

**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH**  
**CERTIFICATE OF NEED (CON) REVIEW STANDARDS**  
**FOR CARDIAC CATHETERIZATION SERVICES**

(By authority conferred on the CON 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 of the initiation, replacement, expansion, or acquisition of cardiac catheterization services, and the delivery of these services under Part 222 of the Code. Pursuant to Part 222 of the Code, cardiac catheterization services are a covered clinical service. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

**Section 2. Definitions**

Sec. 2. (1) For purposes of these standards:

(a) "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.

(b) "Cardiac catheterization procedure" means any cardiac procedure, including diagnostic, therapeutic, and electrophysiology studies, performed on a patient during a single session in a laboratory. 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. This term does not include "float catheters" that are performed at the bedside or in settings outside the laboratory or the implantation of cardiac permanent pacemakers and implantable cardioverter defibrillators (ICD) devices that are performed in an interventional radiology laboratory or operating room.

(c) "Cardiac catheterization service" means the provision of one or more of the following types of procedures: adult diagnostic cardiac catheterizations; pediatric diagnostic cardiac catheterizations; adult therapeutic cardiac catheterizations; and pediatric therapeutic cardiac catheterizations.

(d) "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.

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

(f) "Department" means the Michigan Department of Community Health (MDCH).

(g) "Diagnostic cardiac catheterization service" means providing diagnostic cardiac catheterization procedures on an organized, regular basis in a laboratory to diagnose anatomical and/or physiological problems in the heart. Procedures include the intra coronary administration of drugs; left heart catheterization; right heart catheterization; coronary angiography; diagnostic electrophysiology studies; and cardiac biopsies (echo-guided or fluoroscopic). A hospital that provides diagnostic cardiac catheterization services may also perform implantations of cardiac permanent pacemakers and ICD devices.

(h) "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 ICD devices.

(i) "Hospital" means a health facility licensed under Part 215 of the Code.

(j) "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.

(k) " Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C. 1396 to 1396g and 1396i to 1396u.

(l) "Pediatric cardiac catheterization service" means providing cardiac catheterization services on an organized, regular basis to infants and children ages 18 and below, except for electrophysiology studies that 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 (anomalous atrioventricular excitation), 427.0 (cardiac dysrhythmias), and 745.0 through 747.99 (bulbus cordis anomalies and anomalies of cardiac septal closure, other congenital anomalies of heart, and other congenital anomalies of circulatory system).

(m) "Primary percutaneous coronary intervention (PCI)" means a PCI performed on an acute myocardial infarction (AMI) patient with confirmed ST elevation or new left bundle branch block.

(n) "Procedure equivalent" means a unit of measure that reflects the relative average length of time one patient spends in one session in a laboratory based on the type of procedures being performed.

(o) "Therapeutic cardiac catheterization service" means providing therapeutic cardiac catheterizations on an organized, regular basis in a laboratory to treat and resolve anatomical and/or physiological problems in the heart. Procedures include PCI, PTCA, atherectomy, stent, laser, cardiac valvuloplasty, balloon atrial septostomy, catheter ablation, cardiac permanent pacemaker, ICD device implantations, transcatheter valve, other structural heart disease procedures, percutaneous transluminal coronary angioplasty (PTCA) and coronary stent implantation and left sided arrhythmia therapeutic procedures. The term does not include the intra coronary administration of drugs where that is the only therapeutic intervention.

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

### **Section 3. Requirements to initiate cardiac catheterization services**

Sec. 3. An applicant proposing to initiate cardiac catheterization services shall demonstrate the following, as applicable to the proposed project.

(1) An applicant proposing to initiate an adult diagnostic cardiac catheterization service shall demonstrate the following as applicable to the proposed project:

(a) An applicant proposing to initiate a diagnostic cardiac catheterization service with a single laboratory in a rural or micropolitan statistical area county shall project a minimum of 500 procedure equivalents including 300 procedure equivalents in the category of diagnostic cardiac catheterization procedures based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

(b) An applicant proposing to initiate a diagnostic cardiac catheterization service with a single laboratory in a metropolitan statistical area county shall project a minimum of 750 procedure equivalents that includes 300 procedure equivalents in the category of diagnostic cardiac catheterization procedures based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

(c) An applicant proposing to initiate a diagnostic cardiac catheterization service with two or more laboratories shall project a minimum of 1,000 procedure equivalents per laboratory that includes 300 procedure equivalents in the category of diagnostic cardiac catheterization procedures based on data

from the most recent 12-month period preceding the date the application was submitted to the Department.

(2) An applicant proposing to initiate an adult therapeutic cardiac catheterization service shall demonstrate the following:

(a) The applicant provides, is approved to provide, or has applied to provide adult diagnostic cardiac catheterization services at the hospital. The applicant must be approved for adult diagnostic cardiac catheterization services in order to be approved for adult therapeutic cardiac catheterization services.

(b) An applicant operating an adult diagnostic cardiac catheterization service has performed a minimum of 300 procedure equivalents in the category of adult diagnostic cardiac catheterizations during the most recent 12-month period preceding the date the application was submitted to the Department if the service has been in operation more than 24 months.

(c) The applicant has applied to provide adult open heart surgery services at the hospital. The applicant must be approved for an adult open heart surgery service in order to be approved for an adult therapeutic cardiac catheterization service.

(d) The applicant shall project a minimum of 300 procedure equivalents in the category of adult therapeutic cardiac catheterizations based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

(3) An applicant proposing to initiate a pediatric cardiac catheterization service shall demonstrate the following:

(a) The applicant has a board certified pediatric cardiologist with training in pediatric catheterization procedures to direct the pediatric catheterization laboratory.

(b) The applicant has standardized equipment as defined in the most current American Academy of Pediatrics (AAP) guidelines for pediatric cardiovascular centers.

(c) The applicant has on-site ICU as outlined in the most current AAP guidelines above.

(d) The applicant has applied to provide pediatric open heart surgery services at the hospital. The applicant must be approved for a pediatric open heart surgery service in order to be approved for pediatric cardiac catheterization services.

(e) The applicant shall project a minimum of 600 procedure equivalents in the category of pediatric cardiac catheterizations based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

(4) An applicant proposing to initiate primary PCI service without on-site open heart surgery services shall demonstrate the following:

(a) The applicant operates an adult diagnostic cardiac catheterization service that has performed a minimum of 500 procedure equivalents that includes 400 procedure equivalents in the category of cardiac catheterization procedures during the most recent 12 months preceding the date the application was submitted to the Department.

(b) The applicant has at least two interventional cardiologists to perform the primary PCI procedures and each cardiologist has performed at least 75 PCI sessions annually as the primary operator during the most recent 24-month period preceding the date the application was submitted to the Department.

(c) The nursing and technical catheterization laboratory staff: are experienced in handling acutely ill patients and comfortable with interventional equipment; have acquired experience in dedicated interventional laboratories at an open heart surgery hospital; and participate in an un-interrupted 24-hour, 365-day call schedule. Competency shall be documented annually.

(d) The laboratory or laboratories are equipped with optimal imaging systems, resuscitative equipment, and intra-aortic balloon pump (IABP) support, and stocked with a broad array of interventional equipment.

(e) The cardiac care unit nurses are adept in hemodynamic monitoring and IABP management. Competency shall be documented annually.

(f) A written agreement with an open heart surgery hospital that includes all of the following:

- (i) Involvement in credentialing criteria and recommendations for physicians approved to perform primary PCI procedures.
- (ii) Provision for ongoing cross-training for professional and technical staff involved in the provision of primary PCI to ensure familiarity with interventional equipment. Competency shall be documented annually.
- (iii) Provision for ongoing cross training for emergency department, catheterization laboratory, and critical care unit staff to ensure experience in handling the high acuity status of primary PCI patient candidates. Competency shall be documented annually.
- (iv) Regularly held joint cardiology/cardiac surgery conferences to include review of all primary PCI cases.
- (v) Development and ongoing review of patient selection criteria for primary PCI patients and implementation of those criteria.
- (vi) A mechanism to provide for appropriate patient transfers between facilities and an agreed plan for prompt care.
- (vii) Written protocols, signed by the applicant and the open heart surgery hospital, for the immediate transfer, within 1 hour from the cardiac catheterization laboratory to evaluation on site in the open heart surgery hospital, of patients requiring surgical evaluation and/or intervention 365 days a year. The protocols shall be reviewed and tested on a quarterly basis.
- (viii) Consultation on facilities, equipment, staffing, ancillary services, and policies and procedures for the provision of interventional procedures.
- (g) A written protocol must be established and maintained for case selection for the performance of primary PCI.
- (h) A system to ensure prompt and efficient identification of potential primary PCI patients and rapid transfer from the emergency department to the cardiac catheterization laboratory must be developed and maintained so that door-to-balloon targets are met.
- (i) At least two physicians credentialed to perform primary PCI must commit to functioning as a coordinated group willing and able to provide this service at the hospital on a 24-hour per day, 365 day per year call schedule, with ability to be on-site and available to operate within 30 minutes of identifying the need for primary PCI. These physicians must be credentialed at the facility and actively collaborate with administrative and clinical staff in establishing and implementing protocols, call schedules, and quality assurance procedures pertaining to primary PCI designed to meet the requirements for this certification and in keeping with the current guidelines for the provision of primary PCI promulgated by the American College of Cardiology and American Heart Association.
- (j) The applicant shall project a minimum of 36 primary PCI cases based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

#### **Section 4. Requirements to replace an existing cardiac catheterization service or laboratory**

Sec. 4. Replacing a cardiac catheterization laboratory means a change in the angiography x-ray equipment or a relocation of the service to a new site. The term does not include a change in any of the other equipment or software used in the laboratory. An applicant proposing to replace a cardiac catheterization laboratory or service shall demonstrate the following as applicable to the proposed project:

- (1) An applicant proposing to replace cardiac catheterization laboratory equipment shall demonstrate the following:
  - (a) The existing laboratory or laboratories to be replaced are fully depreciated according to generally accepted accounting principles or demonstrates either of the following:
    - (i) The existing angiography x-ray equipment to be replaced poses a threat to the safety of the patients.
    - (ii) The replacement angiography x-ray equipment offers technological improvements that enhance quality of care, increases efficiency, and reduces operating costs.
  - (b) The existing angiography x-ray equipment to be replaced will be removed from service on or before beginning operation of the replacement equipment.

- (2) An applicant proposing to replace a cardiac catheterization service to a new site shall demonstrate the following:
- (a) The proposed project is part of an application to replace the entire hospital.
  - (b) The applicant has performed the following during the most recent 12-month period preceding the date the application was submitted to the Department as applicable to the proposed project:
    - (i) A minimum of 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures.
    - (ii) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac catheterization procedures.
    - (iii) A minimum of 600 procedure equivalents in the category of pediatric cardiac catheterization procedures.
    - (iv) A minimum of 500 procedure equivalents for a hospital in a rural or micropolitan county with one laboratory.
    - (v) A minimum of 750 procedure equivalents for a hospital in a metropolitan county with one laboratory.
    - (vi) A minimum of 1,000 procedure equivalents per cardiac catheterization laboratory for a hospital with two or more laboratories.
  - (c) The existing cardiac catheterization service has been in operation for at least 36 months as of the date the application has been submitted to the Department.

#### **Section 5. Requirements to expand a cardiac catheterization service**

Sec. 5. An applicant proposing to add a laboratory to an existing cardiac catheterization service shall demonstrate the following:

- (1) The applicant has performed the following during the most recent 12-month period preceding the date the application was submitted to the Department as applicable to the proposed project:
- (a) A minimum of 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures.
  - (b) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac catheterization procedures.
  - (c) A minimum of 600 procedure equivalents in the category of pediatric cardiac catheterization procedures.
- (2) The applicant has performed a minimum of 1,400 procedure equivalents per existing and approved laboratories during the most recent 12-month period preceding the date the application was submitted to the Department.

#### **Section 6. Requirements to acquire a cardiac catheterization service**

Sec. 6. Acquiring a cardiac catheterization service and its laboratories means obtaining possession and control by contract, ownership, lease or other comparable arrangement or renewal of a lease for existing angiography x-ray equipment. An applicant proposing to acquire a cardiac catheterization service or renew a lease for equipment shall demonstrate the following as applicable to the proposed project:

- (1) An applicant proposing to acquire a cardiac catheterization service shall demonstrate the following:
- (a) The proposed project is part of an application to acquire the entire hospital.
  - (b) An application for the first acquisition of an existing cardiac catheterization service after February 27, 2012 shall not be required to be in compliance with the applicable volume requirements in subsection

(c). The cardiac catheterization service shall be operating at the applicable volumes set forth in the project delivery requirements in the second 12 months of operation of the service by the applicant and annually thereafter.

(c) The applicant has performed the following during the most recent 12-month period preceding the date the application was submitted to the Department as applicable to the proposed project :

- (i) A minimum of 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures.
- (ii) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac catheterization procedures.
- (iii) A minimum of 600 procedure equivalents in the category of pediatric cardiac catheterization procedures.
- (iv) A minimum of 500 procedure equivalents for a hospital in a rural or micropolitan county with one laboratory.
- (v) A minimum of 750 procedure equivalents for a hospital in a metropolitan county with one laboratory.
- (vi) A minimum of 1,000 procedure equivalents per cardiac catheterization laboratory for two or more laboratories.

(2) An applicant proposing to renew a lease for existing angiography x-ray equipment shall demonstrate the renewal of the lease is more cost effective than replacing the equipment.

#### **Section 7. Requirements for a hybrid operating room/cardiac catheterization laboratory (OR/CCL)**

Sec. 7. A hybrid OR/CCL means an operating room located on a sterile corridor and equipped with an angiography system permitting minimally invasive procedures of the heart and blood vessels with full anesthesia capabilities. An applicant proposing to add one or more hybrid OR/CCLs at an existing cardiac catheterization service shall demonstrate each of the following:

(1) The applicant operates an open heart surgery service which is in full compliance with the current CON Review Standards for Open Heart Surgery Services.

(2) The applicant operates a therapeutic cardiac catheterization program which is in full compliance with section 4(2) of these standards.

(3) If the hybrid OR/CCL(s) represents an increase in the number of cardiac catheterization laboratories at the facility, the applicant is in compliance with Section 5 of these standards.

(4) If the hybrid OR/CCL(s) represents conversion of an existing cardiac catheterization laboratory(s), the applicant is in compliance with the provisions of Section 4, if applicable.

(5) The applicant meets the applicable requirements of the CON Review Standards for Surgical Services.

(6) Each case performed in a hybrid OR/CCL shall be included either in the surgical volume or the therapeutic cardiac catheterization volume of the facility. No case shall be counted more than once.

(7) For each hybrid OR/CCL, a facility shall have 0.5 excluded from its inventory of cardiac catheterization laboratories for the purposes of computing the procedure equivalents per room. A facility will not be limited to the number of hybrid OR/CCLs within a single licensed facility.

## **Section 8. Requirement for Medicaid participation**

Sec. 8. An applicant shall provide verification of Medicaid participation at the time the application is submitted to the Department. An applicant that is initiating a new service or is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved.

## **Section 9. Project delivery requirements and terms of approval for all applicants**

Sec. 9. An applicant shall agree that, if approved, the cardiac catheterization service and all existing and approved laboratories shall be delivered in compliance with the following terms of approval:

- (1) Compliance with these standards.
  - (2) Compliance with the following quality assurance standards:
    - (a) Cardiac catheterization procedures shall be performed in a cardiac catheterization laboratory located within a hospital, and have within, or immediately available to the room, dedicated emergency equipment to manage cardiovascular emergencies.
    - (b) The service 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.
    - (c) 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, morbidity and mortality, success rates and the number of procedures performed.
    - (d) 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 and annually thereafter. The annual case load for a physician means adult therapeutic cardiac catheterization procedures performed by that physician in any combination of hospitals.
    - (e) 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 and annually thereafter. The annual case load for a physician means pediatric diagnostic cardiac catheterization procedures performed by that physician in any combination of hospitals.
    - (f) 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 and annually thereafter. The annual case load for a physician means pediatric therapeutic cardiac catheterization procedures performed by that physician in any combination of hospitals.
    - (g) An adult diagnostic cardiac catheterization service shall have a minimum of two appropriately trained physicians on its active hospital staff. The Department may accept other evidence or shall consider it appropriate training if the staff physicians:
      - (i) are trained consistent with the recommendations of the American College of Cardiology;
      - (ii) are credentialed by the hospital to perform adult diagnostic cardiac catheterizations; and
      - (iii) have each performed a minimum of 100 adult diagnostic cardiac catheterizations in the preceding 12 months.
    - (h) An adult therapeutic cardiac catheterization service shall have a minimum of two appropriately trained physicians on its active hospital staff. The Department may accept other evidence or shall consider it appropriate training if the staff physicians:
      - (i) are trained consistent with the recommendations of the American College of Cardiology;
      - (ii) are credentialed by the hospital to perform adult therapeutic cardiac catheterizations; and
      - (iii) have each performed a minimum of 75 adult therapeutic cardiac catheterization procedures in the preceding 12 months.

(i) A pediatric cardiac catheterization service shall have an appropriately trained physician on its active hospital staff. The Department may accept other evidence or shall consider it appropriate training if the staff physician:

- (i) is board certified or board eligible in pediatric cardiology by the American Board of Pediatrics;
- (ii) is credentialed by the hospital to perform pediatric cardiac catheterizations; and
- (iii) has trained consistently with the recommendations of the American College of Cardiology.

(j) A cardiac catheterization service shall be directed by an appropriately trained physician. The Department shall consider appropriate training of the 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 five preceding years. The Department may accept other evidence that the director is appropriately trained.

(k) A cardiac catheterization service shall be operated consistently with the recommendations of the American College of Cardiology.

(3) Compliance with the following access to care requirements:

(a) The service shall accept referrals for cardiac catheterization from all appropriately licensed practitioners.

(b) The service shall participate in Medicaid at least 12 consecutive months within the first two years of operation and annually thereafter.

(c) The service shall not deny cardiac catheterization services to any individual based on ability to pay or source of payment.

(d) The operation of and referral of patients to the cardiac catheterization service shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.1621; MSA 14.15 (16221).

(4) Compliance with the following monitoring and reporting requirements:

(a) the service shall be operating at or above the applicable volumes in the second 12 months of operation of the service, or an additional laboratory, and annually thereafter:

(i) 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures.

(ii) 300 procedure equivalents in the category of adult therapeutic cardiac catheterization procedures.

(iii) 600 procedure equivalents in the category of pediatric cardiac catheterization procedures.

(iv) 500 procedure equivalents for a hospital in a rural or micropolitan county with one laboratory.

(v) 750 procedure equivalents for a hospital in a metropolitan county with one laboratory.

(vi) 1,000 procedure equivalents per cardiac catheterization laboratory for two or more laboratories.

(vii) 36 adult primary PCI cases for a primary PCI service.

(b) The hospital shall participate in a data collection network established and administered by the Department or its designee. Data may include, but is not limited to, annual budget and cost information, operating schedules, patient demographics, morbidity and mortality information, and payor. The Department may verify the data through on-site review of appropriate records.

(c) The hospital shall participate in a quality improvement data registry administered by the Department or its designee. The hospital shall submit summary reports as required by the Department. The hospital shall provide the required data in a format established by the Department or its designee. The hospital is liable for the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes and assure quality. The hospital must become a member of the data registry upon initiation of the service and continue to participate annually thereafter for the life of that service.

(5) Compliance with the following primary PCI requirements, if applicable:

(a) The requirements set forth in Section 3(4).

(b) The hospital shall immediately report to the Department any changes in the interventional cardiologists who perform the primary PCI procedures.

(c) The hospital shall perform a minimum of 36 primary PCI procedures at the hospital in the preceding 12-month period of operation of the service and annually thereafter.

(d) The hospital shall maintain a 90-minute door-to-balloon time or less in at least 75% of the primary PCI sessions.

(e) The hospital shall participate in a data registry, administered by the Department or its designee. The Department or its designee shall require that the applicant submit data on all consecutive cases of primary PCI as is necessary to comprehensively assess and provide comparative analyses of case selection, processes and outcome of care, and trend in efficiency. The applicant shall provide the required data in a format established by the Department or its designee. The applicant shall be liable for the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes and assure quality.

(6) The agreements and assurances required by this section shall be in the form of a certification agreed to by the applicant or its authorized agent.

**Section 10. Methodology for computing cardiac catheterization equivalents**

Sec. 10. The following shall be used in calculating procedure equivalents and evaluating utilization of a cardiac catheterization service and its laboratories:

Procedure Type	Procedure equivalent	
	Adult	Pediatric
Diagnostic cardiac catheterization/peripheral sessions	1.5	2.7
Therapeutic cardiac catheterization/peripheral sessions	2.7	4.0
Complex percutaneous valvular sessions*	4.0	7.0
* Complex percutaneous valvular sessions includes, but is not limited to, procedures performed percutaneously or with surgical assistance to repair or replace aortic, mitral and pulmonary valves such as transcatheter aortic valvular implantation (Tavi) procedures. These sessions can only be performed at hospitals approved with open heart surgery services.		

**Section 11. Documentation of projections**

Sec. 11. An applicant required to project volumes shall demonstrate the following as applicable to the proposed project:

(1) The applicant shall specify how the volume projections were developed. Specification of the projections shall include a description of the data source(s) used and assessment of the accuracy of the data. The Department shall determine if the projections are reasonable.

(2) An applicant proposing to initiate a primary PCI service shall demonstrate and certify that the hospital treated or transferred 36 ST segment elevation AMI cases during the most recent 12-month period preceding the date the application was submitted to the Department. Cases may include thrombolytic eligible patients documented through pharmacy records showing the number of doses of thrombolytic therapy ordered and medical records of emergency transfers of AMI patients to an appropriate hospital for a primary PCI procedure.

**Section 12. Comparative reviews; Effect on prior CON Review Standards**

Sec. 12. Proposed projects reviewed under these standards shall not be subject to comparative review. These CON Review Standards supersede and replace the CON Review Standards for Cardiac

Catheterization Services approved by the CON Commission on December 11, 2007 and effective on February 25, 2008.

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Rural Michigan counties are as follows:

Alcona	Hillsdale	Ogemaw
Alger	Huron	Ontonagon
Antrim	Iosco	Osceola
Arenac	Iron	Oscoda
Baraga	Lake	Otsego
Charlevoix	Luce	Presque Isle
Cheboygan	Mackinac	Roscommon
Clare	Manistee	Sanilac
Crawford	Mason	Schoolcraft
Emmet	Montcalm	Tuscola
Gladwin	Montmorency	
Gogebic	Oceana	

Micropolitan statistical area Michigan counties are as follows:

Allegan	Gratiot	Mecosta
Alpena	Houghton	Menominee
Benzie	Isabella	Midland
Branch	Kalkaska	Missaukee
Chippewa	Keweenaw	St. Joseph
Delta	Leelanau	Shiawassee
Dickinson	Lenawee	Wexford
Grand Traverse	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	Ionia	Newaygo
Bay	Jackson	Oakland
Berrien	Kalamazoo	Ottawa
Calhoun	Kent	Saginaw
Cass	Lapeer	St. Clair
Clinton	Livingston	Van Buren
Eaton	Macomb	Washtenaw
Genesee	Monroe	Wayne
Ingham	Muskegon	

Source:  
65 F.R., p. 82238 (December 27, 2000)  
Statistical Policy Office  
Office of Information and Regulatory Affairs  
United States Office of Management and Budget