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. 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) "Balloon atrial septostomy" means a procedure in which a balloon-tipped catheter is placed across the atrial septum and withdrawn to create an enlarged atrial opening.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. 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.
(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) "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.
(F) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.
(G) "Department" means the Michigan Department of Community Health (MDCH).
(H) "Diagnostic cardiac catheterization service" means providing diagnostic-only cardiac catheterizations on an organized, regular basis, in a 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.

(I) "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.

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

(K) "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) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6
and 1396r-8 to 1396v.

(M) "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.

(N) "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.

(O) "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 hospital.

(P) "Pediatric cardiac catheterization service" means the offering and provision of cardiac
catheterizations 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 745.99.

(Q) "Primary percutaneous coronary intervention (PCI)" means 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.

(R) "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 based on the type of procedures
being performed.

(S) "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.

(T) "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. 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.

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

Section 3. Requirements TO INITIATE A CARDIAC CATHETERIZATION SERVICE

Sec. 3. To 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. AN APPLICANT PROPOSING TO INITIATE CARDIAC
CATHETERIZATION SERVICES SHALL DEMONSTRATE THE FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT.

(1) 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.

(2) An applicant proposing to initiate an adult diagnostic cardiac catheterization service in a new single laboratory 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.
   (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.

(3) An applicant proposing to initiate an adult diagnostic cardiac catheterization service in 2 or more laboratories shall project a minimum of 1,000 procedure equivalents per laboratory which shall include 300 procedure equivalents in the category of adult diagnostic cardiac catheterization in the second 12 months of operation after initiation of the service, and annually thereafter.

(4) AN APPLICANT PROPOSING TO PERFORM ADULT THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES SHALL DEMONSTRATE ALL OF THE FOLLOWING:
   (A) AN APPLICANT PROVIDES OR HAS CON APPROVAL TO PROVIDE AN ADULT DIAGNOSTIC CARDIAC CATHETERIZATION SERVICE.
   (B) AN APPLICANT PROVIDES OR HAS CON APPROVAL TO PROVIDE AN ADULT OPEN HEART SURGERY SERVICE 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.
   (D) 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:
      (I) A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT THERAPEUTIC CARDIAC CATHETERIZATIONS.

(5) AN APPLICANT PROPOSING TO INITIATE A PEDIATRIC CARDIAC CATHETERIZATION SERVICE AT A HOSPITAL THAT WILL PERFORM CARDIAC CATHETERIZATION PROCEDURES IS REQUIRED TO HAVE EACH OF THE FOLLOWING 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.
   (E) AN APPLICANT PROPOSING TO INITIATE A PEDIATRIC CARDIAC CATHETERIZATION SERVICE AT A HOSPITAL THAT CURRENTLY PERFORMS CARDIAC CATHETERIZATION PROCEDURES SHALL PROJECT THAT A MINIMUM OF 600 PROCEDURE EQUIVALENTS IN THE CATEGORY OF PEDIATRIC CARDIAC CATHETERIZATIONS WILL BE PERFORMED IN THE SECOND 12 MONTHS OF OPERATION AFTER INITIATION OF THE PEDIATRIC CARDIAC CATHETERIZATION SERVICE, AND ANNUALLY THEREAFTER.
(6) An applicant proposing to initiate 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.

(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 patients and 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.
(J) 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 4. Requirements to replace AN EXISTING cardiac catheterization laboratory

Sec. 4. REPLACE/UPGRADE MEANS ANY EQUIPMENT CHANGE THAT INVOLVES A CAPITAL EXPENDITURE OF $500,000 OR MORE IN ANY CONSECUTIVE 24-MONTH PERIOD WHICH RESULTS IN THE APPLICANT OPERATING THE SAME NUMBER OF CARDIAC CATHETERIZATION LABORATORIES BEFORE AND AFTER PROJECT COMPLETION. An applicant, other than a hospital that provides only pediatric cardiac catheterization services, proposing to replace/upgrade its only laboratory, shall demonstrate that it meets each of the following, as applicable:

(1) 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 EITHER OF THE FOLLOWING:
   (A) The existing equipment poses a threat to the safety of the PATIENTS.
   (B) THE REPLACEMENT EQUIPMENT offers technological improvements THAT enhance quality of care, increase efficiency, and reduce operating costs AND PATIENT CHARGES.

(2) THE APPLICANT AGREES THAT THE EQUIPMENT TO BE REPLACED WILL BE REMOVED FROM SERVICE ON OR BEFORE BEGINNING OPERATION OF THE REPLACEMENT EQUIPMENT.

(3) AN APPLICANT PROPOSING TO REPLACE A CARDIAC CATHETERIZATION SERVICE TO A NEW SITE SHALL DEMONSTRATE THE FOLLOWING:
   (A) THE PROPOSED SITE IS WITHIN A XX-MILE RADIUS OF THE EXISTING SITE FOR A METROPOLITAN STATISTICAL AREA COUNTY OR A XX-MILE RADIUS FOR A RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY.
   (B) THE EXISTING CARDIAC CATHETERIZATION SERVICE PERFORMED XXX CARDIAC CATHETERIZATION PROCEDURES PER ROOM IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE DEPARTMENT.
   (C) THE EXISTING CARDIAC CATHETERIZATION SERVICE HAS BEEN IN OPERATION FOR AT LEAST 36 MONTHS AS OF THE DATE OF THE APPLICATION SUBMITTED TO THE DEPARTMENT.

Section 5. Requirements to expand a cardiac catheterization service

Sec. 5. EXPANDING A CARDIAC CATHETERIZATION SERVICE MEANS EITHER AN INCREASE IN THE NUMBER OF CARDIAC CATHETERIZATION LABORATORIES AT A HOSPITAL OR 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. An applicant proposing to add a laboratory to an existing cardiac catheterization service shall demonstrate the following:

(1) 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.
Section 6. REQUIREMENTS TO ACQUIRE A CARDIAC CATHETERIZATION SERVICE

SEC. 6. ACQUIRING A CARDIAC CATHETERIZATION SERVICE AND ITS EQUIPMENT MEANS OBTAINING POSSESSION AND CONTROL BY CONTRACT, OWNERSHIP, LEASE OR OTHER COMPARABLE ARRANGEMENT AND RENEWAL OF LEASE FOR AN EXISTING CARDIAC CATHETERIZATION SERVICE. AN APPLICANT PROPOSING TO ACQUIRE A HOSPITAL THAT HAS BEEN APPROVED TO PERFORM CARDIAC CATHETERIZATION SERVICES MAY ALSO ACQUIRE THE EXISTING CARDIAC CATHETERIZATION SERVICE IF IT CAN DEMONSTRATE THAT THE PROPOSED PROJECT MEETS ALL OF THE FOLLOWING:

(1) AN APPLICATION FOR THE FIRST ACQUISITION OF AN EXISTING CARDIAC CATHETERIZATION SERVICE AFTER <INSERT EFFECTIVE DATE OF THESE STANDARDS> SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE APPLICABLE VOLUME REQUIREMENTS ON THE DATE OF ACQUISITION. THE CARDIAC CATHETERIZATION SERVICE SHALL BE OPERATING AT XXX PROCEDURE EQUIVALENTS IN THE SECOND 12 MONTHS AFTER THE DATE THE SERVICE IS ACQUIRED, AND ANNUALLY THEREAFTER.

(2) EXCEPT AS PROVIDED FOR IN SUBSECTION (1), AN APPLICATION FOR THE ACQUISITION OF AN EXISTING CARDIAC CATHETERIZATION SERVICE AFTER <INSERT EFFECTIVE DATE OF THESE STANDARDS> SHALL BE OPERATING AT XXX PROCEDURE EQUIVALENTS IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE DEPARTMENT PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT.

(3) THE APPLICANT AGREES TO OPERATE THE CARDIAC CATHETERIZATION SERVICE IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN SECTION 8 OF THESE STANDARDS.

SECTION 7. REQUIREMENT FOR MEDICAID PARTICIPATION

SEC. 7. 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 8. PROJECT DELIVERY REQUIREMENTS AND TERMS OF APPROVAL FOR ALL APPLICANTS

SEC. 8. (1) AN APPLICANT SHALL AGREE THAT, IF APPROVED, THE CARDIAC CATHETERIZATION SERVICES SHALL BE DELIVERED IN COMPLIANCE WITH THE FOLLOWING TERMS OF APPROVAL.

(1) COMPLIANCE WITH THESE STANDARDS.

(2) COMPLIANCE WITH THE FOLLOWING QUALITY ASSURANCE REQUIREMENTS:
   (A) 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.
   (B) 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.

(C) 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.

(D) 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.

(E) 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 EACH 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.

(F) FOR PURPOSES OF EVALUATING SUBDIVISIONS (V) OR (VI), 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.

(G) 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:

(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. HOWEVER, THE APPLICANT MAY SUBMIT AND THE DEPARTMENT MAY ACCEPT OTHER EVIDENCE THAT THE STAFF PHYSICIANS PERFORMING ADULT DIAGNOSTIC CARDIAC CATHETERIZATIONS ARE APPROPRIATELY TRAINED.

(H) 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:

(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. HOWEVER, THE APPLICANT MAY SUBMIT AND THE DEPARTMENT MAY ACCEPT OTHER EVIDENCE THAT THE STAFF PHYSICIANS PERFORMING ADULT THERAPEUTIC CARDIAC CATHETERIZATIONS ARE APPROPRIATELY TRAINED.

(J) 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.

(K) AN APPROVED 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 CARDIAC CATHETERIZATION SERVICES SHALL ACCEPT REFERRALS FOR CARDIAC CATHETERIZATION SERVICES FROM ALL APPROPRIATELY LICENSED PRACTITIONERS.

(B) THE CARDIAC CATHETERIZATION SERVICE SHALL PARTICIPATE IN MEDICAID AT LEAST 12 CONSECUTIVE MONTHS WITHIN THE FIRST TWO YEARS OF OPERATION AND CONTINUE TO PARTICIPATE ANNUALLY THEREAFTER.
C THE CARDIAC CATHETERIZATION 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 APPROVED SERVICES SHALL BE OPERATING AT THE APPLICABLE REQUIRED
VOLUMES WITHIN THE TIME PERIOD SPECIFIED IN THESE STANDARDS, AND ANNUALLY
THEREAFTER.
(B) 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.
(C) 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.
(D) THE CARDIAC CATHETERIZATION SERVICE SHALL PROVIDE THE DEPARTMENT WITH
TIMELY NOTICE OF THE PROPOSED PROJECT IMPLEMENTATION CONSISTENT WITH
APPLICABLE STATUTE AND PROMULGATED RULES.
(E) EQUIPMENT THAT IS REPLACED SHALL BE REMOVED FROM THE CARDIAC
CATHETERIZATION SERVICE.

(5) COMPLIANCE WITH THE FOLLOWING PRIMARY PCI REQUIREMENTS, IF APPLICABLE:
(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).
(C) THE APPLICANT SHALL HAVE PERFORMED A MINIMUM OF 48 PRIMARY PCI
PROCEDURES AT THE FACILITY IN THE PRECEDING 12 MONTHS AND ANNUALLY THEREAFTER.
(D) 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.
(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 9. Methodology for computing cardiac catheterization equivalents – procedures and weights

Sec. 9. (1) The following procedure equivalents shall be used in calculating and evaluating utilization of a cardiac catheterization laboratory:

<table>
<thead>
<tr>
<th>PROCEDURE TYPE</th>
<th>PROCEDURE TYPE</th>
<th>PROCEDURE EQUIVALENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic cardiac catheterization</td>
<td>Adult</td>
<td>1.0</td>
</tr>
<tr>
<td>Therapeutic cardiac catheterization</td>
<td>Pediatric</td>
<td>3.0</td>
</tr>
<tr>
<td>Therapeutic, other (PFO/ASD/Valvuloplasty/LVAD)</td>
<td>Adult</td>
<td>1.5</td>
</tr>
<tr>
<td>Therapeutic, other (PFO/ASD/Valvuloplasty/LVAD)</td>
<td>Pediatric</td>
<td>3.0</td>
</tr>
<tr>
<td>Diagnostic, peripheral</td>
<td>Adult</td>
<td>2.5</td>
</tr>
<tr>
<td>Therapeutic, peripheral – Carotid, Subclavian, Renal, Iliac, Mesenteric</td>
<td>Pediatric</td>
<td>2.0</td>
</tr>
<tr>
<td>Therapeutic, peripheral – Superficial Femoral Artery</td>
<td>Adult</td>
<td>2.5</td>
</tr>
<tr>
<td>Therapeutic, peripheral – Superficial Femoral Artery</td>
<td>Pediatric</td>
<td>2.5</td>
</tr>
<tr>
<td>Therapeutic, peripheral – Infrapopliteal</td>
<td>Adult</td>
<td>3.0</td>
</tr>
<tr>
<td>Therapeutic, peripheral – Aorta</td>
<td>Pediatric</td>
<td>3.0</td>
</tr>
<tr>
<td>Diagnostic, electro physiology (EP)</td>
<td>Adult</td>
<td>4.0</td>
</tr>
<tr>
<td>Therapeutic, EP – Permanent Pacemaker, ICD</td>
<td>Pediatric</td>
<td>4.0</td>
</tr>
<tr>
<td>Therapeutic, EP – Ablation Non-AF</td>
<td>Adult</td>
<td>2.0</td>
</tr>
<tr>
<td>Therapeutic, EP – Ablation AF or VT</td>
<td>Pediatric</td>
<td>3.5</td>
</tr>
<tr>
<td>Therapeutic, EP – Cardioversion</td>
<td>Adult</td>
<td>1.0</td>
</tr>
<tr>
<td>Therapeutic, EP – Cardioversion</td>
<td>Pediatric</td>
<td>1.0</td>
</tr>
<tr>
<td>Other procedures (IVC Filter, Temporary Venous Pacemaker, IABP, other radiological procedures)</td>
<td>Adult</td>
<td>1.0</td>
</tr>
<tr>
<td>Other procedures (IVC Filter, Temporary Venous Pacemaker, IABP, other radiological procedures)</td>
<td>Pediatric</td>
<td>2.0</td>
</tr>
</tbody>
</table>

The sum of procedure weights minus 0.5 for each procedure after the first procedure

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

(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. 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 10. Documentation of projections

Sec. 10. An applicant required to project volumes of service under sections 4, 5, 6, and 7 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 11. COMPARATIVE REVIEWS; Effect on prior CON Review Standards

Sec. 11. PROPOSED PROJECTS REVIEWED UNDER THESE STANDARDS SHALL NOT BE SUBJECT TO COMPARATIVE REVIEW. These CON Review Standards supercede and replace the CON Standards for Cardiac Catheterization Services approved by the CON Commission on DECEMBER 11, 2007 and effective on FEBRUARY 25, 2008.
APPENDIX A

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