

1 | **MICHIGAN DEPARTMENT OF COMMUNITY HEALTH**

2 | **CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR**
3 | **OPEN HEART SURGERY SERVICES**

4 | (By the authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts
5 | of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being
6 | sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)

7 | **Section 1. Applicability**

8 | Sec. 1. (1) These standards are requirements for approval and delivery of services for all projects
9 | approved and certificates of need issued under Part 222 of the Code which involve open heart surgery
10 | services.

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

12 | (3) The Department shall use sections 3, 4, 5, 6, 8, and 9, as applicable, in applying Section
13 | 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

14 | (4) The Department shall use Section 7 in applying Section 22225(2)(c) of the Code, being Section
15 | 333.22225(2)(c) of the Michigan Compiled Laws.

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

18 | **Section 2. Definitions**

19 | Sec. 2. (1) FOR PURPOSES OF A~~s used in~~ these standards:

20 | (a) "Adult open heart surgery" means open heart surgery offered and provided to individuals age 15
21 | and older AS DEFINED IN SUBSECTION (I).

22 | (b) "Cardiac surgical team" means the designated specialists and support personnel who
23 | consistently work together in the performance of open heart surgery.

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

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

28 | (e) "Department" means the Michigan Department Of Community Health (MDCH).

29 | (f) "ICD-9-CM code" means the disease codes and nomenclature found in the International
30 | Classification of Diseases - 9th Revision - Clinical Modification, prepared by the Commission on
31 | Professional and Hospital Activities for the U.S. National Center for Health Statistics.

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

34 | (h) "Michigan inpatient data base" or "MIDB" means the data base compiled by the Michigan Health
35 | and Hospital Association or successor organization. The data base consists of inpatient discharge
36 | records from all Michigan hospitals and Michigan residents discharged from hospitals in border states for
37 | a specific calendar year.

38 | (i) "Open heart surgery" means any cardiac surgical procedure involving the heart and/or thoracic
39 | great vessels (excluding organ transplantation) that is intended to correct congenital and acquired cardiac
40 | and coronary artery disease and/or great vessels and often uses a heart-lung pump (pumps and
41 | oxygenates the blood) or its equivalent to perform the functions of circulation during surgery. These
42 | procedures may be performed off-pump (beating heart), although a heart-lung pump is still available
43 | during the procedure.

55 | (J) "OPEN HEART SURGICAL CASE" MEANS A SINGLE VISIT TO AN OPERATING ROOM
56 | DURING WHICH ONE OR MORE OPEN HEART SURGERY PROCEDURES ARE PERFORMED.

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

60 | (L) "Pediatric open heart surgery" means open heart surgery offered and provided to infants and
61 | children age 14 and ~~YOUNGER~~below, and to other individuals with congenital heart disease as defined
62 | by the ICD-9-CM codes of 745.0 through 747.99.

63 | (M) "Planning area" means the groups of counties shown in Section 10.

64 |
65 | (2) The definitions in Part 222 shall apply to these standards.
66 |

67 | **Section 3. Requirements for ALL APPLICANTS PROPOSING TO INITIATE OPEN HEART**
68 | **SURGERY SERVICES**~~Approval -- all applicants~~

69 |
70 | Sec. 3. (1) An applicant proposing to initiate either adult or pediatric open heart surgery as a new
71 | service shall ~~BE OPERATING OR APPROVED TO OPERATE~~ ~~A have in place, or meet the CON review~~
72 | ~~standards for initiation of~~ diagnostic and therapeutic adult or pediatric cardiac catheterization services,
73 | respectively.
74 |

75 | (2) A hospital proposing to initiate open heart surgery as a new service shall have a written
76 | consulting agreement with a hospital which has an existing active open heart surgery service performing
77 | a minimum of ~~400350~~ open heart surgical ~~CASES~~procedures per year ~~FOR 3 CONSECUTIVE YEARS~~.
78 | The agreement must specify that the existing service shall, for the first 3 years of operation of the new
79 | service, provide the following services to the applicant hospital:

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

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

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

85 | (d) Work with the medical staff and governing body to design and implement a process that will ~~at~~
86 | ~~least~~ annually measure, evaluate, and report to the medical staff and governing body, the clinical
87 | outcomes of the new service, including: (i) Mortality rates, (ii) Complication rates, (iii) Success rates, and
88 | (iv) Infection rates.
89 |

90 | ~~(3) An applicant shall provide verification of Medicaid participation at the time the application is~~
91 | ~~submitted to the Department. If the required documentation is not submitted with the application on the~~
92 | ~~designated application date, the application will be deemed filed on the first applicable designated~~
93 | ~~application date after all required documentation is received by the Department.~~

94 |
95 | **Section 4. Requirements for approval -- all applicants for adult open heart surgery services**

96 |
97 | ~~Sec. 4. (3)~~ An applicant proposing to initiate adult (~~non-pediatric~~) open heart surgery as a new
98 | service shall demonstrate ~~that~~ 300 adult open heart surgical ~~CASES~~procedures ~~BASED ON~~ result from
99 | ~~application of~~ the methodology ~~SET FORTH~~described in Section 8.
100 |

101 | **Section 5. Requirements for approval -- all applicants for pediatric open heart surgery services**

102 |
103 | ~~Sec. 5. (4)~~ An applicant proposing to initiate pediatric open heart surgery as a new service shall
104 | demonstrate ~~that~~ 100 pediatric open heart surgical ~~CASES~~procedures ~~BASED ON~~ result from ~~application~~
105 | ~~of~~ the methodology ~~SET FORTH~~described in Section 9.
106 |

107 | **SECTION 4. REQUIREMENTS FOR APPROVAL FOR APPLICANTS PROPOSING TO ACQUIRE AN**
108 | **EXISTING OPEN HEART SURGERY SERVICE**

109
110 SEC. 4. AN APPLICANT PROPOSING TO ACQUIRE A HOSPITAL THAT HAS BEEN APPROVED
111 TO PERFORM OPEN HEART SURGERY SERVICES MAY ALSO ACQUIRE THE EXISTING OPEN
112 HEART SURGERY SERVICE IF IT CAN DEMONSTRATE THAT THE PROPOSED PROJECT MEETS
113 ALL OF THE FOLLOWING:

114
115 (1) AN APPLICATION FOR THE FIRST ACQUISITION OF AN EXISTING OPEN HEART SURGERY
116 SERVICE AFTER THE EFFECTIVE DATE OF THESE STANDARDS SHALL NOT BE REQUIRED TO
117 BE IN COMPLIANCE WITH THE APPLICABLE VOLUME REQUIREMENTS ON THE DATE OF
118 ACQUISITION. THE OPEN HEART SURGERY SERVICE SHALL BE OPERATING AT THE
119 APPLICABLE VOLUME REQUIREMENTS SET FORTH IN SECTION 7 OF THESE STANDARDS IN
120 THE SECOND 12 MONTHS AFTER THE DATE THE SERVICE IS ACQUIRED, AND ANNUALLY
121 THEREAFTER.

122
123 (2) EXCEPT AS PROVIDED FOR IN SUBSECTION (1), AN APPLICATION FOR THE ACQUISITION
124 OF AN EXISTING OPEN HEART SURGERY SERVICE AFTER THE EFFECTIVE DATE OF THESE
125 STANDARDS SHALL BE REQUIRED TO BE IN COMPLIANCE WITH THE APPLICABLE VOLUME
126 REQUIREMENTS, AS SET FORTH IN THE PROJECT DELIVERY REQUIREMENTS, ON THE DATE AN
127 APPLICATION IS SUBMITTED TO THE DEPARTMENT.

128
129 (3) THE APPLICANT AGREES TO OPERATE THE OPEN HEART SURGERY SERVICE IN
130 ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN
131 SECTION 7 OF THESE STANDARDS.

132 133 **SECTION 5. REQUIREMENTS FOR ALL APPLICANTS**

134
135 SEC 5. AN APPLICANT SHALL PROVIDE VERIFICATION OF MEDICAID PARTICIPATION. AN
136 APPLICANT THAT IS A NEW PROVIDER NOT CURRENTLY ENROLLED IN MEDICAID SHALL
137 CERTIFY THAT PROOF OF MEDICAID PARTICIPATION WILL BE PROVIDED TO THE DEPARTMENT
138 WITHIN SIX (6) MONTHS FROM THE OFFERING OF SERVICES, IF A CON IS APPROVED.

139 140 **Section 6. Requirements for MIDB data commitments**

141
142 Sec. 6. In order to use MIDB data in support of an application for either adult or pediatric open heart
143 surgery services, an applicant shall demonstrate or agree, as applicable, to all of the following:

144
145 (1) A hospital(s) whose adult MIDB data is used in support of a CON application for adult open heart
146 surgery services shall not use any of its adult MIDB data in support of any other application for adult open
147 heart surgery services prior to 7 years after the initiation of the open heart surgery service for which MIDB
148 data were used to support. -AFTER THE 7-YEAR PERIOD:

149 (A) A HOSPITAL(S) MAY ONLY COMMIT ITS ADULT MIDB DATA IN SUPPORT OF ANOTHER
150 APPLICATION FOR ADULT OPEN HEART SURGERY SERVICES IF THEY HAVE EXPERIENCED AN
151 INCREASE FROM THE PREVIOUSLY COMMITTED MIDB DATA. ONLY THAT ADDITIONAL
152 INCREASE IN MIDB DATA CAN BE COMMITTED TO ANOTHER APPLICANT TO INITIATE OPEN
153 HEART SURGERY SERVICES, OR;

154 (B) A HOSPITAL THAT HAS EXPERIENCED AN INCREASE IN ITS ADULT MIDB DATA AND
155 WANTS TO START ITS OWN PROGRAM, THEN THE HOSPITAL MAY USE ONLY ITS ENTIRE
156 PROJECTED VOLUME (PREVIOUSLY COMMITTED MIDB DATA PLUS THE INCREASE OF ADULT
157 MIDB DATA) TO SUPPORT ITS OWN APPLICATION TO INITIATE AN OPEN HEART SURGERY
158 SERVICE.

159
160 (2) A hospital(s) whose pediatric MIDB data is used in support of a CON application for pediatric
161 open heart surgery services shall not use any of its pediatric MIDB data in support of any other

162 application for pediatric open heart surgery services prior to 7 years after the initiation of the open heart
163 surgery service for which MIDB data were used to support. AFTER THE 7-YEAR PERIOD:

164 (A) A HOSPITAL(S) MAY ONLY COMMIT ITS PEDIATRIC MIDB DATA IN SUPPORT OF
165 ANOTHER APPLICATION FOR PEDIATRIC OPEN HEART SURGERY SERVICES IF THEY HAVE
166 EXPERIENCED AN INCREASE FROM THE PREVIOUSLY COMMITTED MIDB DATA. ONLY THAT
167 ADDITIONAL INCREASE IN MIDB DATA CAN BE COMMITTED TO ANOTHER APPLICANT TO
168 INITIATE OPEN HEART SURGERY SERVICES, OR;

169 (B) A HOSPITAL THAT HAS EXPERIENCED AN INCREASE IN ITS PEDIATRIC MIDB DATA AND
170 WANTS TO START ITS OWN PROGRAM, THEN THE HOSPITAL MAY USE ONLY ITS ENTIRE
171 PROJECTED VOLUME (PREVIOUSLY COMMITTED MIDB DATA PLUS THE INCREASE OF
172 PEDIATRIC MIDB DATA) TO SUPPORT ITS OWN APPLICATION TO INITIATE AN OPEN HEART
173 SURGERY SERVICE.

174
175 (3) The hospital(s) committing MIDB data does not currently operate an adult or pediatric open heart
176 surgery service or have a valid CON issued under ~~former Part 221 or~~ Part 222 to operate an adult or
177 pediatric open heart surgery service.

178
179 (4) The hospital(s) committing MIDB data is located in the same planning area as the hospital to
180 which MIDB data is being proposed to be committed.

181
182 (5) The hospital(s) committing MIDB data to a CON application has completed the departmental
183 form(s) which (i) authorizes the Department to verify the MIDB data, (ii) agrees to pay all charges
184 associated with verifying the MIDB data, and (iii) acknowledges and agrees that the commitment of the
185 MIDB data is for the period of time specified in subsection (1) or (2), as applicable.

186
187 (6) The hospital(s) committing MIDB data to an application is regularly admitting patients as of the
188 date the Director makes the final decision on that application, under Section 22231~~(9)~~ of the Code, being
189 Section 333.22231~~(9)~~ of the Michigan Compiled Laws.

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

192
193 Sec. 7. (1) An applicant shall agree that if approved, the services shall be delivered in compliance
194 with the following terms of CON approval:

195 (a) Compliance with these standards.

196 (b) Compliance with applicable operating standards.

197 (c) Compliance with the following quality assurance standards:

198 (i) The open heart surgery service shall be operating at an annual level of 300 adult open heart
199 surgical CASESprocedures or 100 pediatric open heart surgical CASESprocedures, as applicable, by the
200 end of the third 12 full months of operation, AND ANNUALLY THEREAFTER.

201 (ii) Each physician credentialed by the applicant hospital to perform adult open heart surgery
202 CASESprocedures, as the attending surgeon, shall perform a minimum of 7550 adult open heart surgery
203 CASESprocedures per year. The annual case load for a physician means adult open heart surgery
204 CASESprocedures performed by that physician, as the attending surgeon, in any hospital or combination
205 of hospitals.

206 (iii) The service shall be staffed with sufficient medical, nursing, technical and other personnel to
207 permit regular scheduled hours of operation and continuous 24 hour on-call availability.

208 (iv) The service shall have the capability for rapid mobilization of a cardiac surgical team for
209 emergency CASESprocedures 24 hours a day, 7 days a week.

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

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

213 (i) provide open heart surgery services to all individuals based on the clinical indications of need for
214 the service and not on ability to pay or source of payment; and

215 (ii) maintain information by source of payment to indicate the volume of care from each source
216 provided annually.

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

218 (e) The applicant shall prepare and present to the medical staff and governing body reports
219 describing activities in the open heart surgery service including complication rates and other morbidity
220 and mortality data.

221 (f) The applicant shall participate in a data collection network established and administered by the
222 Department or its designee. The data may include but is not limited to annual budget and cost
223 information, operating schedules, and demographic, diagnostic, morbidity and mortality information, as
224 well as the volume of care provided to patients from all payor sources. The applicant shall provide the
225 required data in a format established by the Department and in a mutually agreed upon media. The
226 Department may elect to verify the data through on-site review of appropriate records.

227 (G) THE APPLICANT SHALL PARTICIPATE IN A DATA REGISTRY ADMINISTERED BY THE
228 DEPARTMENT OR ITS DESIGNEE THAT MONITORS QUALITY AND RISK ADJUSTED OUTCOMES.
229 THE DEPARTMENT OR ITS DESIGNEE SHALL REQUIRE THAT THE APPLICANT SUBMIT A
230 SUMMARY REPORT AS SPECIFIED BY THE DEPARTMENT. THE APPLICANT SHALL PROVIDE
231 THE REQUIRED DATA IN A FORMAT ESTABLISHED BY THE DEPARTMENT OR ITS DESIGNEE.
232 THE APPLICANT SHALL BE LIABLE FOR THE COST OF DATA SUBMISSION AND ON-SITE
233 REVIEWS IN ORDER FOR THE DEPARTMENT TO VERIFY AND MONITOR VOLUMES AND ASSURE
234 QUALITY. THE APPLICANT SHALL BECOME A MEMBER OF THE DATA REGISTRY SPECIFIED BY
235 THE DEPARTMENT UPON INITIATION OF THE SERVICE. PARTICIPATION SHALL CONTINUE
236 ANNUALLY THEREAFTER. THE OUTCOMES DATABASE MUST UNDERGO STATEWIDE AUDITING.

237 (H) AN APPLICANT THAT FAILS TO COMPLY WITH THE QUALITY ASSURANCE STANDARDS
238 UNDER SUBSECTION (C) SHALL BE REQUIRED TO PROVIDE ITS QUALITY AND RISK ADJUSTED
239 OUTCOMES DATA FROM THE DATA REGISTRY TO THE DEPARTMENT, OR ITS DESIGNEE, AS
240 PART OF THE DEPARTMENT'S ENFORCEMENT AND COMPLIANCE ACTIVITIES.

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

244
245 (2) The agreements and assurances required by this section shall be in the form of a certification
246 AGREED TO BY THE APPLICANT OR ITS AUTHORIZED AGENT~~authorized by the governing body of~~
247 ~~the applicant.~~

248
249 **Section 8. Methodology for computing the number of adult open heart surgical CASESprocedures**

250
251 Sec. 8. (1) THE WEIGHTS FOR THE ADULT PRINCIPAL AND NON-PRINCIPAL DIAGNOSES
252 TABLES FOUND IN APPENDIX A ARE CALCULATED USING THE FOLLOWING METHODOLOGY.
253 FOR THESE TWO TABLES, ONLY THE MIDB DATA FROM LICENSED HOSPITALS THAT HAVE
254 OPERATIONAL OPEN HEART SURGERY PROGRAMS IN MICHIGAN WILL BE USED. USING A
255 HOSPITAL'S ACTUAL INPATIENT DISCHARGE DATA, AS SPECIFIED BY THE MOST RECENT MIDB
256 DATA AVAILABLE TO THE DEPARTMENT, AN APPLICANT SHALL IDENTIFY THE DISCHARGES
257 THAT WERE FROM PATIENTS AGED 15 YEARS AND OLDER. THESE DISCHARGES SHALL BE
258 KNOWN AS THE "ADULT DISCHARGES."

259 (A) TO CALCULATE THE WEIGHTS FOR THE PRINCIPAL DIAGNOSIS, THE FOLLOWING
260 STEPS SHALL BE TAKEN:

261 (I) FOR EACH DIAGNOSTIC GROUP IN THE PRINCIPAL WEIGHT TABLE, THE NUMBER OF
262 DISCHARGES IS COUNTED.

263 (II) FOR THE DISCHARGES IDENTIFIED IN SUBSECTION 8(1)(A)(I), ANY OCCURANCE OF AN
264 OPEN HEART PROCEDURE CODE WILL BE COUNTED AS A SINGLE OPEN HEART SURGERY
265 CASE.

266 (III) THE NUMBER OF OPEN HEART SURGERY CASES FOR EACH DIAGNOSIS CATEGORY
267 WILL BE DIVIDED BY THE NUMBER OF DISCHARGES IDENTIFIED IN SUBSECTION 8(1)(A)(I). THIS

268 WILL BE THE WEIGHT FOR THAT DIAGNOSTIC GROUP. THIS NUMBER SHOULD SHOW SIX
269 DECIMAL POSITIONS.

270 (IV) ALL DISCHARGES UTILIZED FOR THE COMPUTATION OF THE PRINCIPAL WEIGHT TABLE
271 ARE TO BE REMOVED FROM SUBSEQUENT ANALYSES.

272 (B) TO CALCULATE THE WEIGHTS FOR THE NON-PRINCIPAL DIAGNOSIS TABLE, THE
273 FOLLOWING STEPS SHALL BE TAKEN, SEPARATELY, IN THE SEQUENCE SHOWN, AND EACH
274 REMAINING DISCHARGE WILL BE EXAMINED FOR ANY MENTION OF THE DIAGNOSTIC CODES
275 FROM THAT GROUP. IF A MATCH IS FOUND, THAT DISCHARGE IS ASSIGNED TO THAT
276 DIAGNOSTIC GROUP AND REMOVED FROM SUBSEQUENT ANALYSES:

277 (I) FOR EACH DIAGNOSTIC GROUP TAKEN SEPARATELY, IN THE SEQUENCE SHOWN, ANY
278 OCCURANCE OF AN OPEN HEART PROCEDURE CODE FOR EACH DISCHARGE WILL BE
279 COUNTED AS A SINGLE OPEN HEART SURGERY CASE. IF A MATCH IS FOUND, THE DISCHARGE
280 WILL BE COUNTED AS AN OPEN HEART SURGICAL CASE FOR THAT DIAGNOSTIC GROUP AND
281 REMOVED FROM SUBSEQUENT ANALYSES.

282 (II) THE NUMBER OF OPEN HEART SURGERY CASES FOR EACH NON-PRINCIPAL
283 DIAGNOSIS CATEGORY IDENTIFIED IN SUBSECTION 8(1)(B)(I) WILL BE DIVIDED BY THE NUMBER
284 OF DISCHARGES IDENTIFIED IN SUBSECTION 8(1)(B). THIS WILL RESULT IN THE NON-
285 PRINCIPAL WEIGHT FOR THAT DIAGNOSTIC GROUP. THIS NUMBER SHOULD SHOW SIX
286 DECIMAL POSITIONS.

287
288 (2) An applicant shall apply the methodology set forth in this section for computing the PROJECTED
289 number of adult open heart surgical CASES procedures USING BOTH THE PRINCIPAL AND NON-
290 PRINCIPAL DIAGNOSIS TABLES. In applying discharge data in the methodology, each applicable
291 inpatient record shall be used only once. This methodology shall utilize only the inpatient discharges that
292 have one or more of the cardiac diagnoses in Subsection (2). In applying this methodology, tThe
293 following steps shall be taken in sequence:

294 (a) FOR EACH DIAGNOSTIC GROUP IN THE PRINCIPAL WEIGHT TABLE IN APPENDIX A,
295 IDENTIFY THE CORRESPONDING NUMBER OF DISCHARGES. Using a hospital's actual inpatient
296 discharge data, as specified by the most recent Michigan Inpatient Data Base available to the
297 Department, an applicant shall identify the discharges that were from patients aged 15 years and older.
298 These discharges shall be considered "adult discharges."

299 (B) MULTIPLY THE NUMBER OF DISCHARGES FOR EACH DIAGNOSTIC GROUP BY THEIR
300 RESPECTIVE GROUP WEIGHT TO OBTAIN THE PROJECTED NUMBER OF OPEN HEART
301 SURGERY CASES FOR THAT GROUP. ALL DISCHARGES IDENTIFIED IN SUBSECTION 8(2)(A)
302 ARE REMOVED FROM SUBSEQUENT ANALYSIS.

303 (Cb) THE NON-PRINCIPAL WEIGHT TABLE IDENTIFIES THE SEQUENCE THAT MUST BE
304 FOLLOWED TO COUNT THE DISCHARGES FOR THE APPROPRIATE GROUP. AN APPLICANT
305 SHALL START WITH THE FIRST DIAGNOSTIC GROUP AND Using the "adult discharges" identified in
306 Subdivision (a), an applicant shall count the number of discharges with ANY MENTION OF a NON-
307 principal diagnosis corresponding to THAT SPECIFIC DIAGNOSTIC GROUP, each of the first six
308 categories (Groups A through F) of ICD-9-CM codes listed in Subsection (2). When a DISCHARGE
309 THAT BELONGS IN THE SPECIFIC patient has a NON-principal diagnosis IS IDENTIFIED,
310 IT IS ASSIGNED TO THAT GROUP. THIS DISCHARGE IS THEN which falls into one of these six groups
311 (exclude Other Heart Conditions), then they shall be categorized by that diagnosis and their case shall be
312 removed from the data BEFORE COUNTING DISCHARGES FOR THE NEXT DIAGNOSTIC GROUP, to
313 be used in Subdivisions (c), (d) and (e) so that each applicable inpatient record shall be counted only
314 once. THE DISCHARGES COUNTED FOR EACH GROUP WILL BE USED ONLY WITH THE NON-
315 PRINCIPAL DIAGNOSIS WEIGHT TABLE IN APPENDIX A AND WILL BE ENTERED INTO ITS
316 RESPECTIVE DIAGNOSTIC GROUP. MULTIPLY THE NUMBER OF DISCHARGES FOR EACH
317 DIAGNOSTIC GROUP BY THEIR RESPECTIVE GROUP WEIGHT TO OBTAIN THE PROJECTED
318 NUMBER OF OPEN HEART SURGERY CASES FOR THAT GROUP.

319 (D) THE TOTAL NUMBER OF PROJECTED OPEN HEART CASES IS THEN CALCULATED BY
320 SUMMING THE PROJECTED NUMBER OF OPEN HEART CASES FROM BOTH PRINCIPAL AND
321 NON-PRINCIPAL WEIGHT TABLES.

(c) The procedure in this subdivision shall be used to determine in which diagnosis group each appropriate inpatient record is to be included. The first four non-principal diagnosis codes shall be used to determine the categorization of the remaining records. The sequence of the ICD-9-CM groupings in Subsection (2) shall be followed exactly. For each individual inpatient record, an applicant shall start with the first category of Valves (Group A: ICD-9-CM codes 394.0-397.99 and 424.0-424.99) and shall search through the first four non-principal diagnosis codes to determine if any fall into this grouping. If a record has a non-principal diagnosis code for this grouping, it shall be assigned to the Valve group and shall be removed from all subsequent search actions. The remaining inpatient records shall then be searched for the presence of the Valve codes. After all the inpatient records with Valve codes have been removed, the above procedure shall be repeated for each of the remaining five groups (Groups B through F) in sequence. For example: the next step would be a search of remaining inpatient records for codes representing the Congenital Anomalies (Group B: ICD-9-CM codes 745.0-747.99). NOTE: The above procedure shall not apply to the All Other Heart Conditions category (Group G).

(d) Add the count of the number of records for each principal diagnosis group (separately) that was identified under Subdivision (b) with the count of the number of records for its respective non-principal diagnosis group identified under Subdivision (c). The end result shall be a total count for each of the first six diagnostic groups (excluding All Other Heart Conditions - Group G).

(e) Using the remaining discharge data, an applicant shall count the discharges that were from patients that have a principal diagnosis or any of the first four non-principal diagnoses using the ICD-9-CM codes for the All Other Heart Conditions category (Group G) listed in Subsection (2).

(f) An applicant shall multiply the count for each ICD-9-CM category listed in Subsection (2) by its corresponding Adult Open Heart Utilization Weight and add the products together to produce the number of adult open heart surgical procedures for the applicant.

(2) For purposes of the adult open heart methodology, the following cardiac diagnoses shall be used:

DIAGNOSIS GROUPINGS FOR ADULT OPEN HEART SURGICAL PROCEDURES

<u>Group</u>	<u>Major ICD-9-CM Code Group</u>	<u>Category</u>	<u>Adult Open Heart Utilization Weights</u>
A	394 - 397.9 424 - 424.99	Valves	.0808
B	745 - 747.99	Congenital Anomalies	.0766
C	414 - 414.99	Other Chronic Ischemic	.0632
D	411 - 411.99	Other Acute & Sub Acute Ischemic	.0510
E	410 - 410.99	Acute Myocardial Infarct	.0400
F	413 - 413.99 786.5 - 786.59	Angina & Chest Pain	.0102
G	390 - 393 398 - 405.99 412, 415 - 423.9 425 - 429.99	All Other Heart Conditions	.0029

(3) The major ICD-9-CM groupings and Open Heart utilization weights in APPENDIX A Subsection (2) are based on the work of the BUREAU OF HEALTH POLICY, PLANNING AND ACCESS former

376 Division of Planning and Policy Development, Michigan Department of COMMUNITYPublic Health,
377 utilizing the 2005-1986 Michigan Inpatient Data Base.

378 (A) THE DEPARTMENT SHALL RECALCULATE THE OPEN HEART UTILIZATION WEIGHTS ON
379 AN ANNUAL BASIS UTILIZING THE MOST CURRENT MIDB DATA AVAILABLE TO THE
380 DEPARTMENT.

381 (B) MODIFICATIONS MADE BY THE DEPARTMENT PURSUANT TO THIS SUBSECTION SHALL
382 NOT REQUIRE STANDARD ADVISORY COMMITTEE ACTION, A PUBLIC HEARING, OR SUBMITTAL
383 OF THE STANDARD TO THE LEGISLATURE AND GOVERNOR IN ORDER TO BECOME EFFECTIVE.

384 (C) THE DEPARTMENT SHALL NOTIFY THE COMMISSION WHEN THIS MODIFICATION IS
385 MADE AND THE EFFECTIVE DATE OF THE MODIFICATION.

386 (D) THE NEW OPEN HEART UTILIZATION WEIGHTS ESTABLISHED PURSUANT TO THIS
387 SUBSECTION SHALL SUPERCEDE THE WEIGHTS SHOWN IN APPENDIX A AND SHALL BE
388 INCLUDED AS AN AMENDED APPENDIX TO THESE STANDARDS.

389
390 (4) Each applicant shall provide access to verifiable hospital-specific data and documentation using a
391 format established by the Department and a mutually agreed upon media.

392
393 **Section 9. Methodology for computing the number of pediatric open heart surgical**
394 **CASESprocedures**

395
396 Sec. 9. (1) THE WEIGHTS FOR THE PEDIATRIC DIAGNOSIS TABLE FOUND IN APPENDIX B
397 ARE CALCULATED USING THE FOLLOWING METHODOLOGY. ONLY THE MIDB DATA FROM
398 LICENSED HOSPITALS IN MICHIGAN WILL BE USED.

399 (A) USING A HOSPITAL'S ACTUAL INPATIENT DISCHARGE DATA, AS SPECIFIED BY THE
400 MOST RECENT MIDB DATA AVAILABLE TO THE DEPARTMENT, AN APPLICANT SHALL COUNT
401 THE DISCHARGES THAT WERE FROM PATIENTS OF ANY AGE THAT HAVE A DIAGNOSIS (ANY
402 MENTION) OF THE ICD-9-CM CODES LISTED IN THE "CONGENITAL ANOMALIES" CATEGORY IN
403 APPENDIX B. EACH IDENTIFIED RECORD SHALL BE COUNTED ONLY ONCE SO THAT NO
404 RECORD IS COUNTED TWICE. AN APPLICANT SHALL REMOVE THESE CASES FROM
405 SUBSEQUENT ANALYSES.

406 (B) FOR THOSE DISCHARGES IDENTIFIED IN SUBSECTION 9(1)(A), ANY OCCURANCE OF AN
407 OPEN HEART PROCEDURE CODE WILL BE COUNTED AS A SINGLE OPEN HEART SURGERY
408 CASE.

409 (C) THE NUMBER OF OPEN HEART SURGERY CASES FOR THE "CONGENITAL ANOMALIES"
410 CATEGORY WILL BE DIVIDED BY THE NUMBER OF DISCHARGES IDENTIFIED IN SUBSECTION
411 9(1)(A). THIS WILL BE THE WEIGHT FOR THE "CONGENITAL ANOMALIES" DIAGNOSTIC GROUP.
412 THIS NUMBER SHOULD SHOW SIX DECIMAL POSITIONS.

413 (D) USING A HOSPITAL'S REMAINING INPATIENT DISCHARGES, AN APPLICANT SHALL
414 IDENTIFY THE DISCHARGES THAT WERE FROM PATIENTS AGED 14 YEARS AND YOUNGER.
415 THESE DISCHARGES SHALL BE KNOWN AS THE "PEDIATRIC DISCHARGES."

416 (E) USING THE "PEDIATRIC DISCHARGES" IDENTIFIED IN SUBDIVISION (D), AN APPLICANT
417 SHALL COUNT THE NUMBER OF DISCHARGES THAT HAVE A DIAGNOSIS (ANY MENTION) OF
418 THE ICD-9-CM CODES LISTED IN THE "ALL OTHER HEART CONDITIONS" CATEGORY IN
419 APPENDIX B. DISCHARGE RECORDS WHICH DO NOT HAVE ONE OR MORE OF THE "ALL OTHER
420 HEART CONDITIONS" CODES LISTED IN APPENDIX B SHALL NOT BE USED. EACH IDENTIFIED
421 RECORD SHALL BE COUNTED ONLY ONCE SO THAT NO RECORD IS COUNTED TWICE.

422 (F) FOR THOSE DISCHARGES IDENTIFIED IN SUBSECTION 9(1)(E), ANY OCCURANCE OF AN
423 OPEN HEART PROCEDURE CODE WILL BE COUNTED AS A SINGLE OPEN HEART SURGERY
424 CASE.

425 (G) THE NUMBER OF OPEN HEART SURGERY CASES FOR THE "ALL OTHER HEART
426 CONDITIONS" CATEGORY WILL BE DIVIDED BY THE NUMBER OF DISCHARGES IDENTIFIED IN
427 SUBSECTION 9(1)(E). THIS WILL BE THE WEIGHT FOR THE "ALL OTHER HEART CONDITIONS"
428 DIAGNOSTIC GROUP. THIS NUMBER SHOULD SHOW SIX DECIMAL POSITIONS.

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

435 (a) Using a hospital's actual inpatient discharge data, as specified by the most recent MIDB Michigan
436 Inpatient Data Base DATA available to the Department, an applicant shall count the discharges that were
437 from patients of any age that have a principal diagnosis or any of the first four non-principal diagnoses of
438 the ICD-9-CM codes listed in the "Congenital Anomalies" category in APPENDIX B Subsection (2). Each
439 identified record shall be counted only once so that no record is counted twice. An applicant shall remove
440 these cases from the discharge data.

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

444 (c) Using the "pediatric discharges" identified in Subdivision (b), an applicant shall count the number
445 of discharges with a principal diagnosis or any of the first four non-principal diagnoses of the ICD-9-CM
446 codes listed in the "ALL Other Heart CONDITIONS" category in APPENDIX B Subsection (2). Discharge
447 records which do not have one or more of the "ALL Other Heart CONDITIONS" codes listed in
448 APPENDIX B Subsection (2) shall not be used. Each identified record shall be counted only once so that
449 no record is counted twice.

450 (d) An applicant shall multiply the count for the "Congenital" and "ALL Other Heart CONDITIONS"
451 categories by the corresponding Pediatric Open Heart Utilization Weight and add the products together to
452 produce the number of pediatric open heart surgical CASES procedures for the applicant.

453
454 ~~(2) For purposes of the pediatric open heart methodology, the following diagnoses shall be used:~~

455
456 ~~DIAGNOSIS GROUPINGS FOR PEDIATRIC OPEN HEART SURGICAL PROCEDURES~~

Major ICD-9-CM	Category	Pediatric Open Heart
Grouping	Category	Utilization Weights
745.0-747.99	Congenital Anomalies	.1286
390-429.99	Other Heart	.0147
786.5-786.59		

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467 (3) The major ICD-9-CM groupings and Pediatric Open Heart Utilization Weights IN APPENDIX B
468 are based on the work of the BUREAU OF HEALTH POLICY, PLANNING AND ACCESS former Division
469 of Planning and Policy Development, Michigan Department of COMMUNITY Public Health, utilizing the
470 2005-1986 Michigan Inpatient Data Base.

471 (A) THE DEPARTMENT SHALL RECALCULATE THE OPEN HEART UTILIZATION WEIGHTS ON
472 AN ANNUAL BASIS UTILIZING THE MOST CURRENT MIDB DATA AVAILABLE TO THE
473 DEPARTMENT.

474 (B) MODIFICATIONS MADE BY THE DEPARTMENT PURSUANT TO THIS SUBSECTION SHALL
475 NOT REQUIRE STANDARD ADVISORY COMMITTEE ACTION, A PUBLIC HEARING, OR SUBMITTAL
476 OF THE STANDARD TO THE LEGISLATURE AND GOVERNOR IN ORDER TO BECOME EFFECTIVE.

477 (C) THE DEPARTMENT SHALL NOTIFY THE COMMISSION WHEN THIS MODIFICATION IS
478 MADE AND THE EFFECTIVE DATE OF THE MODIFICATION.

479 (D) THE OPEN HEART UTILIZATION WEIGHTS ESTABLISHED PURSUANT TO THIS
480 SUBSECTION SHALL SUPERCEDE THE WEIGHTS SHOWN IN APPENDIX B AND SHALL BE
481 INCLUDED AS AN AMENDED APPENDIX TO THESE STANDARDS.

483 (4) Each applicant must provide access to verifiable hospital-specific data and documentation using
484 a format established by the Department and in a mutually agreed upon media.
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486 **Section 10. Planning Areas**
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488 Sec. 10. Counties assigned to each planning area are as follows:
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490	<u>PLANNING AREA</u>		<u>COUNTIES</u>	
491				
492	1	LIVINGSTON	MONROE	ST. CLAIR
493		MACOMB	OAKLAND	WASHTENAW
494		WAYNE		
495				
496	2	CLINTON	HILLSDALE	JACKSON
497		EATON	INGHAM	LENAWEE
498				
499	3	BARRY	CALHOUN	ST. JOSEPH
500		BERRIEN	CASS	VAN BUREN
501		BRANCH	KALAMAZOO	
502				
503	4	ALLEGAN	MASON	NEWAYGO
504		IONIA	MECOSTA	OCEANA
505		KENT	MONTCALM	OSCEOLA
506		LAKE	MUSKEGON	OTTAWA
507				
508	5	GENESEE	LAPEER	SHIAWASSEE
509				
510	6	ARENAC	HURON	ROSCOMMON
511		BAY	IOSCO	SAGINAW
512		CLARE	ISABELLA	SANILAC
513		GLADWIN	MIDLAND	TUSCOLA
514		GRATIOT	OGEMAW	

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517		7	ALCONA	CRAWFORD	MISSAUKEE
518			ALPENA	EMMET	MONTMORENCY
519			ANTRIM	GD TRAVERSE	OSCODA
520			BENZIE	KALKASKA	OTSEGO
521			CHARLEVOIX	LEELANAU	PRESQUE ISLE
522			CHEBOYGAN	MANISTEE	WEXFORD
523					
524		8	ALGER	GOGEBIC	MACKINAC
525			BARAGA	HOUGHTON	MARQUETTE
526			CHIPPEWA	IRON	MENOMINEE
527			DELTA	KEWEENAW	ONTONAGON
528			DICKINSON	LUCE	SCHOOLCRAFT
529					

Section 11. Application of Rule 325.9403

~~Sec. 11. (1) Pursuant to CON rule 325.9403, a CON for open heart surgery services approved under these standards or standards that became effective on December 5, 1988 shall expire 1 year from its effective date, unless the project is initiated. One 6-month extension may be granted by the Department if the applicant shows that substantial progress toward initiation of the approved open heart surgery service has been made and an obligation for capital expenditure, if any, will occur within the extended time period.~~

~~(2) For purposes of open heart surgery services, "initiated" means when the first open heart surgery procedure is performed.~~

Section 1142. Effect on prior planning policies; comparative reviews

Sec. 1142. (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~~March 11, 2003~~ and effective on JUNE 4, 2004~~May 12, 2003~~.

~~(2) Hospitals recognized by the Department pursuant to the prior State Medical Facilities Plan (SMFP) 1985-90 Planning Policies Pertaining to Cardiac Services as "Level II" cardiac service providers shall not be considered open heart surgery services providers as defined in Section 2. Those hospitals recognized by the Department as Level II providers under Part 221 may continue to provide Level II cardiac services consistent with the 1985-90 State Medical Facilities Plan.~~

~~(23) 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	VALVES	.755521
	421 – 421.9		
	424 – 424.99		
B	441.01, 441.03	AORTIC ANEURYSM	.474638
	441.1, 441.2		
	441.6, 441.7		
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	ALL OTHER HEART CONDITIONS	.013789
	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		

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	AORTIC ANEURYSM	.020900
	441.1, 441.2		
	441.6, 441.7		
C	410 – 410.99	ACUTE MYOCARDIAL INFARCT	.014470
D	394 – 397.9	VALVES	.008064
	421 – 421.9		
	424 – 424.99		
E	414 – 414.99	OTHER CHRONIC ISCHEMIC	.001879

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F	212.7	ALL OTHER HEART CONDITIONS	.001190
	<u>398 – 398.99</u>		
	<u>411 – 411.99</u>		
	<u>423 – 423.9</u>		
	<u>425 – 425.9</u>		
	<u>427 – 427.9</u>		
	<u>428 – 428.9</u>		
	<u>901 – 901.9</u>		
	<u>996.02, 996.03</u>		

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APPENDIX B

DIAGNOSIS GROUPINGS FOR PEDIATRIC OPEN HEART SURGICAL CASES

<u>MAJOR ICD-9-CM</u>		<u>PEDIATRIC OPEN HEART</u>
<u>CODE GROUP</u>	<u>CATEGORY</u>	<u>UTILIZATION WEIGHTS</u>
<u>745.0 – 747.99</u>	<u>CONGENITAL ANOMALIES</u>	<u>.174027</u>
<u>164.1, 212.7</u>	<u>ALL OTHER HEART CONDITIONS</u>	<u>.018182</u>
<u>390 – 429.99</u>		
<u>441.01, 441.03</u>		
<u>441.1, 441.2</u>		
<u>441.6, 441.7</u>		
<u>785.51</u>		
<u>786.5-786.59</u>		
<u>901.0 – 901.9</u>		
<u>996.02</u>		