Children’s Medical Services (CMS) Pediatric Cardiovascular Centers undergo a quality assurance process that ensures such CMS Pediatric Cardiovascular Centers 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 entering into, and continuing in, an agreement with the Department of Health as a CMS Pediatric Cardiovascular Center. A CMS Pediatric Cardiovascular Center will consist of the following co-located components:

I. Pediatric Cardiology Clinic

II. Pediatric Cardiac Catheterization Laboratory

III. Pediatric Cardiac Electrophysiology (EP) Program
IV. Pediatric Cardiovascular Surgery Program

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

For the purposes of CMS Pediatric Cardiovascular Center program evaluation, development and review, each distinct facility component will be surveyed individually within a multi-site Pediatric Cardiovascular Center. Each of its individual components must meet or exceed CMS standards; that is, each hospital-based team must perform the minimum number of echocardiograms, catheterizations, electrophysiologic studies and surgeries specified herein. Each component in the CMS Pediatric Cardiovascular Center shall be evaluated based on its own merits.

All CMS Pediatric Cardiovascular Centers must:
1. Be located within a healthcare facility that maintains accreditation by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and/or the National Committee for Quality Assurance (NCQA).

2. Be HIPAA (Health Insurance Portability and Accountability Act) compliant.

3. Provide limited English proficiency services, in accordance with Federal guidelines.

4. Have quality assurance and quality improvement processes in place that continuously enhance the clinical operation and patient satisfaction with services.

5. Collect and submit quality assurance data annually in accordance with the following CMS forms:
   - Pediatric Cardiology Clinic Laboratory Procedures (DH-CMS 2056, 10/20XX)
   - Pediatric Cardiac Catheterization Procedures (DH-CMS 2057, 10/20XX)
   - Cardiac Catheterization Cases--Primary Cardiac Diagnoses (DH-CMS 2058, 10/20XX).
   - Patients with Fetal Diagnosis of Heart Conditions (DH-CMS 2065, 10/20XX)

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.

6. Actively participate in the Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database.

7. Participate in the STS Congenital Heart Surgery Database Anesthesia Module.

8. Participate in the Improving Pediatric and Adult Congenital Treatments (IMPACT) database.

9. Collect and submit the following quality assurance data annually, from their annual STS Congenital Heart Surgery Database Report:

- Number of patients/operations submitted and an analysis of discharge mortality, and complexity information, by year
- Aristotle Basic Complexity Level Discharge Mortality, by year
- Risk-Adjusted Congenital Heart Surgery (RACHS)-1 Discharge Mortality, by year
- Number of patient/operations in analysis, discharge mortality, and complexity information, by age group
- Aristotle Basic Complexity Level Discharge Mortality, by age group
- RACHS-1 Discharge Mortality, by age group
• Primary Procedure Discharge Mortality based on Aristotle Basic Complexity Score, sorted by anomaly

• STS-EACTS (European Association of Cardio-Thoracic Surgery) Mortality Category Discharge Mortality, by year

• STS-EACTS Mortality Category Discharge Mortality, by age group

All CMS Pediatric Cardiovascular Centers must implement electronic medical record technology.

All CMS Pediatric Cardiovascular Centers with birthing centers must have a neonatal screening program using pulse oximetry to detect critical congenital heart disease.

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 and other licensed healthcare professionals that require credentialing through the CMS credentialing process and are providing care at a CMS Pediatric
Facilities requesting to be involved as a CMS Pediatric Cardiovascular Center must submit a formal request to the Deputy State Health Officer for CMS or designee at 4052 Bald Cypress Way, Bin # A-06, Tallahassee, Florida, 32399-1707.

I. Standards for CMS Hospital Co-located Pediatric Cardiology Clinic

A. The hospital pediatric cardiology clinic must be co-located with a CMS Pediatric Cardiac Catheterization Laboratory.

B. All echocardiography laboratories performing Transthoracic Echoes (TTE), Trans Esophageal Echoes (TEE) and Fetal Echoes (FE) must be accredited by the Intersocietal Accreditation Commission (IAC) prior to their initial or subsequent program evaluation and development review.

C. A pediatric cardiology clinic must be able to perform diagnostic evaluations including, but not limited to, echocardiographic recording, Holter monitoring, exercise testing, and serial pacemaker monitoring. They must either be able to perform fetal echocardiograms or have access to a fetal echocardiography facility. Each center must annually perform at least 50 procedures each for...
Holter monitor recordings and serial pacemaker monitoring procedures. Each center must annually perform at least 50 exercise testing studies.

D. Fetal echocardiograms performed by a physician outside the physical boundaries of an IAC approved facility may be counted toward the required Facility Volume Standards so long as all of the following criteria are met:

1. The physician performing the fetal echocardiogram is on the medical staff of the hospital facility and affiliated with the hospital’s pediatric cardiology program;

2. The physician performing the fetal echocardiogram is a CMS credentialed physician;

3. The program provides evidence that the physician maintains appropriate times of operation and protocols, including proper affiliation agreements to ensure availability and appropriate referrals in the event of emergencies; and

4. The fetal echocardiographic laboratory is accredited by IAC.

E. Cardiology Clinic Components

1. Pediatric Cardiology Clinic:

   i) Physicians – The physician in charge of a Pediatric Cardiology Clinic must be board-certified by the Sub-board of Pediatric Cardiology of the American Board of Pediatrics. Recertification or maintenance of
competency (MOC) certificates of such a physician will be an integral component of all future CMS program evaluation and development reviews. Board eligibility as an equivalent for board certification will not be considered as a criterion for credentialing beyond 5 years of eligibility unless a specific exception is made by the Deputy State Health Officer for CMS or designee.

ii) Nurse - A registered nurse who has expertise with cardiac problems in children must participate in each cardiac clinic.

iii) Social Worker or another individual capable of performing social service functions.

2. Echocardiography Laboratory:

   i) A physician who is board certified in pediatric cardiology.

   ii) A sonographer who is a Registered Diagnostic Cardiac Sonographer (RDCS), American Registry of Diagnostic Medical Sonographers (ARMDS), or Registered Cardiovascular Technologist (RCVT) pediatric certified.

   iii) The echocardiography laboratory workstation must include a study review area with dictation capabilities, and supplies and equipment necessary for compilation and analysis of echocardiographic studies.
3. Holter Monitoring Laboratory:
   A physician who is board certified in pediatric cardiology.

4. Exercise Treadmill Laboratory:
   i) A physician who is board certified in pediatric cardiology.
   ii) A Basic Life Support (BLS) certified cardiology technologist or respiratory care practitioner.
   iii) Pediatric Advanced Life Support (PALS) trained personnel available in-house.
   iv) The exercise treadmill lab must include a remote “code” button and telephone.
   v) Each center should have access to a metabolic exercise laboratory, in which oxygen utilization and the anaerobic threshold can be determined, as an adjunct to detecting early failing cardiopulmonary function.
   vi) All CMS institutions should follow the guidelines set forth in the American Heart Association Scientific Statement on "Clinical Stress Testing in the Pediatric Age Group" (Circulation. 2006; 113:1905-1920).
vii) Specifically, CMS requires that involved institutions:

a) Maintain an appropriate pediatric exercise physiology laboratory, including

1) Age- and size-appropriate treadmill and/or cycle ergometer

2) Age- and size-appropriate blood pressure cuffs

3) Age- and size-appropriate oxygen saturation monitor

4) EKG recording equipment

5) An emergency resuscitation cart that includes emergency drugs, a defibrillator, supplemental oxygen, and a portable suction unit

6) A log demonstrating periodic testing of the defibrillator and oxygen supply, and periodic inspection of emergency drug expiration dates

b) Conduct all stress tests with at least one person trained in pediatric advanced life support (PALS) in the room at all times with the patient during the test

c) Conduct all stress tests with a physician immediately available (i.e. in the building)
d) Perform a minimum of 50 pediatric exercise stress tests per year

e) Obtain meaningful written consent for the stress test (which may be a hospital-wide standard consent form filled out specifically for stress testing)

viii) PCMS institutions are recommended to:

a) Have oversight of the laboratory and testing procedures provided by a physician trained in exercise testing and exercise physiology

b) Be able to perform spirometry/pulmonary function testing

c) Be able to perform metabolic stress tests

d) Be able to perform or refer patients for stress echocardiography

e) Be able to perform or refer patients for pharmacologic stress testing

f) Be able to perform or refer patients for nuclear myocardial blood flow imaging

5. Serial monitoring and management of implanted electronic devices, such as pacemakers and defibrillators should be an integral component of any center.
6. **Adult Congenital Heart Clinic - Each CMS Pediatric Cardiology Clinic**

   must have a specific adult congenital heart clinic, listed by the Adult
   Congenital Heart Association (ACHA). Such a clinic should have a
   physician clinic director with special skills and expertise in dealing with
   adults with congenital heart disease.

7. **Adult Congenital Heart Programs:**

   i) **All adults with congenital heart disease deserve access to**
       appropriate care.

   ii) **Each CMS Pediatric Cardiovascular Center must have as a goal to**
       provide care in alignment with national standards, utilizing as
       guidelines those of the Adult Congenital Heart Association
       (ACHA).

   iii) **More self-sustaining comprehensive Adult Congenital Heart**
       Programs (ACHP) will be needed to provide such type of care in
       the future. Collaboration among CMS Pediatric Cardiovascular
       Centers with some regionalization of expertise is encouraged.

   iv) **Existing national and international guidelines, which outline the**
       care provided in adult congenital heart programs, should be
       utilized.
v) All ACHD programs must be registered with the Adult Congenital Heart Association and submit required data at established intervals.

vi) Personnel

a) The program must be directed by a physician with special skills and training in caring for the adult patient with congenital heart disease.

b) A primary goal of each ACHD program is that the Director of the ACHD program be board certified by the ABP/ABIM ACHD sub-board within five years of the initial examination.

c) Cardiac Surgeon(s) with expertise in the unique surgical aspects and challenges of the adult congenital heart patient.

d) Social Worker who is available to the adult patient to provide counseling and support services.

e) A health professional (ARNP or PA) whose role includes coordinating care for ACHD patients.

f) Availability of Adult Medicine sub-specialty physicians to provide consultative care.

g) All physicians caring for the adult congenital heart disease patient be ACLS certified.
h) All staff performing exercise testing on adult congenital heart
disease patient be ACLS certified.

vii) Clinic Physical Space

a) The clinic space used for evaluation of adult patients must be
in accordance with their specific needs.

b) Facility must be accessible to handicapped Individuals.

c) Availability of EKG, X-Rays, MRI studies, Echocardiography,
and exercise/metabolic stress testing

d) Availability of a conference room for multi-disciplinary
meetings.

viii) Hospital and Inpatient Facilities

a) The admitting facility must have expertise in the care of this
complex adult congenital heart patient population.

b) The ACHD Program must have access to a fully equipped
cardiac laboratory with appropriately trained personnel.

c) The ACHD Program must meet national standards in all
cardiac catheterization interventional and electrophysiology
procedures.
d) The ACHD Program must offer a comprehensive cardiovascular surgical program with established commitment from cardiac intensivists, anesthesiologists, and other adult medical and surgical subspecialties.

ix) Patient Care Characteristics Specific to an ACHD Program – Recommendations and Specific Requirements:

a) Patient care transition services must be emphasized during patient encounters. Transition education of the pediatric patient should start at age 12 years and should be documented in clinic notes. Such transition programs should be coordinated with the area Children’s Medical Services transition program where available.

b) All adult patients (18 years or older) must be referred for an initial evaluation by an adult congenital heart specialist.

c) Adult female patients with congenital heart disease must have access to professional staff expert in the management of contraception and pre-pregnancy counseling. In addition, Genetic Counseling and Fetal Echocardiography studies must be available.
d) Pregnant patients with congenital heart disease must be evaluated as a High-Risk Pregnancy and referred to Maternal-Fetal Medicine Physicians.

e) Health maintenance programs for adolescents and adult patients with CHD should be initiated by providing each patient with information related to, but not limited, to recommendations on endocarditis prophylaxis, anticoagulation therapy, diet, weight control, contraception, pregnancy risk and exercise limitations.

f) There must be a major educational component that forms the foundation of the ACHD program that will advance public awareness, educate the medical and health care community and empower those individuals with adult CHD to have opportunities to be successful contributing adults to their respective communities.

g) The ACHD program is strongly encouraged to develop partnership with sister institutions to do collaborative research, cultivate working relationships and form advocacy groups to support their patients with CHD. These partnership building
activities should aim to address the critical issues in ACHD patients and aid in achieving health equity for all such adult patients with congenital heart disease.

8. Annual updates on information submitted by each center to the ACHA regarding adult congenital heart disease activities should be forwarded to the CMS program staff within 30 days of such submission.

9. High Risk Obstetrical Cases with Fetal Cardiac Anomalies - Each CMS Pediatric Cardiovascular Center must have an established protocol to address the needs of such patients, usually high-risk obstetrical cases having a cardiac fetal anomaly diagnosed by fetal echocardiography and/or ultrasound.

F. Physical Facility General requirements:

1. The area must be suitable for performance of a high quality cardiovascular examination.

2. Examination areas must be adequately lighted, have adjustable temperature, and offer privacy to patients.

3. A conference room must be available for discussing cases.

G. Equipment - All clinic equipment must be monitored and maintained in accordance with manufacturers’ recommendations.
H. Radiological equipment- Access to a Radiological facility at which chest x-rays and other indicated radiological studies can be expeditiously performed, including access to Magnetic Resonance Imaging (MRI) studies, particularly to evaluate the large vessels of the chest associated with the heart.

I. Records

1. Permanent record of real time study must include, at a minimum, video, disk, chart, or digital or electronic medical records.

2. Permanent record of real time study of Holter Monitoring studies must include one or more of the following: cassette tape, disk, printed paper, or digital or electronic medical records.

3. Permanent record of real time study of exercise treadmill testing must include EKG and blood pressure recordings.

4. Permanent record of real time study of serial pacemaker testing must be available.

5. Interpretation and final approval of study reports must be performed by a physician who is board certified in pediatric cardiology.

6. Medical records must be retained for a period of no less than seven (7) years in a locked area.
J. Initial Evaluation

1. Program evaluation and development review: When a request is received for involvement as a CMS Hospital co-located Pediatric Cardiology Clinic, along with attestation of compliance with these standards, a program evaluation and development review by members or designees of the CMS Cardiac Technical Advisory Panel will be scheduled. A request for involvement shall not be deemed complete until the Deputy State Health Officer for CMS or designee receives the recommendation of the CMS Cardiac Technical Advisory Panel.

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 and Practitioner Volume Standards: A facility requesting to participate as a CMS Pediatric Cardiovascular Center must meet requirements for and have documentation of IAC accreditation.

4. Facility Criteria: include all standards in the CMS Hospital co-located Pediatric Cardiology Clinic Component section.

5. The Deputy State Health Officer for CMS or designee considers new facilities for upon the recommendation of the CMS Cardiac Technical
Advisory Panel and the criteria established above. The Deputy State Health Officer for CMS or designee shall make the final decision on whether a facility may participate by entering into an agreement with the Department of Health.

K. Re-evaluation of CMS Pediatric Cardiovascular Centers

1. Program Evaluation and Development Review: Each Hospital co-located Pediatric Cardiology Clinic must be re-evaluated at a minimum of once every three (3) years on-site by members or designees of the CMS Cardiac Technical Advisory Panel. The re-evaluation process is not complete until the Deputy State Health Officer for CMS or designee receives the recommendation of the CMS Cardiac Technical Advisory Panel.

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.


If all IAC requirements are not met, 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 standards. If the facility has not achieved the volume

standards necessary for IAC accreditation at the end of a second year of

probationary status, the facility shall be provided with a notice of intent to

end the agreement between the CMS Pediatric Cardiovascular Center and

the Department of Health as a participating CMS Pediatric Cardiovascular

Center.

4. IAC Accreditation: By the initial or subsequent program evaluation and
development review, all echocardiography laboratories, TTE, TEE, and
FE must be accredited by the IAC, whether within the center or “off-site”.

5. Facility Criteria: include all standards in the CMS Hospital co-located
Pediatric Cardiology Clinic Component section. If all facility criteria
other than volume standards are not met, the facility must submit a
corrective action plan for approval by the Deputy State Health Officer for
CMS or designee, upon the recommendation of the CMS Cardiac
Technical Advisory Panel. 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 all the facility criteria. If the facility is not in
compliance with all the facility criteria at the end of a second year of
probationary status, the facility shall be provided with a notice of intent to end the agreement between the CMS Pediatric Cardiovascular Center and the Department of Health. After a 90-day transition period, the facility will receive formal notice of the end of the agreement between the CMS Pediatric Cardiovascular Center and the Department of Health.

6. Data Submission: All CMS Pediatric Cardiology Clinics must collect and submit quality assurance data annually in accordance with the following CMS form:

- Pediatric Cardiology Clinic Laboratory Procedures (DH-CMS 2056, 10/20XX)

7. In the event that a facility’s participation with CMS is terminated by either the facility or CMS, a 90-day notice shall be provided to the CMS Pediatric Cardiovascular Center. The CMS Deputy State Health Officer for CMS or designee considers existing facilities for continuing involvement upon the recommendation of the CMS Cardiac Technical Advisory Panel and the criteria established above. The Deputy State Health Officer for CMS or designee shall make the final decision on whether or not a facility by continue such an agreement with the Department of Health.
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.

B. Cardiac Team

1. Physician in Charge

The physician in charge of the procedure must be board-certified by the Sub-Board of Pediatric Cardiology of the American Board of Pediatrics. Pediatric cardiologists either trained in other countries or for any reason not eligible for certification by the Sub-Board of Pediatric Cardiology of the American Board of Pediatrics may be credentialed as a CMS physician by the Deputy State Health Officer for CMS or designee, as a special...
situation after a review and in-depth evaluation by the CMS Cardiac Technical Advisory Panel, which recommended such approval.

2. Consulting Physicians

In addition to the physician listed above, in interventional cardiac catheterizations, 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.

3. 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.

4. Cardiovascular Technologist

Each laboratory must have a cardiovascular technologist with special training in cardiac catheterization laboratory techniques.
5. Dedicated Trained Cardiovascular Recorder

Each laboratory must have a dedicated trained cardiovascular recorder who has no other responsibilities during procedures.

6. Each laboratory must have immediate access to personnel trained in equipment repair and maintenance.

7. Although the above required functions are well defined, it is not necessary for one person to fulfill each separate job category. Well defined adequate cross training for other personnel classifications permits 24-hour coverage of essential team functions.

8. 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 intra-cardiac anatomy.
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, chart, or digital/electronic recordings.

2. Interpretation and final approval of study reports must be performed by a physician who is board certified in pediatric cardiology.

3. Medical records must be retained for a period of no less than seven (7) years in a secure locked area.

F. Initial Evaluation

1. Program Evaluation Review: When a request is received for participation as a CMS Pediatric Cardiac Catheterization Laboratory facility, along with attestation of compliance with all these standards, a program evaluation
and development review by members or designees of the CMS Cardiac Technical Advisory Panel will be scheduled as the final component of the application process. A request for participation shall not be deemed complete until the Deputy State Health Officer for CMS or designee receives the recommendation of the CMS Cardiac Technical Advisory Panel.

2. Medical Records Review: A minimum of 25 consecutive pediatric cardiac catheterization cases within a specified time period must be available to warrant initial program evaluation and development review of any facility.

3. Facility Volume Standards: The minimum annual number of pediatric cardiac catheterizations in a facility requesting to participate as a CMS Pediatric Cardiovascular Center is 150 per facility (with a minimum of 50 interventional).

4. Practitioner Volume Standards: The minimum annual number of pediatric cardiac catheterizations performed by each practitioner in a facility

requesting to participate as a CMS Pediatric Cardiovascular Center is 50 per year. Practitioners doing interventional procedures must do a minimum of 25 interventional catheterizations per year.


5. Facility Criteria: include all standards in the CMS Pediatric Cardiac Catheterization Laboratory Component section.

6. The CMS Deputy State Health Officer for CMS or designee considers new facilities for involvement upon the recommendation of the CMS Cardiac Technical Advisory Panel and all the criteria established above for pediatric cardiac catheterizations. The Deputy State Health Officer for CMS or designee shall make the final decision on whether or not a facility may continue such entering into an agreement with the Department of Health.

G. Re-evaluation of CMS Facilities

1. Program Evaluation and Development Review: Each CMS Pediatric Cardiac Catheterization Laboratory Facility must be evaluated on-site by
members or designees of the CMS Cardiac Technical Advisory Panel at a minimum of once every three (3) years. The re-evaluation process is not complete until the Deputy State Health Officer for CMS or designee receives the recommendation of the CMS Cardiac Technical Advisory Panel.

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.

Facility Volume Standards: The minimum annual number of cardiac catheterizations in a CMS Pediatric Cardiovascular Center is 150 per facility (with a minimum of 50 interventional). If the facility volume is below 150 for the twelve (12) month reporting period, 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 end the agreement between the CMS Pediatric Cardiovascular Center and the Department of Health.
3. Practitioner Volume Standards: By the first or subsequent three-year program evaluation and development review, the minimum number of cardiac catheterizations performed by each practitioner in a CMS Pediatric Cardiovascular Center is 50 per year. Practitioners doing interventional procedures must do a minimum of 25 interventional catheterizations per year.

4. Facility Criteria: include all standards, other than facility volume standards, in the CMS Pediatric Cardiac Catheterization Laboratory Component section.

If the facility is not in compliance with all the required criteria other than the volume standards, the facility must submit a corrective action plan for approval by the Deputy State Health Officer for CMS or designee upon the recommendation of the CMS Cardiac Technical Advisory Panel. If the plan is approved, the facility shall be granted one-year probationary status. Probationary status may be extended one (1) additional year if the facility documents improvements toward achieving all the facility criteria. If the facility is not in compliance with all the facility criteria at the end of a second year of probationary status, the facility shall be provided with a notice of intent to end the agreement between the CMS Pediatric
Cardiovascular Center and the Department of Health. After the 90 day patient care transition period, the facility will receive formal notice of the end of the agreement between the CMS Pediatric Cardiovascular Center and the Department of Health.

5. Data Submission: All CMS Pediatric Cardiac Catheterization Laboratories must collect and submit quality assurance data annually in accordance with the following CMS forms:

- Pediatric Cardiac Catheterization Procedures (DH-CMS 2057, 10/20XX); and
- Cardiac Catheterization Cases--Primary Cardiac Diagnoses (DH-CMS 2058, 10/20XX).

6. In the event that a facility’s participation with CMS is terminated by either the facility or CMS, a 90 day notice shall be provided to the CMS Pediatric Cardiovascular Center.

7. The CMS Deputy State Health Officer for CMS or designee considers existing facilities for continuing involvement based upon the recommendation of the CMS Cardiac Technical Advisory Panel and all the criteria established above. The Deputy State Health Officer for CMS
or designee shall make the final decision on whether or not a facility may continue such an agreement with the Department of Health.

III. Standards for CMS Pediatric Cardiac Electrophysiology (EP) Programs

A Pediatric Cardiac Electrophysiology (EP) Program is an integral part of a CMS Pediatric Cardiovascular Center. The EP program has two main components: (1) An Interventional program in a Pediatric Cardiac Electrophysiology Laboratory and (2) an outpatient arrhythmia evaluation and management service.

An institution participating as a CMS Pediatric Cardiovascular Center, may elect not to participate in both components of these EP Standards.

All CMS designated centers must participate in the outpatient arrhythmia evaluation and management services.

If an institution elects not to participate in the EP interventional program in a pediatric cardiology electrophysiology laboratory, it must have a written format establishing an effective triage to another CMS EP facility as defined below. Such a protocol must include a formal document signed by the CEO's of both involved institutions and approved by the CMS Deputy State Health Officer for CMS or designee.
A. Laboratory Component: The Pediatric Cardiac Electrophysiology Laboratory

must be co-located within a facility completely equipped to accommodate all
aspects of the medical and surgical care of the pediatric patient.

1. Cardiac Team

   i) Physician in Charge: The physician in charge of the laboratory must be
   board-certified by the Sub-Board of Pediatric Cardiology of the
   American Board of Pediatrics and must be a pediatric
electrophysiologist as defined below:

   a) Pediatric Electrophysiologist is a Pediatric Cardiology Board
   Certified physician, whose primary clinical practice is dedicated to
   pediatric electrophysiology activities.

   b) In addition, the individual to be credentialed by CMS as a pediatric
   electrophysiologist must meet the International Board of Heart
   Rhythm Examiners (IBHRE) board eligibility criteria by meeting
   or exceeding the requirements outlined by one or both of the tracks
   outlined below:
International Board of Heart Rhythm Examiners. Eligibility

Requirements Policy: IBHRE Board Certification Examination in Cardiac Electrophysiology for the Physician 10.29.2010

Pediatric Electrophysiologist: Credentials

1) Track 1: Training Completed After July 1, 2005

(i) Successful completion of a pediatric cardiovascular medicine fellowship program and board-certified in Pediatric Cardiology by the American Board of Pediatrics.

(ii) Successful completion of a minimum of 1 additional year of cardiac electrophysiology training in a pediatric electrophysiology fellowship program. The training program must meet the minimum criteria set forth by the task force in pediatric cardiology training. ACCF/AHA/AAP Recommendations for Training in Pediatric Cardiology. A Report of the American College of Cardiology Foundation/American Heart Association/American Committee to Develop Training Recommendations for Pediatric Cardiology) College of Physicians Task Force on Clinical Competence Circulation. 2005;112:2555-2580
(iii) In addition, the electrophysiologist must monitor on a continuing basis at least 30 patients with implanted devices. However, the involved pediatric electrophysiologist does not necessarily have to perform all such device implantations.

2) Track 2: Training Completed Before July 1, 2005

(i) Pediatric EP applicants completing training prior to July 1, 2005 may qualify either by satisfying Track 1 requirements above, or by demonstrating a minimum level of practice experience consisting of at least 5 years of active pediatric electrophysiology experience, in which the applicant’s primary clinical interest is pediatric electrophysiology. The candidate must be actively involved in the management and care of pediatric arrhythmia patients.

(ii) Past Experience:

(a) A minimum 5 year history of practicing pediatric electrophysiology as his or her primary clinical interest.
(b) In that 5 year span, performance of a minimum of 150 EP studies of which at least 90 or 60% of the total must have been catheter ablation procedures.


(c) In addition, the individual must monitor on a continuing basis at least 30 patients with implanted devices. However, the involved pediatric electrophysiologist does not necessarily have to perform any or all such device implantations.

3) Foreign Trainees: Pediatric cardiologists either trained in other countries, or for any other reason not eligible for certification by the Sub-Board of Pediatric Cardiology of the American Board of Pediatrics may be credentialed as a CMS physician.
specializing in electrophysiology by the Deputy State Health Officer for CMS or designee as a special situation after a review and in-depth evaluation by the CMS Cardiac Technical Advisory Panel, which recommended such credentialing.

ii) Consulting Physicians: In addition to the physician listed above, in interventional EP cardiac catheterizations, 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.

iii) 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 and post catheterization evaluation, and management. In addition, this individual must have skills in and be able to coordinate patient and family education and instructions pre and post procedure.

v) Dedicated Trained Cardiovascular EP Recorder:

a) Each laboratory must have a dedicated trained cardiovascular EP recorder who has no other responsibilities during such procedures.

b) Each laboratory must have immediate access to personnel trained in equipment repair and maintenance.

c) Although the above-required functions are well defined, it is not necessary for one person to fulfill each separate job category. Adequate cross training for other personnel classifications permits 24-hour coverage of essential team functions.

d) 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.

2. Equipment:

i) 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. In addition, a pediatric electrophysiology laboratory must have:

a) Multi Channel EP recording system

b) External Defibrillation system
c) Cardiopulmonary monitoring system
d) Radiofrequency Energy Source
e) It is strongly recommended that Pediatric Electrophysiology laboratories also have:

1) 3 Dimensional Mapping System

2) Cryo ablation System

ii) 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.

3. Records

i) Permanent record of real time study must include, at a minimum, video, disk, chart, or digital/electronic recordings.

ii) Interpretation and final approval of such EP study reports must be performed by a physician who is board certified in pediatric cardiology
and meets the standards to be qualified as a pediatric electrophysiologist,

as defined previously.

iii) Medical records must be retained for a period of no less than seven (7) years in a secure locked area.

4. Initial Evaluation

i) Program Evaluation and Development Review: When a request is received for participation as a CMS Pediatric Cardiac Electrophysiology Laboratory facility, along with attestation of compliance with all these standards, a program evaluation and development review by members or designees of the CMS Cardiac Technical Advisory Panel will be scheduled as the final component of the application process. An application shall not be deemed complete until the Deputy State Health Officer for CMS or designee receives the recommendation of the CMS Cardiac Technical Advisory Panel.

ii) Medical Records Review:

a) A minimum of 12 consecutive pediatric cardiac catheterization electrophysiologic studies within a year must be available to warrant initial inspection of any facility.
b) A minimum of 7 consecutive pediatric implantable device insertions (pacemakers and/or Implantable Cardioverter Defibrillators) studies within a year must be available to warrant initial inspection of any facility.

iii) Facility Volume Standards: Facilities shall be evaluated independently for two separate areas of expertise within a pediatric electrophysiology program: EP studies with ablations and device insertions.

a) EP studies and ablation: The minimum annual number of pediatric electrophysiologic studies in an applicant facility is recommended to be at least 30 per facility with a minimum of 18 ablations, or 60% of the total number of studies per year. 

Source: PACES SURVEY, 2012

b) Device implantations: Pacemaker and/or Implantable - Cardioverter Defibrillators (ICD) insertions. The minimum number of device implantations (pacemakers and/or ICD’s) in an applicant facility is recommended to be at least 10 per year. For the purpose of facility volume standards, device insertions may be performed by either a credentialed CMS pediatric cardiovascular surgeon and/or a credentialed CMS pediatric electrophysiologist.
iv) Practitioner Volume Standards:

a) Pediatric electrophysiologists shall be evaluated independently for two separate areas of expertise within a pediatric electrophysiology program: EP Studies with Ablation and Device Insertions

b) A practitioner may choose to be credentialed to perform EP Studies / Ablations and Device insertions, or both.

1) The minimum annual number of pediatric cardiac electrophysiologic studies performed by each practitioner in an applicant facility is recommended to be at least 30 per year, of which at least 18, or 60% of the total number of studies per year, are catheter ablation procedures.

2) The minimum annual number of pediatric device implants (pacemaker and/or ICD) performed by each practitioner in an applicant facility is recommended to be at least 10 per year.

Electrophysiology Society Clinical Competency Statement:

Training pathways for implantation of cardioverter-defibrillators and cardiac resynchronization therapy devices in pediatric and congenital heart patients. Developed in collaboration with the American College of Cardiology and the American Heart
(i) Practitioners whose volume falls below 10 per year must then demonstrate that they have an established working relationship with either a credentialed CMS pediatric cardiovascular surgeon or a credentialed CMS pediatric electrophysiologist performing device implants or an adult electrophysiologist trained in device implantation, and demonstrate that such physicians are available in case they are needed.

v) Outcomes Standards:

The members of the CMS Cardiac Technical Advisory Panel’s EP Task Force will develop and recommend that all CMS Cardiac Centers participate in a database into which the involved EP physicians would report the outcomes of their EP Studies and device insertions. Such database recommendations will be submitted to the CMS Cardiac Technical Advisory Panel and implemented if the Panel supports such recommendations.

a) Outcomes Standards - Initial Phase
1) Initially, CMS Pediatric Electrophysiology programs will be evaluated utilizing existing outcome expectations based on current literature, with the understanding that more data needs to be generated which incorporates modern technologies and expectations.

2) The presently appointed Florida CMS EP Task Force will create a pilot data-tracking tool, which will serve as a preliminary data repository. This will be implemented after a recommendation by the CMS Cardiac Technical Advisory Panel to, and approval by, the Director of the Division of Children’s Medical Services or his/her designee.

(i) Supraventricular Tachycardia (SVT) or Ventricular Tachycardia (VT) ablation outcomes in post-surgical or abnormal anatomy substrate. Acceptable success and complication standards are not yet defined. However, each will be reported for ongoing analysis.

(ii) Endocardial Device Insertion Procedures. Acceptable success and complication rates are not yet defined in the pediatric
population. However, outcomes will be reported for ongoing analysis.

(iii) Epicardial Device Insertion procedures are considered cardiac surgeries and outcomes evaluated in the context of the involved cardiovascular surgical program.

b) Outcomes Standards - Second Phase:

1) When a proposed national database (MAP-IT) is implemented and incorporated into the existing national cardiac catheterization database (IMPACT), the existing CMS EP data tracking tool is strongly recommended to be incorporated into this national database. All CMS pediatric cardiovascular centers are strongly recommended to participate and report their data to the MAP-IT national database when implemented.

2) When national outcome standards are defined, they will be submitted to the CMS Cardiac Technical Advisory Panel as the new outcome standards for Florida CMS pediatric electrophysiology centers.

3) Once procedural success and complication rates are measured and published, the CMS EP Task force shall recommend that
acceptable program and or practitioner volume and outcomes are within two standard deviations from the national mean. This recommendation shall be presented to the CMS Cardiac Technical Advisory Panel and submitted for incorporation into the present Rules by the Director of the Division of Children's Medical Services or his/her designee. Once these new volume and outcome standards are incorporated into the present Rules, programs whose volume or outcomes are below the new standards shall be subject to increased surveillance and potential probationary status as defined below.

vi) Facility Criteria: Includes all standards in the CMS Pediatric Cardiac Catheterization Laboratory Component section.

vii) The Deputy State Health Officer for CMS or designee considers new facilities for involvement in the CMS cardiac program upon the recommendation of the CMS Cardiac Technical Advisory Panel after meeting all the criteria established above for such pediatric cardiac catheterizations. The Deputy State Health Officer for CMS or designee shall make the final decision on whether to approve an applicant to be a Center.
5. Re-evaluation of CMS Centers:

a) Program Evaluation and Development Review: Each CMS Pediatric Cardiac Electrophysiology Laboratory Facility must be evaluated on-site by members or designees of the CMS Cardiac Technical Advisory Panel at a minimum of once every three (3) years. The re-evaluation process is not complete until the Deputy State Health Officer for CMS or designee receives the recommendations of the CMS Cardiac Technical Advisory Panel.

b) Medical Record Review: A minimum of 12 consecutive pediatric cardiac electrophysiologic studies must be available within a specified time period for review at the time of the re-evaluation. Volume Standards are as follows:

c) Facility Volume Standards: The minimum annual number of pediatric electrophysiologic studies in an applicant facility is recommended to be at least 30 per facility with a minimum of 18 ablations, or 60% of the total number of studies per year.

d) Practitioner Volume Standards:

(i) By the first or subsequent three-year review, the minimum annual number of pediatric cardiac electrophysiologic studies performed by each practitioner in an applicant facility is recommended to be at least 30 per
year, of which at least 18, or 60% of the total number of studies per year are catheter ablation procedures.

(ii) Pediatric electrophysiologists performing device implantations are recommended to perform at least 10 device implantation procedures per year.

e) During the initial phase of the development of outcomes standards, defined in Section III.A.4.v)a), EP facilities will be evaluated by examining their completeness of data submission. During this initial phase, the primary evaluative assessment will be procedural outcomes as deemed acceptable based on existing literature.

f) The second phase of outcomes evaluation, Section III.A.4.v)b), will be completed once national standards are derived from national databases into which all Florida EP programs are expected to submit their data. National volume and outcome standards, once created, will be recommended by the EP Task force to the CMS Cardiac Technical Advisory Panel and submitted for approval by the Deputy State Health Officer for CMS or designee. Once approved, these will become the volume and outcome standards by which each program is to be evaluated.
g) If the site review team determines the facility meets acceptable standards and has acceptable outcomes, then the facility and practitioner will be subject to be a component of the three year review cycle of CMS Pediatric Cardiovascular Centers.

h) If the facility is below acceptable standards and with less than acceptable outcomes, then the facility will be reviewed by the CMS Cardiac Technical Advisory Panel which may recommend that the facility 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 outcomes standard. If the facility has not achieved the acceptable outcomes standard at the end of a second year of probationary status, the facility shall be provided with a notice of intent to end the agreement between the CMS Pediatric Cardiovascular Center and the Department of Health. After a 90 day transition period, the facility will receive a formal notice to end the agreement between the CMS Pediatric Cardiovascular Center and the Department of Health.

B. Outpatient Clinic Component
1. Facility Criteria: include all standards, as outlined in the outpatient clinic section. In addition, an outpatient electrophysiology program must have the following components:

   i) Personnel:

      a) The physician in charge of this clinic is to be board certified in Pediatric Cardiology and Basic Life Support and have special expertise in arrhythmias and device management.

      b) The involved nurse/technician is to have special expertise in device management and be certified in both Basic Life Support and Pediatric Advanced Life Support.

   ii) Device Management: Pacemaker, Implantable Cardioverter Defibrillator (ICD) and Cardiac Resynchronization Therapy (CRT) device monitoring is performed by combining both in-clinic and remote (home) monitoring. Criteria for intervals for device follow-up must recognize that the complexity of the underlying heart disease dictates the intervals for such surveillance. A reasonable guide for in-clinic monitoring is as follows:

      a) Anti-bradycardia devices: At a minimum, the patient will be seen in the clinic one week and then 3 months post implant. Then the
patient should be seen no less frequently than annually as long as clinic visits are supplemented by remote monitoring from home no less frequently than every three months, and more frequently as may be clinically indicated. Complexity of the issues managed or device related issues may require a more intensive and frequent monitoring schedule. Evaluation of surgical site may be performed by physicians in the patient’s local community when deemed appropriate.

b) ICD and CRT devices: At a minimum, the patient will be seen in the clinic within one week and then 3 months post implant. Then the patient should be seen no less frequently than bi-annually as long as clinic visits are supplemented by remote monitoring from home no less frequently than every three months, and more frequently as may be clinically indicated. Complexity of the issues managed, or device related issues, may require a more intensive and frequent monitoring schedule. Evaluation of surgical site may be performed by physicians in the patient’s local community when deemed appropriate.

iii) Equipment

a) For in-clinic monitoring – the following items must be available:

Electrocardiographic (EKG) recording machine, External Defibrillator, Device programmers for: Pacemakers, Implantable-Cardioverter Defibrillators (ICD’s) and Cardiac Resynchronization Therapy (CRT’s).

b) For remote monitoring, some form of surveillance must be available including traditional trans-telephonic monitoring (TTM).

iv) Volume: It is recommended that the involved EP physicians should have managed, in their professional career, at least 75 patients with devices and maintained competence by performing 30 assessments annually.
v) Records: A complete database of patients with devices should be maintained and to include all device models and ID numbers, Lead models and ID numbers.

a) A permanent record of real time study of serial device testing must be maintained and kept for at least 7 years.

vi) Arrhythmia Management

a) Pediatric Electrophysiology clinics must be staffed by a pediatric electrophysiologist and at least one skilled nurse. Visit frequency is dictated individually by the severity of the arrhythmia.

1) Visits are recommended to include:

(i) Antiarrhythmic drug management, verification of drug dosages and drug-drug interactions

(ii) Surveillance of arrhythmia monitoring tests which may include a 12 lead electrocardiogram, Holter monitor electrocardiography, event or memory loping monitors, and a stress test.

(iii) Cardiac channelopathy patients are monitored as frequently as the specific disease requires. Proper management of these syndromes is recommended to include genetic testing
of the proband followed by family specific testing, and
genotype specific drug management and counseling.

vii) Evaluation of Participating Facilities:

1) If the facility is not in compliance with all the required personnel
and equipment criteria as described previously, the facility must
submit a corrective action plan for approval by the Deputy State
Health Officer for CMS or designee upon the recommendation of
the CMS Cardiac Technical Advisory Panel. If the plan is
approved, the facility shall be granted a one-year probationary
status. Probationary status may be extended one (1) additional year
if the facility documents improvements toward achieving all the
facility criteria. If the facility is not in compliance with all the
facility criteria at the end of a second year of probationary status,
the facility shall be provided with a notice of intent to end the
agreement between the CMS Pediatric Cardiovascular Center and
the Department of Health. After a 90 day transition period, the
facility will receive a formal notice to end the agreement between
the CMS Pediatric Cardiovascular Center and the Department of
Health.
2) Data Submission: The staff of all CMS Pediatric Cardiac Electrophysiology Centers must collect and submit quality assurance data annually in accordance with the following CMS forms:

(i) Cardiac Catheterization Procedures (DH-CMS 2057, 10/20XX);

(ii) Cardiac Catheterization Cases—Primary Cardiac Diagnoses (DH-CMS 2058, 10/20XX); and

(iii) Pediatric Cardiac Electrophysiology Laboratories (DH-CMS XXXX, XX/XX).

The Deputy State Health Officer for CMS or designee considers existing facilities for continuing involvement based upon the recommendation of the CMS Cardiac Technical Advisory Panel and all the criteria established above. The Deputy State Health Officer for CMS or designee shall make the final decision as to whether or not to continue such an agreement with the Department of Health.
Laboratory Component and a CMS Pediatric Cardiology Clinic 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 credentialed thoracic and cardiovascular surgeon with special

training, interest and experience with pediatric cardiac patients and
certification by the American Board of Thoracic Surgery. All such
surgeons will have 5 years to become Board Certified after becoming
eligible for such an examination. (? specialty Certificate in Congenital
Cardiac Surgery by the ABTS)

2. CMS credentialed associate thoracic and cardiovascular surgeon with

special training interest and experience with pediatric cardiac patients and
certification by the American Board of Thoracic Surgery. Such an
associate surgeon should be either “on-site”, available through an
established agreement with another CMS Pediatric Cardiovascular Center, or available by an established organizational format approved by the Deputy State Health Officer for CMS or designee.

3. In regards to the above thoracic and cardiovascular surgeons, since the new Sub-Board of Pediatric Cardiovascular Surgery under the American Board of Thoracic Surgery is now fully implemented, each surgeon who started such training after July 1, 2008 must be certified by this new Board within 5 years of becoming eligible. (and must complete maintenance of certification (MOC) as per the ABTS and subspecialty certification by the ABTS)

4. Pediatric cardiovascular surgeons, either trained in other countries or for any other reason not eligible for certification by the American Board of Thoracic Surgery, or the new Sub-Board of Pediatric Cardiovascular Surgery, may be credentialed as a CMS physician by the Deputy State Health Officer for CMS or designee as a special situation after a review and in-depth evaluation by the CMS Cardiac Technical Advisory Panel, which recommended such approval.

5. Pediatric sub-specialists with expertise in hematology, nephrology, neurology, infectious disease, critical care, genetics, gastroenterology and
58

pulmonology must be available for consultation and management of patients with heart disease.

6. Radiologist trained in cardiopulmonary disease.

7. Anesthesiologist with training and experience in open and closed heart pediatric anesthesia.

8. Respiratory Therapist with training and experience in short and long-term ventilatory support in infants and children.

9. Technicians available 24 hours a day for laboratory and radiology procedures.

10. Perfusionist who is certified by the American Board of Cardiovascular Perfusion. **number to be specified?**


12. Pathologist with skills and training in cardiovascular pathology.

13. The facility must identify and utilize a core surgical team.

14. Involved staff will make a priority of maintaining ongoing communication throughout the patient’s hospital course with the patient’s primary care physician. *(pediatrician? referring cardiologist?)*
15. Continuous availability of a team skilled in performing intra-operative TEE’s to aid in the post-surgical assessment of operative procedures.

16. Availability of Extra Corporeal Life Support (ECLS) ECMO??

E. Pre-operative Preparation

1. Dedicated pediatric patient rooms with provision for a parent, relative or guardian to remain overnight with hospitalized child.

2. Clear instructions to parents and patient with pre-operative visits to catheterization laboratory, intensive care unit, 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 documented in the patient record.

F. Post-operative Care

1. All post-operative care must be under the direction of the involved CMS credentialed cardiovascular surgeons in constant (24/7) communication with, and in support of, the post-operative cardiovascular team composed of pediatric intensivists, cardiologists, neonatologists, anesthesiologists, and other personnel as needed. In certain cases, the involved pediatric cardiovascular surgeon may transfer primary responsibilities (define) to
another member of the team, such as cases with arrhythmias, or neonates on Extra Corporeal Membrane Oxygenation (ECMO) in the neonatal intensive care unit (NICU).

2. Each CMS Pediatric Cardiovascular Surgical Facility must have a dedicated Pediatric Cardiovascular Intensive Care Unit with personnel specially trained in Congenital Heart Surgery, including physicians, nurses, respiratory specialists, and ancillary staff. Such a unit may be either a separate cardiac ICU or a dedicated component within a Pediatric Intensive Care Unit.

Guidelines for Pediatric Cardiovascular Centers: Pediatrics. 2002: Vol. 109 No. 3 544-549

G. Initial Evaluation

1. Program Evaluation and Development Review: When a request is received for involvement as a CMS pediatric cardiovascular surgery facility, along with attestation of compliance with all these standards, a program evaluation and development review by members or designees of the CMS Cardiac Technical Advisory Panel shall be scheduled as the final component of the application process. An application shall not be deemed complete until the Deputy State Health Officer for CMS or designee for
CMS or designee receives the recommendation of the CMS Cardiac Technical Advisory Panel.

2. Medical Records Review: A minimum of 25 consecutive pediatric cardiac surgical cases must be available within a specified time period to warrant initial program evaluation and development review of any facility.

Facility Volume Standard: The minimum annual (12 consecutive months) number of pediatric cardiac surgeries in a facility requesting to become a CMS Pediatric Cardiovascular Center is 101 index cardiac operations as defined by Society of Thoracic Surgeons (STS).

Additionally, each center must do 90 open heart cases in a 12 month period, i.e. on Cardiopulmonary (CB) bypass. Open heart cases are now counted by CMS criteria not STS criteria. Thus, multiple CB operations on the same patient during the same admission count individually. (101, 150, provide data to support) Surgical Volume for Pediatric and Congenital Heart Surgery: Total Programmatic Volume and Programmatic Volume Stratified by Five STS-EACTS Mortality Levels: NATIONAL QUALITY FORUM. Measure Evaluation 4.1 2009;1-21.

Association of Center Volume With Mortality and Complications in Pediatric Heart Surgery: Pediatrics 2012;129; e370-e376

i) **NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR PEDIATRIC CARDIAC SURGERY: A CONSENSUS REPORT.**

*National Quality Forum 2012: 1-18.* For the purposes of counting cardiac surgical volume in a CMS Pediatric Cardiovascular Center, CMS further defines pediatric cardiac surgeries to include the following:

a) Cardiac Surgery: Cardiac surgical cases performed by each facility’s pediatric cardiovascular surgeon(s), including:

1) Only cardiac operations count, as defined by the STS Congenital Heart Surgery Database as CPB (Cardio Pulmonary Bypass) or No CPB Cardiovascular;

2) Cardiac surgeries performed on pediatric patients (pediatric patient is defined by the Society of Thoracic Surgeons Database as from birth to 18 years of age);
3) Cardiac surgeries performed on adult heart disease patients in whom the primary cardiac surgical component is congenital;

4) Non-cardiac surgeries performed on cardiopulmonary bypass by the facility’s pediatric cardiovascular surgeon(s);

5) Surgical closure of a patent ductus arteriosus, including all premature infants, regardless of age;

6) Placement of a cardiac pacemaker or defibrillator, in which the facility’s pediatric cardiovascular surgeon(s) is the primary physician of record implanting physician/surgeon; and

7) Hybrid cardiac cases involving a surgical component.

b) Additionally, the following procedures are NOT considered when determining cardiac surgical volume:

1) Cardiac surgeries not performed by the facility’s pediatric cardiovascular surgeon(s);

2) Delayed sternal closure;

3) Re-exploration of the mediastinum; for example, excessive bleeding.
4) Operations where ECMO cannulation or decannulation is the primary procedure and any operations classified by the STS Congenital Heart Surgery Database as Operation Type = ECMO, and

5) Any operation classified by the STS Congenital Heart Surgery Database as an Operation Type other than CPB (CPB = Non-cardiac surgeries performed on cardiopulmonary bypass by the facility’s pediatric cardiovascular surgeon(s));

5.1) Surgical closure of a patent ductus arteriosus, including all premature infants, regardless of age;

6) Placement of a cardiac pacemaker or defibrillator, in which the facility’s pediatric cardiovascular surgeon(s) is the primary physician of record, and

7) Hybrid cardiac cases involving a surgical component.

Additionally, the following procedures are NOT considered when determining cardiac surgical volume:
Children's Medical Services
Pediatric Cardiovascular Center Standards
August 2014

1) Cardiac surgeries not performed by the facility's pediatric cardiovascular surgeon(s);

2) Delayed sternal closure;

3) Re-exploration of the mediastinum; for example, excessive bleeding;

4) Operations where ECMO cannulation or decannulation is the primary procedure and any operations classified by the STS Congenital Heart Surgery Database as Operation Type = ECMO, and

5) Any operation classified by the STS Congenital Heart Surgery Database as an Operation Type other than CPB (CPB = Cardio Pulmonary Bypass) or No CPB Cardiovascular.

ii) To further clarify surgical volume for the purposes of CMS volume requirements, surgical volume should be calculated based on each cardiac surgical admission that involves a cardiac surgical operation. For example, if patient A comes to the facility and has a cardiac operation and then has a second cardiac operation later but during the same admission, that would be counted as one surgery.
This seems to contradict volume calculations as noted in line 1124.

component procedures performed during the same cardiac
operation, that would also be counted as one operation. Such
guidelines are identical to the rules used by The Society of
Thoracic Surgeons Database to calculate programmatic volume
using index cardiac operations. CMS utilizes such national
standards whenever available. (including social admissions?)

Disposition displacement due to hurricane, for example?

3. The facility must be co-located with a CMS Pediatric Cardiology Clinic
   Facility and a CMS Pediatric Catheterization facility.

4. Facility Criteria: include all standards in the CMS Pediatric
   Cardiovascular Surgery Program Component section. If the facility is not
   in compliance with all the required criteria other than the volume
   standards, the facility must submit a corrective action plan for approval by
   the Deputy State Health Officer for CMS or designee upon the
   recommendation of the CMS Cardiac Technical Advisory Panel. 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 all the facility criteria.

If the facility is not in compliance with all the facility criteria at the end of a second year of probationary status, the facility shall be provided with a notice of intent to end the agreement between the CMS Pediatric Cardiovascular Center and the Department of Health.

5. The Deputy State Health Officer for CMS or designee considers new facilities for involvement upon the recommendation of the Cardiac Technical Advisory Panel and after fulfilling all criteria established above for pediatric cardiac surgery. The Deputy State Health Officer for CMS or designee shall make the final decision on whether or not a facility may continue such an agreement with the Department of Health.

II. Re-evaluation of Approved Facilities

1. Program Evaluation and Development Review: Each CMS Pediatric Cardiovascular Surgical Facility must be re-evaluated on-site by members or designees of the CMS Cardiac Technical Advisory Panel at a minimum of once every three (3) years. Who visits, what is the structure of such visits? Feedback, reports? To whom?? FP The process of re-evaluation is not complete until the Deputy State Health Officer for CMS or designee
receives the recommendation of the CMS Cardiac Technical Advisory Panel.

2. Medical Record Review: A minimum of 25 consecutive pediatric cardiac surgical cases must be available within a specified time what time period is specified? period for review at the time of the re-evaluation.

3. Facility Volume Standard: By the first and all subsequent three year program evaluation and development reviews, the minimum annual number of pediatric cardiac surgeries for a CMS Pediatric Cardiovascular Center is 101, at least 90 of which must be cases involving open heart surgery. Should this be an averaged volume of 101/90 over the 3 year time period?? (meaning cardiopulmonary bypass procedures).

   i) For the purposes of counting cardiac surgical volume in a CMS Pediatric Cardiovascular Center, CMS further defines pediatric cardiac surgeries to include the following:

   a) Cardiac Surgery: Cardiac surgical cases performed by each facility’s pediatric cardiovascular surgeon(s), including:

      1) Only cardiac operations count, as defined by the STS Congenital Heart Surgery Database as CPB (Cardio) Pulmonary (by Bypass) or No CPB Cardiovascular.
2) Cardiac surgeries performed on pediatric patients (pediatric patient is defined by the Society of Thoracic Surgeons Database as from birth to 18 years of age);

3) Cardiac surgeries performed on adult heart disease patients in whom the primary cardiac component is congenital:

4) Non-cardiac surgeries performed on cardiopulmonary bypass by the facility’s pediatric cardiovascular surgeon(s);

5) Surgical closure of a patent ductus arteriosus, including all premature infants, regardless of age;

6) Placement of a cardiac pacemaker or defibrillator, in which the facility’s pediatric cardiovascular surgeon(s) is the primary physician of record; and

7) Hybrid cardiac cases involving a surgical component;

Additionally, the following procedures are NOT considered when determining cardiac surgical volume:

8) Cardiac surgeries not performed by the facility’s pediatric cardiovascular surgeon(s);
2) Delayed sternal closure;

3) Re-exploration of the mediastinum; for example, excessive bleeding;

4) Operations where ECMO cannulation or de-cannulation is the primary procedure and any operations classified by the STS Congenital Heart Surgery Database as Operation Type = ECMO, and

5) Any operation classified by the STS Congenital Heart Surgery Database as an Operation Type other than CPB (CPB = Cardio-Pulmonary Non-cardiac surgeries) performed on cardiopulmonary bypass by the facility’s pediatric cardiovascular surgeon(s);

5) Surgical closure of a patent ductus arteriosus, including all premature infants, regardless of age;

6) Placement of a cardiac pace-maker or defibrillator in which the facility’s pediatric cardiovascular surgeon(s) is the primary physician of record; and

7) Hybrid cardiac cases involving a surgical component.
b) Additionally, the following procedures are NOT considered when determining cardiac surgical volume:

1) Cardiac surgeries not performed by the facility’s pediatric cardiovascular surgeon(s);

2) Delayed sternal closure;

3) Re-exploration of the mediastinum; for example, excessive bleeding;

4) Operations where ECMO cannulation or decannulation is the primary procedure and any operations classified by the STS Congenital Heart Surgery Database as Operation Type = ECMO; and

5) Any operation classified by the STS Congenital Heart Surgery Database as an Operation Type other than CPB (CPB = Cardiopulmonary Bypass or No CPB) Cardiovascular.

ii) To further clarify surgical volume for the purposes of CMS volume requirements, surgical volume should be calculated based on each cardiac surgical admission that involves a cardiac surgical operation. For example, if patient A comes to the facility and has a
cardiac operation and then has a second cardiac operation later but
during the same admission, that would be counted as one surgery.

As another example, if patient B has multiple component
procedures performed during the same cardiac operation, that
would also be counted as one operation. Such guidelines are
identical to the rules used by The Society of Thoracic Surgeons
Database to calculate programmatic volume using index cardiac
operations. CMS utilizes such national standards whenever
available.

i.

4. If the facility volume is below [50], the required figure is 101 total [90]

CPB: That should be probationary threshold???

4. (101? [50]?) 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 end the agreement between the CMS Pediatric
Cardiovascular Center and the Department of Health. After a 90 day
transition period, the facility will receive a formal notice to end the agreement between the CMS Pediatric Cardiovascular Center and the Department of Health.

5. Facility Criteria: include all standards, other than facility volume standards, in the CMS Pediatric Cardiovascular Surgery Program Component section.

If the facility is not in compliance with all the required criteria other than the volume standards, the facility must submit a corrective action plan for approval by the Deputy State Health Officer for CMS or designee upon the recommendation of the CMS Cardiac Technical Advisory Panel. If the plan is approved, the facility shall be granted one-year probationary status. Probationary status may be extended one (1) additional year if the facility documents improvements toward achieving all the facility criteria. If the facility is not in compliance with all the facility criteria at the end of a second year of probationary status, the facility shall be provided with a notice of intent to end the agreement between that CMS Pediatric Cardiovascular Center and the Department of Health the facility as a CMS Pediatric Cardiovascular Center. After a 90-day transition period, the
facility will receive a formal notice to end the agreement between that
CMS Pediatric Cardiovascular Center and the Department of Health.

6. All CMS Pediatric Cardiovascular Centers must collect and submit the
following quality assurance data to STS:

   • Number of patients/operations submitted and an analysis, discharge
     mortality, and complexity information, by year

   • Aristotle Basic Complexity Level Discharge Mortality, by year

   • RACHS-1 Discharge Mortality, by year

   • Number of patients/operations in analysis, discharge mortality, and
     complexity information, by age group

   • Aristotle Basic Complexity Level Discharge Mortality, by age group

   • RACHS-1 Discharge Mortality, by age group

   • Primary procedure outcomes, by anomaly

   • STS-EACTS Mortality Category Discharge Mortality, by year

   • STS-EACTS Mortality Category Discharge Mortality, by age group

7. Collect and submit quality assurance data annually in accordance with
following CMS form:
• Patients with Fetal Diagnosis of Heart Conditions (DH-CMS 2065, 10/20XX)

8. In the event that a facility’s participation with CMS is terminated by either the facility or CMS, a 90-day notice shall be provided to that CMS Pediatric Cardiovascular Center.

9. The CMS Deputy State Health Officer for CMS or designee considers existing facilities for continued involvement upon the recommendation of the CMS Cardiac Technical Advisory Panel and fulfillment of all the criteria established above. The Deputy State Health Officer for CMS or designee shall make the final decision as to whether or not to continue such an agreement with the Department of Health.