

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED REVIEW STANDARDS FOR CARDIAC CATHETERIZATION SERVICES

(By authority conferred on the Certificate of Need Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and Sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being Sections 333.22215, 24.207 and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval and delivery of services for all projects approved and Certificates of Need issued under Part 222 of the Code which involve cardiac catheterization services.

(2) Cardiac catheterization services are covered clinical services for purposes of Part 222 of the Code.

(3) The Department shall use Sections 3, 4, 5, 6, 7, 8, 9, and 11, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(4) The Department shall use Section 10 in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

Sec. 2. (1) As used in these standards:

(a) "Balloon atrial septostomy" means a procedure in which a balloon-tipped catheter is placed across the atrial septum and withdrawn to create an enlarged atrial opening.

(b) "Cardiac catheterization laboratory" or "laboratory" means an individual radiological room equipped with a variety of x-ray machines and devices such as electronic image intensifiers, high speed film changers and digital subtraction units to assist in performing diagnostic or therapeutic cardiac catheterizations or electrophysiology studies.

(c) "Cardiac catheterization procedure" means any cardiac procedure, including diagnostic, therapeutic, and electrophysiology studies, as applicable, performed on a patient during a single session in a cardiac catheterization laboratory or a multi purpose special radiological room. Cardiac catheterization is a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in a patient; subsequently the free end of the catheter is manipulated by a physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aides in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures in the heart. Cardiac catheterization shall not include "float catheters" which are performed at the bedside or in settings outside the cardiac catheterization laboratory or multi purpose special radiological room.

(d) "Cardiac catheterization service" means the provision of one or more of the following types of procedures in compliance with Part 222 of the Code: adult diagnostic cardiac catheterizations; pediatric diagnostic cardiac catheterizations; adult therapeutic cardiac catheterizations; pediatric therapeutic cardiac catheterizations.

(e) "Central service coordinator" means the organizational unit which has operational responsibility for a mobile cardiac catheterization network. It shall be a legal entity authorized to do business in Michigan.

(f) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(g) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

- (h) "Department" means the Michigan Department of Community Health.
- (i) "Diagnostic cardiac catheterization service" means providing diagnostic-only cardiac catheterizations on an organized, regular basis, either in a room dedicated to that service or in a multi purpose special radiological room. The term includes, but is not limited to: the intra coronary administration of drugs; left heart catheterization; right heart catheterization; coronary angiography; diagnostic electrophysiology studies; and cardiac biopsies (echo-guided or fluoroscopic). For purposes of these standards, the term also includes balloon atrial septostomy procedure in a hospital that provides pediatric diagnostic cardiac catheterization services.
- (j) "Electrophysiology study" means a study of the electrical conduction activity of the heart and characterization of atrial and ventricular arrhythmias, obtained by means of a cardiac catheterization procedure. The term also includes the implantation of permanent pacemakers and defibrillators.
- (k) "Expand a cardiac catheterization service" means either:
- (i) an increase in the number of cardiac catheterization laboratories or multi purpose special radiological rooms at a hospital; or
 - (ii) expanding the types of cardiac catheterization procedures authorized to be performed including adult or pediatric, diagnostic or therapeutic, at a hospital that currently performs cardiac catheterization procedures. For purposes of these standards, a hospital that provides pediatric diagnostic cardiac catheterizations shall not be required to seek certificate of need approval for a pediatric therapeutic cardiac catheterization service in order to perform a balloon atrial septostomy procedure.
- (l) "Hospital" means a health facility licensed under Part 215 of the Code.
- (m) "Host facility" means a hospital at which a mobile cardiac catheterization network is authorized to provide cardiac catheterization services.
- (n) "ICD-9-CM code" means the disease codes and nomenclature found in the International Classification of Diseases - 9th Revision - Clinical Modification, prepared by the Commission on Professional and Hospital Activities for the U.S. National Center for Health Statistics.
- (o) "Initiate a cardiac catheterization service" means to begin performing cardiac catheterization procedures at a hospital that does not perform cardiac catheterization procedures as of the date an application is submitted to the Department.
- (p) "Mobile cardiac catheterization network" means the provision of adult diagnostic-only cardiac catheterization services by a central service coordinator and two or more host facilities.
- (q) "Multi purpose special radiological room" or "room" means an individual radiological room equipped with a variety of x-ray machines and devices such as electronic image intensifiers, high speed film changers and digital subtraction units to assist in performing special procedures and cardiac catheterization procedures.
- (r) "Pediatric cardiac catheterization service" means the offering and provision of cardiac catheterization services on an organized, regular basis to infants and children ages 18 and below, except for electrophysiology studies which are offered and provided to infants and children ages 14 and below, and others with congenital heart disease as defined by the ICD-9-CM codes of 426.7, 427.0, and 745.0 through 747.99.
- (s) "Procedure equivalent" means a unit of measure which reflects the relative average length of time one patient spends in one session in a cardiac catheterization laboratory or a multi purpose special radiological room based on the type of procedures being performed.
- (i) The following procedure equivalents shall be used in calculating and evaluating utilization of a cardiac catheterization laboratory or a multi purpose special radiological room:

<u>Procedure Type</u>	<u>Procedure Equivalent</u>	
	<u>Adult</u>	<u>Pediatric</u>
Diagnostic cardiac catheterization	1.0	3.0
Therapeutic cardiac catheterization	1.5	3.0
Diagnostic electrophysiology study	3.0	4.0
Therapeutic electrophysiology study (including ablations)	4.0	6.0
Special procedure (non-cardiac)	1.0	1.0
Special procedure (cardiac, non-cath)	1.0	1.0
Diagnostic cardiac catheterization followed by a therapeutic cardiac catheterization in the same session	2.0	4.5
Multiple therapeutic procedures performed in the same session	2.0	4.5

(ii) For purposes of evaluating whether an applicant meets applicable volume requirements set forth in these standards, the applicable procedure equivalents for a "diagnostic cardiac catheterization followed by a therapeutic cardiac catheterization in the same session" shall be allocated entirely to the category of therapeutic cardiac catheterization.

(iii) For purposes of evaluating whether an applicant meets applicable volume requirements set forth in these standards, a balloon atrial septostomy procedure shall be considered a therapeutic cardiac catheterization, except for a hospital and a physician that performs this procedure as part of a diagnostic-only pediatric cardiac catheterization service, in which case the procedure shall be considered a pediatric diagnostic cardiac catheterization procedure.

(t) "Replace/upgrade" means an equipment change proposed by an applicant which results in that applicant operating the same number of cardiac catheterization laboratories or multi purpose special radiological rooms before and after project completion.

(u) "Rural county" means a county not located in a metropolitan area as that term is defined pursuant to the "Revised standards for defining metropolitan areas in the 1990's" by the Statistical Policy Office of the Office of Information and Regulatory Affairs of the United States Office of Management and Budget, 55 F.R. p.12154 (March 30, 1990).

(v) "Special procedure" means any angiographic or other invasive radiologic study other than a diagnostic or therapeutic cardiac catheterization or electrophysiology study performed during a single session in a cardiac catheterization laboratory or a multi purpose special radiological room.

(w) "Therapeutic cardiac catheterization procedure" means a cardiac catheterization procedure used to treat and resolve anatomical and/or physiological problems in the heart. The term includes, but is not limited to: percutaneous transluminal coronary angioplasty (PTCA), atherectomy, stent, laser, cardiac valvuloplasty, balloon atrial septostomy, or catheter ablation. The term does not include the intra coronary administration of drugs where that is the only therapeutic intervention.

(x) "Therapeutic cardiac catheterization service" means providing therapeutic cardiac catheterizations on an organized, regular basis, either in a laboratory dedicated to that service or in a multi purpose special radiological room.

(2) Terms defined in the Code have the same meanings when used in these standards.

Section 3. Requirements for approval -- all applicants

Sec. 3. (1) Cardiac catheterization procedures shall be performed in a cardiac catheterization laboratory or multi purpose special radiological room located within a hospital, and have within, or immediately available to the room, dedicated emergency equipment to manage cardiovascular emergencies.

(2) An application involving the provision of mobile cardiac catheterization services shall demonstrate that cardiac catheterization procedures will be performed within a hospital. The Department shall consider procedures performed in a mobile cardiac catheterization unit as within a hospital, if the mobile unit is or will be physically adjoined to the hospital by means of a connector such that patients will not be transported outside the hospital in order to receive cardiac catheterization services.

Section 4. Requirements for approval -- applicants for an adult diagnostic cardiac catheterization service

Sec. 4. (1) An applicant proposing to initiate an adult diagnostic cardiac catheterization service shall project a minimum of 300 procedure equivalents in the category of adult diagnostic cardiac catheterization will be performed in the second 12 months of operation after initiation of the adult diagnostic cardiac catheterization service, and annually thereafter.

(2) An applicant proposing to initiate an adult diagnostic cardiac catheterization service in a new single laboratory or room shall project the following volume of procedure equivalents, as applicable, will be performed in the second 12 months of operation after initiation of the service, and annually thereafter:

(a) For a hospital located in a rural county, a minimum of 500 procedure equivalents which shall include the 300 procedure equivalents in the category of adult diagnostic cardiac catheterization required under subsection (1).

(b) For a hospital located in a non-rural county, a minimum of 750 procedure equivalents which shall include the 300 procedure equivalents in the category of adult diagnostic cardiac catheterization required under subsection (1).

(3) An applicant proposing to initiate an adult diagnostic cardiac catheterization service in 2 or more laboratories or rooms shall project that a minimum of 1,000 procedure equivalents per laboratory/room will be performed in the second 12 months of operation after initiation of the service, and annually thereafter. The projected volume shall include the procedure equivalents required by subsection (1).

(4) If the adult diagnostic cardiac catheterizations are to be performed in an additional laboratory or room added as part of an expansion of an existing cardiac catheterization service, an applicant shall also meet the requirements set forth in Section 6, as applicable.

Section 5. Requirements for approval -- applicants for a pediatric diagnostic cardiac catheterization service

Sec. 5. (1) An applicant proposing to initiate a pediatric diagnostic cardiac catheterization service at a hospital that will perform only pediatric diagnostic cardiac catheterization procedures shall demonstrate each of the following, as applicable:

(a) A minimum of 450 procedure equivalents in the category of pediatric diagnostic cardiac catheterizations will be performed in the second 12 months of operation after initiation of the pediatric diagnostic cardiac catheterization service, and annually thereafter.

(b) If pediatric diagnostic cardiac catheterizations are to be performed in a new single laboratory or room, an applicant shall project the following volume of procedure equivalents, as applicable, will be performed in the second 12 months of operation after initiation of the service, and annually thereafter:

(i) For a hospital located in a rural county, a minimum of 500 procedure equivalents which shall include the 450 procedure equivalents in the category of pediatric diagnostic cardiac catheterizations as required by subsection (a).

(ii) For a hospital located in a non-rural county, a minimum of 750 procedure equivalents which shall include the 450 procedure equivalents in the category of pediatric diagnostic cardiac catheterizations as required by subsection (a).

(2) An applicant proposing to initiate a pediatric diagnostic cardiac catheterization service at a

hospital that currently performs adult diagnostic cardiac catheterization procedures shall demonstrate each of the following, as applicable:

(a) A minimum of 150 procedure equivalents in the category of pediatric diagnostic cardiac catheterizations will be performed in the second 12 months of operation after initiation of the pediatric diagnostic cardiac catheterization service, and annually thereafter.

(b) A minimum of 1,000 procedure equivalents in the category of adult diagnostic cardiac catheterization was performed in the most recent 12-month period preceding the date the application was submitted to the Department.

(c) If an application involves an additional laboratory or room, an applicant shall also demonstrate the proposed application meets the requirements of Section 6, as applicable.

Section 6. Requirements for approval -- applicants proposing to add a cardiac catheterization laboratory or multi purpose special radiological room

Sec. 6. An applicant proposing to add a laboratory or room, whether a dedicated cardiac catheterization laboratory or a multi purpose special radiological room, to an existing cardiac catheterization service shall demonstrate both of the following:

(a) An average of 1,500 procedure equivalents per room per year was performed in each existing cardiac catheterization laboratory and multi purpose special radiological room in the hospital during the most recent 12-month period preceding the date the application was submitted to the Department.

(b) An average of 1,000 procedure equivalents will be performed in each cardiac catheterization laboratory and multi purpose special radiological room (both existing and proposed) in the second 12 months of operation after initiating operation of the additional room, and annually thereafter.

Section 7. Requirements for approval -- applicants for a therapeutic cardiac catheterization service

Sec. 7. (1) An applicant proposing to perform therapeutic cardiac catheterization procedures shall demonstrate both of the following:

(a) An applicant provides or has Certificate of Need approval to provide an adult or pediatric, as applicable, diagnostic cardiac catheterization service.

(b) An applicant provides or has Certificate of Need approval to provide an adult or pediatric, as applicable, open heart surgery service performing emergent, urgent, and elective open heart surgery within the hospital in which the therapeutic cardiac catheterizations are to be performed.

(c) Subsections (a) and (b) do not preclude an applicant from simultaneously applying for a diagnostic and therapeutic cardiac catheterization service and an open heart surgery service.

(2) An applicant proposing to perform therapeutic cardiac catheterization procedures shall project the following volume of procedure equivalents, as applicable, will be performed in the second 12 months of operation after initiation of the service, and annually thereafter:

(a) A minimum of 150 procedure equivalents in the category of pediatric therapeutic cardiac catheterizations.

(b) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac catheterizations.

(3) If the therapeutic cardiac catheterization procedures are proposed to be performed in a new or additional laboratory or room added as part of the initiation or an expansion of cardiac catheterization service, an applicant shall also meet the requirements set forth in Section 4 or 6, as applicable.

Section 8. Requirements for approval -- applicants for replacement/upgrading of cardiac catheterization laboratories or multi purpose special radiological rooms

Sec. 8. (1) If an applicant, other than a hospital that provides only pediatric cardiac catheterization services, is proposing to replace/upgrade an existing cardiac catheterization laboratory or multi purpose special radiological room and the laboratory or room is the only laboratory or room at the hospital in which cardiac catheterization procedures are performed, an applicant shall demonstrate that it meets each of the following, as applicable:

(a) For a hospital located in a rural county:

(i) A minimum of 500 procedure equivalents were performed in the applicant's cardiac catheterization/multi purpose special radiological room during the most recent 12 months of normal operation preceding the date the application was submitted to the Department; and

(ii) A minimum of 500 procedure equivalents will be performed in the applicant's cardiac catheterization laboratory/multi purpose special radiological room in the first 12 months of operation after installation of the new equipment, and annually thereafter.

(b) For a hospital located in a non-rural county:

(i) A minimum of 750 procedure equivalents was performed in the applicant's cardiac catheterization laboratory/multi purpose special radiological room during the most recent 12 months of normal operation preceding the date the application was submitted to the Department; and

(ii) A minimum of 750 procedure equivalents will be performed in the applicant's cardiac catheterization laboratory/multi purpose special radiological room in the first 12 months of operation after installation of the new equipment, and annually thereafter.

(2) If an applicant is a hospital that provides only pediatric cardiac catheterization services proposes to replace/upgrade an existing cardiac catheterization laboratory or multi purpose special radiological room and the room is the only room at the hospital in which cardiac catheterization procedures are performed, an applicant shall demonstrate that it meets each of the following:

(a) A minimum of 500 procedure equivalents was performed in the applicant's cardiac catheterization laboratory/multi purpose special radiological room in the most recent 12 months of normal operation preceding the date the application was submitted to the Department; and

(b) A minimum of 500 procedure equivalents will be performed in the applicant's cardiac catheterization laboratory/multi purpose special radiological room in the first 12 months of operation after installation of the new equipment, and annually thereafter.

(3) If an applicant is proposing to replace/upgrade an existing cardiac catheterization laboratory or multi purpose special radiological room and there are 2 or more existing rooms at the hospital in which cardiac catheterization procedures are performed, the applicant shall demonstrate that it meets each of the following:

(a) An average of 1,000 procedure equivalents per room was performed in each existing cardiac catheterization laboratory and multi purpose special radiological room in the hospital during the most recent 12 months of normal operation preceding the date the application was submitted to the Department, and

(b) A minimum of 1,000 procedure equivalents will be performed in each cardiac catheterization laboratory and multi purpose special radiological room in the first 12 months of operation after installation of the new equipment, and annually thereafter.

(4) An applicant proposing to replace equipment shall demonstrate that the existing equipment to be replaced is fully depreciated according to generally accepted accounting principles, or can clearly demonstrate that the existing equipment poses a threat to the safety of the public, or offers significant technological improvements which enhance quality of care, increases efficiency, and/or reduces operating costs.

(5) If an application involves the replacement/upgrade of equipment used by a mobile cardiac

catheterization network, an applicant shall demonstrate both of the following:

- (a) At least 500 procedure equivalents were performed in the most recent 12 months of normal operation preceding the date the application was submitted to the Department; and
- (b) A minimum of 500 procedure equivalents will be performed in the first 12 months of operation after installation of the new equipment, and annually thereafter.
- (c) In evaluating compliance with subsections (a) and (b), the Department shall consider the combined utilization for all approved host facilities.

(6) In demonstrating compliance with the minimum volume requirements set forth in each applicable subsection of this section, an applicant shall demonstrate that the minimum volume requirement applicable to the specific type of cardiac catheterization procedures offered by an applicant (adult, pediatric, diagnostic or therapeutic) as set forth in Section 4(1), 5(1)(a), 5(2)(a) or 7(2)(a) or (b), as applicable, have also been met.

Section 9. Requirements for approval -- applicants for a mobile cardiac catheterization network

Sec. 9. An application involving a mobile cardiac catheterization network shall demonstrate that it meets each of the following, as applicable:

- (1) An application will not result in an increase in the number of mobile cardiac catheterization networks with valid Certificate of Need approval as of the effective date of these standards.
- (2) An application will not result in an increase in the number of host facilities being served by a mobile cardiac catheterization network from the number of host facilities authorized to be served by that same network as of the effective date of these standards.
- (3) An application does not involve the initiation of a mobile cardiac catheterization network not authorized by a valid Certificate of Need as of the effective date of these standards.

Section 10. Project delivery requirements -- terms of approval for all applicants

Sec. 10. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance with the following terms of Certificate of Need approval:

- (a) Compliance with these standards.
- (b) Compliance with applicable operating standards.
- (c) Compliance with the following quality assurance standards:
 - (i) The approved services and/or laboratories/rooms shall be operating at the applicable required volumes within the time periods specified in these standards, and annually thereafter.
 - (ii) The approved services shall be staffed with sufficient medical, nursing, technical and other personnel to permit regular scheduled hours of operation and continuous 24 hour on-call availability.
 - (iii) The medical staff and governing body shall receive and review at least annual reports describing the activities of the cardiac catheterization service including: complication rates (including emergency surgical procedures); morbidity and mortality data; success rates and the number of procedures performed.
 - (iv) Each physician credentialed by a hospital to perform adult diagnostic cardiac catheterizations shall perform, as the primary operator, a minimum of 100 adult diagnostic cardiac catheterization procedures per year in the second 12 months after being credentialed to perform procedures at the applicant hospital, and annually thereafter. The annual case load for a physician means adult diagnostic cardiac catheterization procedures performed by that physician in any hospital or in any combination of hospitals. The applicant shall be responsible for reporting to the Department, on an annual basis, the name and the number of adult diagnostic cardiac catheterization procedures performed by each physician credentialed to perform adult diagnostic cardiac catheterization procedures.
 - (v) Each physician credentialed by a hospital to perform adult therapeutic cardiac catheterization

procedures shall perform, as the primary operator, a minimum of 75 adult therapeutic cardiac catheterization procedures per year in the second 12 months after being credentialed to perform procedures at the applicant hospital, and annually thereafter. The annual case load for a physician means adult therapeutic cardiac catheterization procedures performed by that physician in any hospital or in any combination of hospitals. The applicant shall be responsible for reporting to the Department, on an annual basis, the name and the number of adult therapeutic cardiac catheterization procedures performed by each physician credentialed to perform adult therapeutic cardiac catheterization procedures.

(vi) Each physician credentialed by a hospital to perform pediatric diagnostic cardiac catheterizations shall perform, as the primary operator, a minimum of 50 pediatric diagnostic cardiac catheterization procedures per year in the second 12 months after being credentialed to perform procedures at the applicant hospital, and annually thereafter. The annual case load for a physician means pediatric diagnostic cardiac catheterization procedures performed by that physician in any hospital or in any combination of hospitals. The applicant shall be responsible for reporting to the Department, on an annual basis, the name and the number of pediatric diagnostic cardiac catheterization procedures performed by each physician credentialed to perform pediatric diagnostic cardiac catheterization procedures.

(vii) Each physician credentialed by a hospital to perform pediatric therapeutic cardiac catheterizations shall perform, as a primary operator, a minimum of 25 pediatric therapeutic cardiac catheterizations per year in the second 12 months after being credentialed to perform procedures at the applicant hospital, and annually thereafter. The annual case load for a physician means pediatric therapeutic cardiac catheterization procedures performed by that physician in any hospital or in any combination of hospitals. The applicant shall be responsible for reporting to the Department, on an annual basis, the name and the number of pediatric therapeutic cardiac catheterization procedures performed by each physician credentialed to perform pediatric therapeutic cardiac catheterization procedures.

(viii) For purposes of evaluating subdivisions (iv), (v), (vi), or (vii), a diagnostic cardiac catheterization followed by a therapeutic cardiac catheterization (including electrophysiology studies) in the same session shall be considered both 1 diagnostic procedure and 1 therapeutic procedure. Two physicians, one credentialed to perform diagnostic cardiac catheterizations and one credentialed to perform therapeutic cardiac catheterizations, each may be considered to have performed either 1 diagnostic or 1 therapeutic catheterization if both were involved in performing a diagnostic cardiac catheterization procedure followed by a therapeutic procedure in the same session.

(ix) An applicant proposing to offer an adult diagnostic cardiac catheterization service shall have a minimum of two (2) appropriately trained physicians on its active hospital staff. For purposes of evaluating this subsection, the Department shall consider it prima facie evidence of appropriate training if the staff physicians:

- (A) are trained consistent with the recommendations of the American College of Cardiology;
- (B) are credentialed by the hospital to perform adult diagnostic cardiac catheterizations; and
- (C) have each performed a minimum of 100 adult diagnostic cardiac catheterizations in the preceding 12 months.

However, the applicant may submit and the Department may accept other evidence that the staff physicians performing adult diagnostic cardiac catheterizations are appropriately trained.

(x) An applicant proposing to offer an adult therapeutic cardiac catheterization service shall have a minimum of two (2) appropriately trained physicians on its active hospital staff. For purposes of evaluating this subsection, the Department shall consider it prima facie evidence of appropriate training if the staff physicians:

- (A) are trained consistent with the recommendations of the American College of Cardiology;
- (B) are credentialed by the hospital to perform adult therapeutic cardiac catheterizations; and
- (C) have each performed a minimum of 75 adult therapeutic cardiac catheterization procedures in the preceding 12 months.

However, the applicant may submit and the Department may accept other evidence that the staff physicians performing adult therapeutic cardiac catheterizations are appropriately trained.

(xi) An applicant proposing to offer a pediatric cardiac catheterization service shall demonstrate an appropriately trained physician(s) shall be on the active hospital staff to perform diagnostic or therapeutic, as applicable, pediatric cardiac catheterizations. For purposes of evaluating this subsection, the

Department shall consider it *prima facie* evidence of appropriate training if the staff physician(s) is:

(A) board certified or board eligible in pediatric cardiology by the American Board of Pediatrics;
(B) credentialed by the hospital to perform diagnostic or therapeutic, as applicable, pediatric cardiac catheterizations; and

(C) trained consistently with the recommendations of the American College of Cardiology.

However, the applicant may submit and the Department may accept other evidence that the staff physician(s) performing pediatric cardiac catheterizations is appropriately trained.

(xii) A cardiac catheterization service shall be directed by an appropriately trained physician. For purposes of evaluating this subsection, the Department shall consider it *prima facie* evidence of appropriate training and experience of the cardiac catheterization service director if the physician is board certified in cardiology, cardiovascular radiology or cardiology, adult or pediatric, as applicable. The director of an adult cardiac catheterization service shall have performed at least 200 catheterizations per year during each of the 5 preceding years. However, the applicant may submit and the Department may accept other evidence that the cardiac catheterization service director is appropriately trained.

(xiii) An approved cardiac catheterization service shall be operated consistently with the recommendations of the American College of Cardiology.

(d) Compliance with the following terms of approval:

(i) Equipment that is replaced shall be removed from the cardiac catheterization service.

(ii) The applicant, to assure appropriate utilization by all segments of the Michigan population, shall:

(A) Not deny cardiac catheterization services to any individual based on ability to pay or source of payment;

(B) Provide cardiac catheterization services to all individuals based on the clinical indications of need for the service; and

(C) Maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

Compliance with selective contracting requirements shall not be construed as a violation of this term.

(iii) The applicant shall participate in a data collection network established and administered by the Department. The data may include, but is not limited to, annual budget and cost information, operating schedules, and demographic, diagnostic, morbidity and mortality information, as well as the volume of care provided to patients from all payor sources and other data requested by the Department and approved by the Commission. The applicant shall provide the required data on a separate basis for each separate and distinct site or unit as required by the Department, in a format established by the Department and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(iv) The applicant, within 10 days of initiating operation of new, additional or replacement equipment, shall provide the Department with a notice stating the first date on which the approved service/equipment began operation.

(v) The applicant shall accept referrals for cardiac catheterization services from all appropriately licensed health care practitioners.

(2) The agreements and assurances required by this section shall be in the form of a certification authorized by the governing body of the applicant.

Section 11. Documentation of projections

Sec. 11. An applicant required to project volumes of service under Sections 4 to 9 shall specify how the volume projections were developed. This specification of the projections shall include a description of the data source(s) used, assessments of the accuracy of these data, and the statistical method used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.

Section 12. Effect on prior Certificate of Need Review Standards; comparative reviews

Sec. 12. (1) These Certificate of Need Review Standards supercede and replace the Certificate of Need Review Standards for Cardiac Catheterization Services approved by the Certificate of Need Commission and effective on July 8, 1994.

(2) Projects reviewed under these standards shall not be subject to comparative review.