MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR
OPEN HEART SURGERY SERVICES

(By the 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 open heart surgery services.

(2)   Open heart surgery is a covered clinical service for purposes of Part 222 of the Code.

(3)   The Department shall use sections 3, 4, 6, 8, and 9, 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 7 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 5 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) For purposes of these standards:
(a) "Adult open heart surgery" means open heart surgery offered and provided to individuals age 15 and older as defined in subsection (i).
(b) "Cardiac surgical team" means the designated specialists and support personnel who consistently work together in the performance of open heart surgery.
(c) "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.
(d) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.
(e) "Department" means the Michigan Department Of Community Health (MDCH).
 (f) "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.
(g) " Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and1396r-8 to 1396v.
(h) "Michigan inpatient data base" or "MIDB" means the data base compiled by the Michigan Health and Hospital Association or successor organization. The data base consists of inpatient discharge records from all Michigan hospitals and Michigan residents discharged from hospitals in border states for a specific calendar year.
 (i) "Open heart surgery" means any cardiac surgical procedure involving the heart and/or thoracic great vessels (excluding organ transplantation) that is intended to correct congenital and acquired cardiac and coronary artery disease and/or great vessels and often uses a heart-lung pump (pumps and oxygenates the blood) or its equivalent to perform the functions of circulation during surgery. These procedures may be performed off-pump (beating heart), although a heart-lung pump is still available during the procedure.

(j) "Open heart surgical case" means a single visit to an operating room during which one or more open heart surgery procedures are performed.

(k) "Open heart surgery service" means a hospital program that is staffed with surgical teams and other support staff for the performance of open heart surgical procedures. An open heart surgery service performs open heart surgery procedures on an emergent, urgent and scheduled basis.

(l) "Pediatric open heart surgery" means open heart surgery offered and provided to infants and children age 14 and younger, and to other individuals with congenital heart disease as defined by the ICD-9-CM codes of 745.0 through 747.99.

(m) "Planning area" means the groups of counties shown in Section 10.

(2) The definitions in Part 222 shall apply to these standards.

Section 3. Requirements for all applicants proposing to initiate open heart surgery services

Sec. 3. (1) An applicant proposing to initiate either adult or pediatric open heart surgery as a new service shall be operating or approved to operate a diagnostic and therapeutic adult or pediatric cardiac catheterization service, respectively.

(2) A hospital proposing to initiate open heart surgery as a new service shall have a written consulting agreement with a hospital which has an existing active open heart surgery service performing a minimum of 400 open heart surgical cases per year for 3 consecutive years. The agreement must specify that the existing service shall, for the first 3 years of operation of the new service, provide the following services to the applicant hospital:

(a) Receive and make recommendations on the proposed design of surgical and support areas that may be required;

(b) Provide staff training recommendations for all personnel associated with the new proposed service;

(c) Provide recommendations on staffing needs for the proposed service; and

(d) Work with the medical staff and governing body to design and implement a process that will annually measure, evaluate, and report to the medical staff and governing body the clinical outcomes of the new service, including: (i) Mortality rates, (ii) Complication rates, (iii) Success rates, and (iv) Infection rates.

(3) An applicant proposing to initiate adult open heart surgery as a new service shall demonstrate 300 adult open heart surgical cases based on the methodology set forth in Section 8.

(4) An applicant proposing to initiate pediatric open heart surgery as a new service shall demonstrate 100 pediatric open heart surgical cases based on the methodology set forth in Section 9.

Section 4. Requirements for approval for applicants proposing to acquire an existing open heart surgery service

Sec. 4. An applicant proposing to acquire a hospital that has been approved to perform open heart surgery services may also acquire the existing open heart surgery service if it can demonstrate that the proposed project meets all of the following:

(1) An application for the first acquisition of an existing open heart surgery service after the effective date of these standards shall not be required to be in compliance with the applicable volume requirements on the date of acquisition. The open heart surgery service shall be operating at the applicable volume requirements set forth in Section 7 of these standards 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 open heart surgery service after the effective date of these standards shall be required to be in compliance with the applicable volume requirements, as set forth in the project delivery requirements, on the date an application is submitted to the Department.

(3)   The applicant agrees to operate the open heart surgery service in accordance with all applicable project delivery requirements set forth in Section 7 of these standards.

Section 5. Requirements for all applicants

Sec 5. An applicant shall provide verification of Medicaid participation. An applicant that 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 6. Requirements for MIDB data commitments

Sec. 6. In order to use MIDB data in support of an application for either adult or pediatric open heart surgery services, an applicant shall demonstrate or agree, as applicable, to all of the following:

(1)   A hospital(s) whose adult MIDB data is used in support of a CON application for adult open heart surgery services shall not use any of its adult MIDB data in support of any other application for adult open heart surgery services prior to 7 years after the initiation of the open heart surgery service for which MIDB data were used to support. After the 7-year period, a hospital(s) may only commit its adult MIDB data in support of another application for adult open heart surgery services if they have experienced an increase from the previously committed MIDB data. Only that additional increase in MIDB data can be committed to another applicant to initiate open heart surgery services.

(2)   A hospital(s) whose pediatric MIDB data is used in support of a CON application for pediatric open heart surgery services shall not use any of its pediatric MIDB data in support of any other application for pediatric open heart surgery services prior to 7 years after the initiation of the open heart surgery service for which MIDB data were used to support. After the 7-year period, a hospital(s) may only commit its pediatric MIDB data in support of another application for pediatric open heart surgery services if they have experienced an increase from the previously committed MIDB data. Only that additional increase in MIDB data can be committed to another applicant to initiate open heart surgery services.

(3)   The hospital(s) committing MIDB data does not currently operate an adult or pediatric open heart surgery service or have a valid CON issued under Part 222 to operate an adult or pediatric open heart surgery service.

(4)   The hospital(s) committing MIDB data is located in the same planning area as the hospital to which MIDB data is being proposed to be committed.

(5)   The hospital(s) committing MIDB data to a CON application has completed the departmental form(s) which (i) authorizes the Department to verify the MIDB data, (ii) agrees to pay all charges associated with verifying the MIDB data, and (iii) acknowledges and agrees that the commitment of the MIDB data is for the period of time specified in subsection (1) or (2), as applicable.

(6)   The hospital(s) committing MIDB data to an application is regularly admitting patients as of the date the Director makes the final decision on that application, under Section 22231 of the Code, being Section 333.22231 of the Michigan Compiled Laws.

Section 7. Project delivery requirements -- terms of approval for all applicants

Sec. 7. (1) An applicant shall agree that if approved, the services 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 open heart surgery service shall be operating at an annual level of 300 adult open heart surgical cases or 100 pediatric open heart surgical cases, as applicable, by the end of the third 12 full months of operation, and annually thereafter.
   (ii)   Each physician credentialed by the applicant hospital to perform adult open heart surgery cases, as the attending surgeon, shall perform a minimum of 75 adult open heart surgery cases per year. The annual case load for a physician means adult open heart surgery cases performed by that physician, as the attending surgeon, in any hospital or combination of hospitals.
   (iii)   The service shall be staffed with sufficient medical, nursing, technical and other personnel to permit regular scheduled hours of operation and continuous 24 hour on-call availability.
   (iv)   The service shall have the capability for rapid mobilization of a cardiac surgical team for emergency cases 24 hours a day, 7 days a week.
   (v)   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)   The applicant, to assure appropriate utilization by all segments of the Michigan population, shall:
   (i)   provide open heart surgery services to all individuals based on the clinical indications of need for the service and not on ability to pay or source of payment; and
   (ii)   maintain information by source of payment 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.
  (e)   The applicant shall prepare and present to the medical staff and governing body reports describing activities in the open heart surgery service including complication rates and other morbidity and mortality data.
  (f)   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. The applicant shall provide the required data 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.
  (g)   The applicant shall participate in a data registry administered by the Department or its designee that monitors quality and risk adjusted outcomes. The Department or its designee shall require that the applicant submit a summary report as specified 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. The applicant shall become a member of the data registry specified by the Department upon initiation of the service. Participation shall continue annually thereafter. The outcomes database must undergo statewide auditing.
  (h)   An applicant that fails to comply with the quality assurance standards under subsection (c) shall be required to provide its quality and risk adjusted outcomes data from the data registry to the Department, or its designee, as part of the Department's enforcement and compliance activities.
   (i)   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.

  (2)   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 8. Methodology for computing the number of adult open heart surgical cases

Sec. 8. (1) The weights for the adult principal and non-principal diagnoses tables found in Appendix A are calculated using the following methodology. For these two tables, only the MIDB data from licensed hospitals that have operational open heart surgery programs in Michigan will be used. Using a hospital's actual inpatient discharge data, as specified by the most recent MIDB data available to the Department, an applicant shall identify the discharges that were from patients aged 15 years and older. These discharges shall be known as the "adult discharges."

   (a)   To calculate the weights for the principal diagnosis, the following steps shall be taken:

   (i)   For each diagnostic group in the principal weight table, the number of discharges is counted.

   (ii)   For the discharges identified in subsection 8(1)(a)(i), any occurrence of an open heart procedure code will be counted as a single open heart surgery case.

   (iii)   The number of open heart surgery cases for each diagnosis category will be divided by the number of discharges identified in subsection 8(1)(a)(i). This will be the weight for that diagnostic group. This number should show six decimal positions.

   (iv)   All discharges utilized for the computation of the principal weight table are to be removed from subsequent analyses.

   (b)   To calculate the weights for the non-principal diagnosis table, the following steps shall be taken, separately, in the sequence shown, and each remaining discharge will be examined for any mention of the diagnostic codes from that group. If a match is found, that discharge is assigned to that diagnostic group and removed from subsequent analyses:

   (i)   For each diagnostic group taken separately, in the sequence shown, any occurrence of an open heart procedure code for each discharge will be counted as a single open heart surgery case. If a match is found, the discharge will be counted as an open heart surgical case for that diagnostic group and removed from subsequent analyses.

   (ii)   The number of open heart surgery cases for each non-principal diagnosis category identified in subsection 8(1)(b)(i) will be divided by the number of discharges identified in subsection 8(1)(b). This will result in the non-principal weight for that diagnostic group. This number should show six decimal positions.

   (2)   An applicant shall apply the methodology set forth in this section for computing the projected number of adult open heart surgical cases using both the principal and non-principal diagnosis tables. The following steps shall be taken in sequence:

   (a)   For each diagnostic group in the principal weight table in Appendix A, identify the corresponding number of discharges.

   (b)   Multiply the number of discharges for each diagnostic group by their respective group weight to obtain the projected number of open heart surgery cases for that group. All discharges identified in subsection 8(2)(a) are removed from subsequent analysis.

   (c)   The non-principal weight table identifies the sequence that must be followed to count the discharges for the appropriate group. An applicant shall start with the first diagnostic group and shall count the number of discharges with any mention of a non-principal diagnosis corresponding to that specific diagnostic group. When a discharge that belongs in the specific non-principal diagnostic group is identified, it is assigned to that group. This discharge is then removed from the data before counting discharges for the next diagnostic group. The discharges counted for each group will be used only with the non-principal diagnosis weight table in Appendix A and will be entered into its respective diagnostic group. Multiply the number of discharges for each diagnostic group by their respective group weight to obtain the projected number of open heart surgery cases for that group.

   (d)   The total number of projected open heart cases is then calculated by summing the projected number of open heart cases from both principal and non-principal weight tables.

   (3)   The major ICD-9-CM groupings and Open Heart utilization weights in Appendix A are based on the work of the Bureau of Health Policy, Planning and Access, Michigan Department of Community Health, utilizing the most current MIDB data available to the Department.

(a)   The Department shall update the open heart utilization weights every 3 years, beginning with the year 2007, according to the methodology described in subsection (1) above, utilizing the most current MIDB data available to the Department.

(b)   Updates to the utilization weights made pursuant to this subsection shall not require standard advisory committee action, a public hearing, or submittal of the standard to the legislature and governor in order to become effective.

(c)   The Department shall notify the Commission when the updates are made and the effective date of the updated utilization weights.

(d)   The updated open heart utilization weights established pursuant to this subsection shall supercede the weights shown in Appendix A and shall be included as an amended appendix to these standards.

(4)   Each applicant shall provide access to verifiable hospital-specific data and documentation using a format established by the Department and a mutually agreed upon media.

Section 9. Methodology for computing the number of pediatric open heart surgical cases

Sec. 9. (1) The weights for the pediatric diagnosis table found in Appendix B are calculated using the following methodology. Only the MIDB data from licensed hospitals in Michigan will be used.

(a)   Using a hospital's actual inpatient discharge data, as specified by the most recent MIDB data available to the Department, an applicant shall count the discharges that were from patients of any age that have a diagnosis (any mention) of the ICD-9-CM codes listed in the "Congenital Anomalies" category in Appendix B. Each identified record shall be counted only once so that no record is counted twice. An applicant shall remove these cases from subsequent analyses.

(b)   For those discharges identified in subsection 9(1)(a), any occurrence of an open heart procedure code will be counted as a single open heart surgery case.

(c)   The number of open heart surgery cases for the "Congenital Anomalies" category will be divided by the number of discharges identified in subsection 9(1)(a). This will be the weight for the "Congenital Anomalies" diagnostic group. This number should show six decimal positions.

(d)   Using a hospital's remaining inpatient discharges, an applicant shall identify the discharges that were from patients aged 14 years and younger. These discharges shall be known as the "pediatric discharges."

(e)   Using the "pediatric discharges" identified in subdivision (d), an applicant shall count the number of discharges that have a diagnosis (any mention) of the ICD-9-CM codes listed in the "All Other Heart Conditions" category in Appendix B. Discharge records which do not have one or more of the "All Other Heart Conditions" codes listed in Appendix B shall not be used. Each identified record shall be counted only once so that no record is counted twice.

(f)   For those discharges identified in subsection 9(1)(e), any occurrence of an open heart procedure code will be counted as a single open heart surgery case.

(g)   The number of open heart surgery cases for the "All Other Heart Conditions" category will be divided by the number of discharges identified in subsection 9(1)(e). This will be the weight for the "All Other Heart Conditions" diagnostic group. This number should show six decimal positions.

(2)   An applicant shall apply the methodology set forth in this section for computing the projected number of pediatric open heart surgical cases. In applying discharge data in the methodology, each applicable inpatient record is used only once. This methodology shall utilize only those inpatient discharges that have one or more of the cardiac diagnoses listed in Appendix B. In applying this methodology, the following steps shall be taken in sequence:

(a)   Using a hospital's actual inpatient discharge data, as specified by the most recent MIDB data available to the Department, an applicant shall count the discharges that were from patients of any age that have a principal diagnosis or any of the first four non-principal diagnoses of the ICD-9-CM codes listed in the "Congenital Anomalies" category in Appendix B. Each identified record shall be counted only once so that no record is counted twice. An applicant shall remove these cases from the discharge data.

(b)   Using a hospital's remaining inpatient discharges, an applicant shall identify the discharges that were from patients aged 14 years and younger. These discharges shall be known as the "pediatric discharges."

(c)   Using the "pediatric discharges" identified in Subdivision (b), an applicant shall count the number of discharges with a principal diagnosis or any of the first four non-principal diagnoses of the ICD-9-CM codes listed in the "All Other Heart Conditions" category in Appendix B. Discharge records which do not have one or more of the "All Other Heart Conditions" codes listed in Appendix B shall not be used. Each identified record shall be counted only once so that no record is counted twice.

(d)   An applicant shall multiply the count for the "Congenital" and "All Other Heart Conditions" categories by the corresponding Pediatric Open Heart Utilization Weight and add the products together to produce the number of pediatric open heart surgical cases for the applicant.

(3)   The major ICD-9-CM groupings and Pediatric Open Heart Utilization Weights in Appendix B are based on the work of the Bureau of Health Policy, Planning and Access, Michigan Department of Community Health, utilizing the most current MIDB data available to the Department.

(a)   The Department shall update the open heart utilization weights every 3 years, beginning with the year 2007, according to the methodology described in subsection (1) above, utilizing the most current MIDB data available to the Department.

(b)   Updates to the utilization weights made pursuant to this subsection shall not require standard advisory committee action, a public hearing, or submittal of the standard to the legislature and governor in order to become effective.

(c)   The Department shall notify the Commission when the updates are made and the effective date of the updated utilization weights.

(d)   The updated open heart utilization weights established pursuant to this subsection shall supercede the weights shown in Appendix B and shall be included as an amended appendix to these standards.

(4)   Each applicant must provide access to verifiable hospital-specific data and documentation using a format established by the Department and in a mutually agreed upon media.

Section 10. Planning Areas

Sec. 10. Counties assigned to each planning area are as follows:

PLANNING AREA	COUNTIES		
1	LIVINGSTON MACOMB WAYNE	MONROE OAKLAND	ST. CLAIR WASHTENAW
2	CLINTON EATON	HILLSDALE INGHAM	JACKSON LENAWEE
3	BARRY BERRIEN BRANCH	CALHOUN CASS KALAMAZOO	ST. JOSEPH VAN BUREN
4	ALLEGAN IONIA KENT LAKE	MASON MECOSTA MONTCALM MUSKEGON	NEWAYGO OCEANA OSCEOLA OTTAWA
5	GENESEE	LAPEER	SHIAWASSEE

6	ARENAC	HURON	ROSCOMMON
	BAY	IOSCO	SAGINAW
	CLARE	ISABELLA	SANILAC
	GLADWIN	MIDLAND	TUSCOLA
	GRATIOT	OGEMAW	
7	ALCONA	CRAWFORD	MISSAUKEE
	ALPENA	EMMET	MONTMORENCY
	ANTRIM	GD TRAVERSE	OSCODA
	BENZIE	KALKASKA	OTSEGO
	CHARLEVOIX	LEELANAU	PRESQUE ISLE
	CHEBOYGAN	MANISTEE	WEXFORD
8	ALGER	GOGEBIC	MACKINAC
	BARAGA	HOUGHTON	MARQUETTE
	CHIPPEWA	IRON	MENOMINEE
	DELTA	KEWEENAW	ONTONAGON
	DICKINSON	LUCE	SCHOOLCRAFT

Section 11. Effect on prior planning policies; comparative reviews

Sec. 11. (1) These CON Review Standards supersede and replace the CON Review Standards for Open Heart Surgery Services approved by the CON Commission on March 9, 2004 and effective on June 4, 2004.

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

DIAGNOSIS GROUPINGS FOR ADULT OPEN HEART SURGICAL CASES
PRINCIPAL DIAGNOSIS

GROUP	MAJOR ICD-9-CM CODE GROUP	CATEGORY	ADULT OPEN HEART UTILIZATION WEIGHTS
A	394 – 397.9 421 – 421.9 424 – 424.99	Valves	.755521
B	441.01, 441.03 441.1, 441.2 441.6, 441.7	Aortic Aneurysm	.474638
C	745 – 747.99	Congenital Anomalies	.304878
D	414 – 414.99	Other Chronic Ischemic	.175495
E	410 – 410.99	Acute Myocardial Infarct	.119218
F	212.7 398 – 398.99 411 – 411.99 423 – 423.9 425 – 425.9 427 – 427.9 428 – 428.9 901 – 901.9 996.02, 996.03	All Other Heart Conditions	.013789

NON-PRINCIPAL DIAGNOSES

GROUP	MAJOR ICD-9-CM CODE GROUP	CATEGORY	ADULT OPEN HEART UTILIZATION WEIGHTS
A	745 – 747.99	Congenital Anomalies	.021698
B	441.01, 441.03 441.1, 441.2 441.6, 441.7	Aortic Aneurysm	.020900
C	410 – 410.99	Acute Myocardial Infarct	.014470
D	394 – 397.9 421 – 421.9 424 – 424.99	Valves	.008064
E	414 – 414.99	Other Chronic Ischemic	.001879

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F	212.7	All Other Heart Conditions	.001190
	398 – 398.99		
	411 – 411.99		
	423 – 423.9		
	425 – 425.9		
	427 – 427.9		
	428 – 428.9		
	901 – 901.9		
	996.02, 996.03		

Source: Calculated based on the 2005 Michigan Inpatient Data Base

DIAGNOSIS GROUPINGS FOR PEDIATRIC OPEN HEART SURGICAL CASES

MAJOR ICD-9-CM CODE GROUP	CATEGORY	PEDIATRIC OPEN HEART UTILIZATION WEIGHTS
745.0 – 747.99	Congenital Anomalies	.174027
164.1, 212.7 390 – 429.99 441.01, 441.03 441.1, 441.2 441.6, 441.7 785.51 786.5-786.59 901.0 – 901.9 996.02	All Other Heart Conditions	.018182

Source: Calculated based on the 2005 Michigan Inpatient Data Base