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 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, 10, **11** and ~~13~~ 14 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 ~~11~~ 12 **and 13** in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

(5) THE DEPARTMENT SHALL USE SECTION 3(2), IN APPLYING SECTION 22215(1)(B) OF THE CODE, BEING SECTION 333.22215(1)(B) OF THE MICHIGAN COMPILED LAWS.

Section 2. Definitions

Sec. 2. (1) ~~As used in~~FOR PURPOSES OF 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"Balloon atrial septostomy" means a procedure in which a balloon-tipped catheter is placed across the atrial septum and withdrawn to create an enlarged atrial opening.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; and pediatric therapeutic cardiac catheterizations.

(e) "Central service coordinator" means the organizational ~~unit~~ ENTITY that 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 (MDCH).

(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.~~LABORATORY. 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. THIS TERM ALSO INCLUDES CARDIAC PERMANENT PACEMAKER/ICD DEVICE IMPLANTATIONS IN A HOSPITAL THAT DOES NOT PROVIDE THERAPEUTIC 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 CON 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) " Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and1396r-8 to 1396v.

(q) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

(r) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

(s) "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.~~HOSPITALS.

~~(t) "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.~~

(~~u~~T) "On-site open heart surgery services" means a facility that does have a CON to perform open heart surgery services and does perform open heart surgery services in the existing ~~facility~~ HOSPITAL.

(~~v~~U) "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.

(~~w~~V) "Primary percutaneous coronary intervention (PCI)" means ~~for the purposes of these standards~~ a PCI performed within 120 minutes for emergency acute myocardial infarction (AMI) patients seen in the emergency room (ER) with confirmed ST elevation or new left bundle branch block.

(~~x~~W) "Procedure equivalent" means a unit of measure that 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:~~

	~~**Procedure Equivalent**~~	
~~**Procedure Type**~~	~~**Adult**~~	~~**Pediatric**~~
~~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.~~

(~~y~~X) "Replace/upgrade" means anY ~~an~~ equipment change THAT INVOLVES A CAPITAL EXPENDITURE OF $500,000 OR MORE IN ANY CONSECUTIVE 24-MONTH PERIOD ~~proposed by an applicant~~ which results in ~~that~~ THE applicant operating the same number of cardiac catheterization laboratories ~~or multi purpose special radiological rooms~~ before and after project completion.

(~~z~~Y) "Rural county" means a county not located in a metropolitan statistical area or micropolitan statistical areas as those terms are defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

~~(aa) "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.~~

~~(bb) "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 coronary intervention (PCI), 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.~~

(~~cc~~Z) "Therapeutic cardiac catheterization service" means providing therapeutic cardiac catheterizations on an organized, regular basis~~, either~~ in a laboratory TO TREAT AND RESOLVE ANATOMICAL AND/OR PHYSIOLOGICAL PROBLEMS IN THE HEART. THE TERM INCLUDES, BUT IS NOT LIMITED TO: PERCUTANEOUS CORONARY INTERVENTION (PCI), PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA), ATHERECTOMY, STENT, LASER, CARDIAC VALVULOPLASTY, BALLOON ATRIAL SEPTOSTOMY, OR CATHETER ABLATION AND CARDIAC PERMANENT PACEMAKER/ICD DEVICE IMPLANTATIONS. THE TERM DOES NOT INCLUDE THE INTRA CORONARY ADMINISTRATION OF DRUGS WHERE THAT IS THE ONLY THERAPEUTIC INTERVENTION.~~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.~~

(~~3~~2) 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. ~~If the required documentation is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.~~

Section 4. Requirements for approval -- applicants ~~for~~ PROPOSING TO INITIATE 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 or micropolitan statistical area 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 metropolitan statistical area 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 7, as applicable.~~

Section 5. Requirements for approval -- applicants ~~for~~ PROPOSING TO INITIATE an adult diagnostic cardiac catheterization service with provision to perform primary PCI for patients experiencing AMI (ST elevation or new left bundle branch block) without on-site open heart surgery services

Sec. 5. (1) An applicant proposing to INITIATE ~~perform~~ primary PCI SERVICE without on-site open heart surgery services shall SUBMIT DOCUMENTATION demonstratING all of the following:

(a) The applicant's adult diagnostic cardiac catheterization service performed a minimum of 400 diagnostic procedures (excluding diagnostic electrophysiology studies and right heart catheterizations) during the most recent 12 months preceding the date the application was submitted to the Department. Mobile cardiac catheterization laboratories are not eligible to apply under Section 5.

(b) The interventional cardiologists (at least two) to perform the primary PCI are experienced interventionalists who have each performed at least 75 interventions annually as the primary operator at an open heart surgery facility during the most recent 24 months preceding the date the application was submitted to the Department, and annually thereafter.

(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 facility; and participate in an un-interrupted 24-hour, 365-day call schedule. Competency should be documented annually.

(d) The catheterization laboratory is well-equipped, with optimal imaging systems, resuscitative equipment, intra-aortic balloon pump (IABP) support, and must be well-stocked with a broad array of interventional equipment.

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

(f) A written agreement with an open heart surgery facility that includes:

(i) Involvement in credentialing criteria and recommendations for physicians approved to perform primary PCI;

(ii) Provision for ongoing cross-training for professional and technical staff involved in the provision of primary PCI to ensure familiarity with interventional equipment; and competency should 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 and competency should 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 facility, must be in place, with provisions for the implementation for immediate and efficient transfer (within 1 hour from cardiac catheterization laboratory to evaluation on site in the open heart surgical facility) of patients requiring surgical evaluation and/or intervention 365 days a year, the protocols shall be reviewed/tested on a regular (quarterly) basis; and

(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 that is consistent with current practice guidelines set forth by the American College of Cardiology and the American Heart Association.

(h) A system to ensure prompt and efficient identification of potential primary PCI patients and rapid transfer from the Emergency Department to the Catheterization Laboratory must be developed and maintained so that door-to-balloon targets are met.

(i) Because primary PCI must be available to emergency patients 24 hours per day, 365 days a year, 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.

(2) An applicant shall project a minimum of 48 primary PCI procedures will be performed in the second 12 months of operation after initiation of service, and annually thereafter. Primary PCI volume shall be projected by documenting, as outlined in Section 13, and certifying that the applicant treated or transferred enough ST segment elevation AMI cases during the most recent 12 months preceding the date the application was submitted to the Department to maintain 48 primary PCI cases annually. Factors that may be considered in projecting primary PCI volume are the number of thrombolytic eligible patients per year seen in the Emergency Department (as documented through hospital pharmacy records showing the number of doses of thrombolytic therapy ordered for AMI in the Emergency Department) and/or documentation of emergency transfers to an open heart surgery facility for primary PCI.

Section 6. Requirements for approval -- applicants ~~for~~ PROPOSING TO INITIATE a pediatric ~~diagnostic~~ cardiac catheterization service

Sec. 6. (1) An applicant proposing to initiate a pediatric ~~diagnostic~~ cardiac catheterization service at a hospital that will perform ~~only pediatric diagnostic~~ cardiac catheterization procedures IS REQUIRED TO HAVE ~~shall demonstrate~~ each of the following~~, as applicable:~~AS OUTLINED IN THE AMERICAN ACADEMY OF PEDIATRICS (AAP), GUIDELINES FOR PEDIATRIC CARDIOVASCULAR CENTERS (MARCH 2002):

(A) A BOARD CERTIFIED PEDIATRIC CARDIOLOGIST WITH TRAINING IN PEDIATRIC CATHETERIZATION PROCEDURES TO DIRECT THE PEDIATRIC CATHETERIZATION LABORATORY;

(B) STANDARDIZED EQUIPMENT AS OUTLINED IN AAP GUIDELINES PUBLICATION;

(C) ON-SITE ICU AS OUTLINED IN AAP GUIDELINES PUBLICATION; AND

(D) ON-SITE PEDIATRIC OPEN HEART SURGERY.

~~(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~~ PROJECT ~~each of the following, as applicable:~~THAT ~~(a)~~ a minimum of ~~150~~ 600 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 7, as applicable.~~

~~**Section 7. Requirements for approval -- applicants proposing to add a cardiac catheterization laboratory or multi purpose special radiological room**~~

~~Sec. 7. 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 ~~8~~7~~.~~ Requirements for approval -- applicants ~~for a~~PROPOSING TO INITIATE AN ADULT therapeutic cardiac catheterization service

Sec. ~~8~~7.~~.~~ (1) An applicant proposing to perform therapeutic cardiac catheterization procedures shall demonstrate both of the following:

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

(b) An applicant provides or has CON 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) 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 7, as applicable.~~

~~**Section 8. Requirements for approval -- applicants for a therapeutic cardiac catheterization service**~~

~~Sec. 8. (1) An applicant proposing to perform therapeutic cardiac catheterization procedures shall demonstrate both of the following:~~
~~(a) An applicant provides or has CON approval to provide an adult or pediatric, as applicable, diagnostic cardiac catheterization service.~~
~~(b) An applicant provides or has CON 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 7, as applicable.~~

Section ~~98~~. ~~.~~ Requirements for approval -- applicants ~~for~~ PROPOSING TO replace~~ment~~/upgradE~~upgrading of~~ cardiac catheterization laboratories. ~~or multi-purpose special radiological rooms~~

Sec. ~~98~~. (1) ~~If an~~ An applicant, other than a hospital that provides only pediatric cardiac catheterization services, ~~is~~ proposing to replace/upgrade ~~an existing cardiac catheterization~~ITS ONLY ~~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 procedures equivalents were 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 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~~ An applicant ~~is proposing to replace/upgrade an existing cardiac catheterization laboratory or multi-purpose special radiological room and there are~~WITH ~~are~~ 2 or more ~~existing rooms at the hospital in which cardiac catheterization procedures are performed,~~LABORATORIES PROPOSING TO REPLACE/UPGRADE ANY OF ITS LABORATORIES ~~the applicant~~ shall demonstrate that it meets each of the following, AS APPLICABLE:

(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), ~~6(1)(a),~~ 6(2)(~~a~~) or ~~8~~7(2)(~~a~~A) ~~or (b)~~, as applicable, have also been met.

SECTION 9. REQUIREMENTS FOR APPROVAL -- APPLICANTS PROPOSING TO EXPAND A CARDIAC CATHETERIZATION SERVICE BY ADDING A LABORATORY

SEC. 9 AN APPLICANT PROPOSING TO ADD A LABORATORY 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 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 (BOTH EXISTING AND PROPOSED) IN THE SECOND 12 MONTHS OF OPERATION AFTER INITIATING OPERATION OF THE ADDITIONAL ROOM, AND ANNUALLY THERE AFTER.

Section 10. Requirements for approval -- applicants for a mobile cardiac catheterization network

Sec. 10. 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 CON 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 CON as of the effective date of these standards.

(4) 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~~Section~~ 11. METHODOLOGY FOR COMPUTING CARDIAC CATHETERIZATION EQUIVALENTS – PROCEDURES AND WEIGHTS~~Project delivery requirements -- terms of approval for all applicants~~

SEC.~~Sec~~.11. (1) THE FOLLOWING PROCEDURE EQUIVALENTS SHALL BE USED IN CALCULATING AND EVALUATING UTILIZATION OF A CARDIAC CATHETERIZATION LABORATORY:

	PROCEDURE EQUIVALENT	
PROCEDURE TYPE	**ADULT**	**PEDIATRIC**
DIAGNOSTIC CARDIAC CATHETERIZATION	1.0	3.0
THERAPEUTIC CARDIAC CATHETERIZATION	1.5	3.0
THERAPEUTIC,OTHER (PFO/ASD/VALVULOPLASTY,LVAD)	2.5	3.5

	PROCEDURE EQUIVALENT	
PROCEDURE TYPE	**ADULT**	**PEDIATRIC**
DIAGNOSTIC, PERIPHERAL[1]	1.0	2.0
THERAPEUTIC, PERIPHERAL-CAROTID,SUBCLAVIAN, RENAL, ILIAC, MESENTERIC	1.5	2.5
THERAPEUTIC, PERIPHERAL – Superficial Femoral Artery	2.5	2.5
THERAPEUTIC, PERIPHERAL – INFRAPOPLITEAL	3.0	3.0
THERAPEUTIC, PERIPHERAL – AORTA	4.0	4.0
DIAGNOSTIC, Electro Physiology (EP)	2.0	3.5
THERAPEUTIC, EP – Permanent Pacemaker, ICD	2.5	5.0
THERAPEUTIC, EP – ABLATION NON-AF	3.0	5.0
THERAPEUTIC, EP – ABLATION AF OR VT	4.0	6.0
THERAPEUTIC, EP – CARDIOVERSION	1.0	1.0
OTHER PROCEDURES (IVC FILTER, TEMPORARY VENOUS PACEMAKER, IABP, OTHER RADIOLOGICAL PROCEDURES	1.0	2.0
MULTIPLE PROCEDURES WITHIN THE SAME SESSION (Diagnostic and/or Therapeutic)	The sum of procedure weights minus 0.5 for each procedure after the first procedure	The sum of procedure weights minus 0.5 for each procedure after the first procedure

(2) FOR PURPOSES OF EVALUATING WHETHER AN APPLICANT MEETS APPLICABLE VOLUME REQUIREMENTS SET FORTH IN THESE STANDARDS, CARDIAC CATHETERIZATION PROCEDURES PER LABORATORY MUST BE MET EXCLUSIVE OF THE INTRA-VASCULAR CATHETERIZATION PROCEDURES WHEN CONSIDERING EXPANSION OR REPLACE/UPGRADE. THE PERIPHERAL NON-CARDIAC PROCEDURES SHALL COUNT TOWARD THE TOTAL VOLUME REQUIREMENTS FOR PROCEDURES BUT THE MINIMUM VOLUMES REMAIN THE SAME FOR INITIATION OF CARDIAC CATHETERIZATION SERVICES.

(A) INTRA-VASCULAR CATHETERIZATION IS A MEDICAL DIAGNOSTIC OR THERAPEUTIC PROCEDURE DURING WHICH A CATHETER IS INSERTED INTO AN ARTERY IN A PATIENT. SUBSEQUENTLY, THE FREE END OF THE CATHETER IS MANIPULATED BY A PHYSICIAN TO TRAVEL ALONG THE COURSE OF A NON-CORONARY ARTERY. X-RAYS AND AN ELECTRONIC IMAGE INTENSIFIER ARE USED AS AIDS IN PLACING THE CATHETER TIP INTO THE DESIRED POSITION. WHEN THE CATHETER IS IN PLACE, THE PHYSICIAN IS ABLE TO PERFORM VARIOUS DIAGNOSTIC STUDIES AND/OR THERAPEUTIC PROCEDURES IN THE ARTERY.

[1] Excludes selective common femoral angiography when performed as part of a diagnostic or therapeutic cardiac catheterization for a possible closure device.

INTRA-VASCULAR CATHETERIZATION SHALL NOT INCLUDE "FLOAT CATHETERS" OR "HEMODYNAMIC MONITORING CATHETERS" WHICH ARE PERFORMED, AND/OR ARE USED AT THE BEDSIDE FOR THE PURPOSES OF MONITORING OR ADMINISTERING HEMODYNAMIC MEDICATION.

Section ~~11~~12. Project delivery requirements -- terms of approval for all applicants

Sec. ~~11~~12.. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance with the following terms of CON 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~~IV) 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~~V)~~)~~ 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~~VI) 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~~VII) For purposes of evaluating subdivisions ~~(iv),~~ (v), OR (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~~VIII) 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~~IX) 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~~X) 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~~XI) 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~~XII) An approved cardiac catheterization service shall be operated consistently with the recommendations of the American College of Cardiology.

(~~xiv~~XIII) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.

(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 or its designee. 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 or its designee 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 SHALL PARTICIPATE IN A QUALITY IMPROVEMENT DATA REGISTRY ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE. THE DEPARTMENT OR ITS DESIGNEE SHALL REQUIRE THAT THE APPLICANT SUBMIT A SUMMARY REPORT AS REQUIRED BY THE DEPARTMENT. 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. AN APPLICANT SHALL BECOME A MEMBER OF THE DATA REGISTRY UPON INITIATION OF THE SERVICE AND CONTINUE TO PARTICIPATE ANNUALLY THEREAFTER.

(~~iv~~V) The applicant shall provide the Department with a notice stating the date on which the first approved service is performed and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(~~v~~VI) 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 AGREED TO BY ~~authorized by the governing body of~~ the applicant OR ITS AUTHORIZED AGENT.

Section ~~12~~13~~.~~ Project delivery requirements – additional terms of approval for applicants approved under Section 5

Sec. ~~12~~ 13. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance with the following terms of CON approval:

(a) Shall immediately report to the Department any changes in the interventional cardiologists who perform the primary PCI procedures.

(b) Compliance with requirements of the standards set forth in Section 5(1).

(2) The applicant shall have performed a minimum of 48 primary PCI procedures at the facility in the preceding 12 months AND ANNUALLY THEREAFTER.

(3) The applicant 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.

Section ~~13~~14. Documentation of projections

Sec. ~~13~~14. An applicant required to project volumes of service under sections 4, 5, 6, and 7~~, 8, and 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 ~~14~~15. Effect on prior CON Review Standards; comparative reviews

Sec. 14. (1) These CON Review Standards supercede and replace the CON Review Standards for Cardiac Catheterization Services approved by the CON Commission on ~~June 10, 2003~~MARCH 9, 2004 and effective on ~~August 4, 2003~~JUNE 4, 2004.

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

APPENDIX A

CON REVIEW STANDARDS
FORCARDIAC CATHETERIZATION SERVICES

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