely related that a CMS Pediatric Cardiovascular Surgery Program and CMS Pediatric Cardiac Catheterization Laboratory Component must be co-located on the same campus.
- B. General pediatric coverage with sub-specialty capability twenty-four hours a day, seven days a week.
- C. An effective system (with documentation) of rapid referral and transportation.
- D. Cardiac Team - Pediatric Cardiovascular Surgery Program must have accredited pediatric and general surgery training programs with house staff or must have other arrangements to provide 24-hour physician or house staff coverage.

1. A CMS approved cardiac surgeon with special training, interest and experience with pediatric cardiac patients and certification by the American Board of Thoracic Surgery or the American Osteopathic Association in the area of thoracic surgery.
 2. CMS approved associate thoracic and cardiovascular surgeon.
 3. Pediatric sub-specialists with expertise in hematology, nephrology, neurology, infectious disease, critical care and pulmonology must be available for consultation and management of patients with heart disease.
 4. Radiologist trained in cardiopulmonary disease.
 5. Anesthesiologist with training and experience in open and closed heart pediatric anesthesia.
 6. Respiratory Therapist with training and experience in short and long-term ventilatory support in infants and children.
 7. Technicians available 24 hours a day for laboratory and radiology procedures.
 8. Perfusionist who is certified by the American Board of Cardiovascular Perfusion or the American Osteopathic Association in the area of cardiovascular perfusion.
 9. Specially trained nurses for preoperative evaluation and instruction of the patient and family, intensive care, and convalescent care.
 10. Pathologist with skills and training in cardiovascular pathology.
 11. The facility must identify and utilize a core surgical team.
- E. Pre-operative Preparation
1. Dedicated pediatric patient rooms with provision for a parent or guardian to remain overnight with their children.
 2. Clear instructions to parents and patient with visits to catheterization laboratory, intensive care, and other sites as needed, consistent with their ability to comprehend.
 3. Care management conference between the pediatric cardiologist, pediatric cardiovascular surgeon, and other professional staff as necessary as documented in the patient record.
- F. Post-operative Care
- All post-operative care must be under the direction of the involved CMS approved cardiovascular surgeons in communication with, and support of, the post-operative cardiovascular team composed of pediatric intensivists, cardiologists, neonatologists, anesthesiologists, and other personnel as needed.
- G. Initial Evaluation
1. On-site Review: When an application requesting approval as a CMS pediatric cardiovascular surgery facility is submitted with documentation of compliance with these standards, an on-site review by representatives or designees of the CMS Cardiac Subcommittee shall be scheduled as the final component of the application process. An application shall not be deemed complete until the Deputy Secretary for CMS receives the recommendation of the CMS Cardiac Subcommittee.
 2. Medical Records Review: A minimum of 25 consecutive pediatric cardiac surgical cases must be available within a specified time period to warrant initial inspection of any facility.
 3. Facility Volume Standard: The minimum annual number of pediatric cardiac surgeries in an applicant facility is 100.
In-Hospital Mortality For Surgical Repair Of Congenital Heart Defects: Preliminary Observations Of Variation By Hospital Caseload. Pediatrics. 1995; 95:323-330.
 4. The Pediatric Cardiovascular Surgery Facility must be within a CMS approved hospital.
 5. The facility must be affiliated with a CMS approved Pediatric Cardiac Clinic Facility.
 6. Facility Criteria: include all standards in the CMS Pediatric Cardiovascular Surgery Program Component section. If the facility criteria other than volume standards are not met the facility must submit a corrective action plan for approval by the Deputy Secretary for CMS upon the recommendation of the CMS Cardiac Subcommittee. If the plan is approved, the facility shall be granted a one (1) year probationary status. Probationary status may be extended one (1) additional year if the facility documents improvements

toward achieving the facility criteria. If the facility is not in compliance with the facility criteria at the end of a second year of probationary status, the facility shall be provided with a notice of intent to disapprove the facility as a CMS cardiovascular facility.

7. The CMS Deputy Secretary considers new facilities for approval upon the recommendation of the Cardiac Subcommittee and the criteria established above for pediatric cardiac surgery. The Deputy Secretary shall make the final decision on whether to approve an application.

H. Re-evaluation of Approved Facilities

1. **On-site Review:** Each CMS approved Pediatric Cardiovascular Surgical Facility must be evaluated on-site by representatives or designees of the CMS Cardiac Subcommittee at a minimum of once every three (3) years. Application for re-evaluation and approval is not complete until the Deputy Secretary for CMS receives the recommendation of the CMS Cardiac Subcommittee.
2. **Medical Record Review:** A minimum of 25 consecutive pediatric cardiac surgical cases must be available within a specified time period for review at the time of the re-evaluation.
3. **Facility Volume Standard:** By the first three-year re-approval review, the minimum annual number of pediatric cardiac surgeries for an approved facility is 150. If the annual facility volume drops below 100 for the twelve (12) month reporting period, the facility shall be provided with a notice of intent to disapprove the facility as a CMS cardiovascular facility. If the facility volume is below 150 but above 100, the facility shall be placed on probationary status for one (1) year. Probationary status may be extended one (1) additional year if the facility documents a positive trend in meeting the volume standard. If the facility has not achieved the volume standard at the end of a second year of probationary status, the facility shall be provided with a notice of intent to disapprove the facility as a CMS cardiovascular facility. After the 90-day transition period, the facility will receive a formal notice of disapproval.
4. **Facility Criteria:** include all standards, other than facility volume standards, in the CMS Pediatric Cardiovascular Surgery Program Component section. If the facility criteria other than volume standards are not met the facility must submit a corrective action plan for approval by the Deputy Secretary for CMS upon the recommendation of the CMS Cardiac Subcommittee. If the plan is approved, the facility shall be granted one-year probationary status. Probationary status may be extended one additional year if the facility documents improvements toward achieving the facility criteria. If the facility is not in compliance with the facility criteria at the end of a second year of probationary status, the facility shall be provided with a notice of intent to disapprove the facility as a CMS cardiovascular facility. After the 90-day transition period, the facility will receive a formal notice of disapproval.
5. **Data Submission:** All CMS approved Pediatric Cardiovascular Surgical Programs must collect and submit quality assurance data annually in accordance with the following CMS forms:
 - Pediatric Cardiac Surgical Procedures--Closed Heart Procedures (DH-CMS 2059, 4/05); and
 - Pediatric Cardiac Surgical Procedures--Open Heart Procedures (DH-CMS 2060, 4/05).
6. In the event that a facility's participation with CMS is terminated by either the facility or CMS, 90 days notice shall be provided to the other party and to CMS patients receiving active treatment at the facility. The 90 day notice is to assure adequate time to transfer care of the patient to another CMS cardiovascular facility
7. The CMS Deputy Secretary considers existing facilities for re-approval for pediatric cardiac surgery upon the recommendation of the CMS Cardiac Subcommittee and the criteria established above. The Deputy Secretary shall make the final decision on whether to re-approve an existing facility.