

1 MICHIGAN DEPARTMENT OF COMMUNITY HEALTH  
2  
3 CERTIFICATE OF NEED (CON) REVIEW STANDARDS  
4 FOR CARDIAC CATHETERIZATION SERVICES  
5

6 (By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of  
7 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being  
8 sections 333.22215, 24.207 and 24.208 of the Michigan Compiled Laws.)  
9

10 **Section 1. Applicability**

11  
12 Sec. 1. (1) These standards are requirements for approval of the initiation, replacement, expansion,  
13 or acquisition of cardiac catheterization services, and the delivery of these services under Part 222 of the  
14 Code. Pursuant to Part 222 of the Code, cardiac catheterization services are a covered clinical service.  
15 The Department shall use these standards in applying Section 22225(1) of the Code, being Section  
16 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section  
17 333.22225(2)(c) of the Michigan Compiled Laws.  
18

19 **Section 2. Definitions**

20  
21 Sec. 2. (1) For purposes of these standards:

22 (a) "Cardiac catheterization laboratory" or "laboratory" means an individual radiological room  
23 equipped with a variety of x-ray machines and devices such as electronic image intensifiers, high speed  
24 film changers and digital subtraction units to assist in performing diagnostic or therapeutic cardiac  
25 catheterizations or electrophysiology studies.

26 (b) "Cardiac catheterization procedure" means any cardiac procedure, including diagnostic,  
27 therapeutic, and electrophysiology studies, performed on a patient during a single session in a laboratory.  
28 Cardiac catheterization is a medical diagnostic or therapeutic procedure during which a catheter is  
29 inserted into a vein or artery in a patient; subsequently the free end of the catheter is manipulated by a  
30 physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays  
31 and an electronic image intensifier are used as aides in placing the catheter tip in the desired position.  
32 When the catheter is in place, the physician is able to perform various diagnostic studies and/or  
33 therapeutic procedures in the heart. This term does not include "float catheters" that are performed at the  
34 bedside or in settings outside the laboratory or the implantation of cardiac permanent pacemakers and  
35 implantable cardioverter defibrillators (ICD) devices that are performed in an interventional radiology  
36 laboratory or operating room.

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

40 (d) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to  
41 Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

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

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

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

52 (h) "ELECTIVE PERCUTANEOUS CORONARY INTERVENTION (PCI)" MEANS A PCI  
53 PROCEDURE PERFORMED ON A NON-EMERGENT BASIS.

54 (i) "ELECTIVE PCI SERVICES WITHOUT ON-SITE OPEN HEART SURGERY (OHS)" MEANS  
55 PERFORMING PCI, PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA), AND  
56 CORONARY STENT IMPLANTATION ON AN ORGANIZED, REGULAR BASIS IN A HOSPITAL  
57 HAVING A DIAGNOSTIC CARDIAC CATHETERIZATION SERVICE AND A PRIMARY PCI SERVICE  
58 BUT NOT HAVING OHS ON-SITE AND ADHERING TO PATIENT SELECTION AS OUTLINED IN THE  
59 SCAI/ACC/AHA EXPERT CONSENSUS DOCUMENT: 2014 UPDATED ON PCI WITHOUT ON-SITE  
60 SURGICAL BACKUP AND PUBLISHED IN CIRCULATION 2014, 129:2610-2626 AND ITS UPDATE OR  
61 FURTHER GUIDELINE CHANGES.

62 (hj) "Electrophysiology study" means a study of the electrical conduction activity of the heart and  
63 characterization of atrial and ventricular arrhythmias obtained by means of a cardiac catheterization  
64 procedure. The term also includes the implantation of permanent pacemakers and ICD devices.

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

66 (lj) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C. 1396 to  
67 1396g and 1396i to 1396u.

68 (mk) "Pediatric cardiac catheterization service" means providing cardiac catheterization services on an  
69 organized, regular basis to infants and children ages 18 and below, except for electrophysiology studies  
70 that are offered and provided to infants and children ages 14 and below, and others with congenital heart  
71 disease as defined by the ICD-9-CM codes (See Appendix B for ICD-10-CM Codes) of 426.7 (anomalous  
72 atrioventricular excitation), 427.0 (cardiac dysrhythmias), and 745.0 through 747.99 (bulbus cordis  
73 anomalies and anomalies of cardiac septal closure, other congenital anomalies of heart, and other  
74 congenital anomalies of circulatory system).

75 (nl) "Primary percutaneous coronary intervention (PCI)" means a PCI performed on an acute  
76 myocardial infarction (AMI) patient with confirmed ST elevation or new left bundle branch block ON AN  
77 EMERGENT BASIS.

78 (o) "PRIMARY PCI SERVICE WITHOUT ON-SITE OHS" MEANS PERFORMING PRIMARY PCI  
79 ON AN EMERGENT BASIS IN A HOSPITAL HAVING A DIAGNOSTIC CARDIAC CATHETERIZATION  
80 SERVICE.

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

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

91  
92 (2) Terms defined in the Code have the same meanings when used in these standards.  
93

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

95  
96 Sec. 3. An applicant proposing to initiate cardiac catheterization services shall demonstrate the  
97 following, as applicable to the proposed project.  
98

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

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

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

111 (c) An applicant proposing to initiate a diagnostic cardiac catheterization service with two or more  
112 laboratories shall project a minimum of 1,000 procedure equivalents per laboratory that includes 300  
113 procedure equivalents in the category of diagnostic cardiac catheterization procedures based on data  
114 from the most recent 12-month period preceding the date the application was submitted to the  
115 Department.

116  
117 (2) An applicant proposing to initiate an adult therapeutic cardiac catheterization service shall  
118 demonstrate the following:

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

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

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

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

132  
133 (3) An applicant proposing to initiate a pediatric cardiac catheterization service shall demonstrate the  
134 following:

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

137 (b) The applicant has standardized BIPLANE equipment as defined in the most current American  
138 Academy of Pediatrics (AAP) AND AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION  
139 (ACCF)/SOCIETY FOR CARDIOVASCULAR ANGIOGRAPHY AND INTERVENTIONS (SCAI) guidelines  
140 for pediatric cardiovascular centers.

141 (c) The applicant has on-site PEDIATRIC AND NEONATAL ICU as outlined in the most current AAP  
142 AND ACCF/SCAI guidelines above.

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

146 (e) THE APPLICANT HAS ON-SITE PEDIATRIC EXTRACORPOREAL MEMBRANE  
147 OXYGENATION (ECMO) CAPABILITY AS OUTLINED IN THE MOST CURRENT ACCF/SCAI  
148 GUIDELINES.

149 (f) A PEDIATRIC CARDIAC CATHETERIZATION SERVICES SHALL HAVE A QUALITY  
150 ASSURANCE PLAN AS OUTLINED IN THE MOST CURRENT ACCF/SCAI GUIDELINES.

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

154  
155 **SECTION 4. REQUIREMENTS TO INITIATE PRIMARY OR ELECTIVE PCI SERVICES WITHOUT ON-**  
156 **SITE OHS SERVICES**

159 |  
160 | —(4)SEC. 4. An applicant proposing to initiate primary OR ELECTIVE PCI serviceS without on-site  
161 | open heart surgeryOHS services shall demonstrate the following:

162 |  
163 | (a1) The applicant operates an adult diagnostic cardiac catheterization service that has performed a  
164 | minimum of 500 procedure equivalents that includes 400 procedure equivalents in the category of cardiac  
165 | catheterization procedures during the most recent 12 months preceding the date the application was  
166 | submitted to the Department.

167 |  
168 | (b2) The applicant has at least two interventional cardiologists to perform the primary-PCI procedures  
169 | and each cardiologist has performed at least 75-50 PCI sessions annually as the primary operator during  
170 | the most recent 24-month period preceding the date the application was submitted to the Department.

171 |  
172 | (e3) The nursing and technical catheterization laboratory staff: are experienced in handling acutely ill  
173 | patients and comfortable with interventional equipment; have acquired experience in dedicated  
174 | interventional laboratories at an open heart surgeryOHS hospital; and participate in an un-interrupted 24-  
175 | hour, 365-day call schedule. Competency shall be documented annually.

176 |  
177 | (d4) The laboratory or laboratories are equipped with optimal imaging systems, resuscitative  
178 | equipment, and intra-aortic balloon pump (IABP) support, and stocked with a broad array of interventional  
179 | equipment.

180 |  
181 | (e5) The cardiac care unit nurses are adept in hemodynamic monitoring and IABP management.  
182 | Competency shall be documented annually.

183 |  
184 | (f6) A written agreement with an open heart surgeryOHS hospital that includes all of the following:

185 | (ia) Involvement in credentialing criteria and recommendations for physicians approved to perform  
186 | primary-PCI procedures.

187 | (ib) Provision for ongoing cross-training for professional and technical staff involved in the provision of  
188 | primary-PCI to ensure familiarity with interventional equipment. Competency shall be documented  
189 | annually.

190 | (iic) Provision for ongoing cross training for emergency department, catheterization laboratory, and  
191 | critical care unit staff to ensure experience in handling the high acuity status of primary-PCI patient  
192 | candidates. Competency shall be documented annually.

193 | (ivd) Regularly held joint cardiology/cardiac surgery conferences to include review of all primary-PCI  
194 | cases.

195 | (ve) Development and ongoing review of patient selection criteria for primary-PCI patients and  
196 | implementation of those criteria.

197 | (vif) A mechanism to provide for appropriate patient transfers between facilities and an agreed plan for  
198 | prompt care.

199 | (viig) Written protocols, signed by the applicant and the open heart surgeryOHS hospital, for the  
200 | immediate transfer, within 4-hour60 MINUTES TRAVEL TIME from the cardiac catheterization laboratory  
201 | to evaluation on site in the open heart surgeryOHS hospital, of patients requiring surgical evaluation  
202 | and/or intervention 365 days a year. IF THE APPLICANT MEETS THE REQUIREMENTS OF SUB-  
203 | SECTION (13)(c), THEN THE OHS HOSPITAL CAN BE MORE THAN 60 MINUTES TRAVEL TIME  
204 | FROM THE PROPOSED SITE. The protocols shall be reviewed and tested on a quarterly basis.

205 | (viih) Consultation on facilities, equipment, staffing, ancillary services, and policies and procedures for  
206 | the provision of interventional procedures.

207 |  
208 | (g7) A written protocol must be established and maintained for case selection for the performance of  
209 | primary-PCI.  
210 |

211 | (h8) A system to ensure prompt and efficient identification of potential primary PCI patients and rapid  
212 | transfer from the emergency department to the cardiac catheterization laboratory must be developed and  
213 | maintained so that door-to-balloon targets are met.

214 |  
215 | (i9) At least two physicians credentialed to perform ~~primary~~ PCI must commit to functioning as a  
216 | coordinated group willing and able to provide this service at the hospital on a 24-hour per day, 365 day  
217 | per year call schedule, with ability to be on-site and available to operate within 30 minutes of identifying  
218 | the need for primary PCI. These physicians must be credentialed at the facility and actively collaborate  
219 | with administrative and clinical staff in establishing and implementing protocols, call schedules, and  
220 | quality assurance procedures pertaining to ~~primary~~ PCI designed to meet the requirements for this  
221 | certification and in keeping with the current guidelines for the provision of ~~primary~~ PCI WITHOUT ON-  
222 | SITE OHS SERVICES promulgated by the American College of Cardiology and American Heart  
223 | Association.

224 | ~~(j) The applicant shall project a minimum of 36 primary PCI cases based on data from the most~~  
225 | ~~recent 12-month period preceding the date the application was submitted to the Department.~~

226 |  
227 | (10) THE APPLICANT HOSPITAL SHALL PARTICIPATE IN A DATA REGISTRY ADMINISTERED  
228 | BY THE DEPARTMENT OR ITS DESIGNEE AS A MEANS TO MEASURE QUALITY AND RISK  
229 | ADJUSTED OUTCOMES WITHIN PCI SERVICES WITHOUT ON-SITE OHS SERVICES, AND THE  
230 | APPLICANT HOSPITAL SHALL IDENTIFY A PHYSICIAN POINT OF CONTACT FOR THE DATA  
231 | REGISTRY.

232 |  
233 | (11) CATH LAB FACILITY REQUIREMENTS AND COLLABORATIVE CARDIOLOGISTS-HEART  
234 | SURGEON RELATIONSHIP REQUIREMENTS SHALL CONFORM TO ALL SCAI/ACC GUIDELINES  
235 | FOR PCI SERVICES WITHOUT ON-SITE OHS INCLUDING THE SCAI/ACC/AHA EXPERT  
236 | CONSENSUS DOCUMENT. THE APPLICANT HOSPITAL SHALL BE LIABLE FOR THE COST OF  
237 | DEMONSTRATING COMPLIANCE WITH THESE CRITERIA IN THEIR APPLICATION.

238 |  
239 | (12) The applicant shall project THE FOLLOWING based on data from the most recent 12-month  
240 | period preceding the date the application was submitted to the Department, AS APPLICABLE.

241 | (a) IF THE APPLICANT IS APPLYING FOR A PRIMARY PCI SERVICE WITHOUT OPEN HEART  
242 | SURGERY, THE APPLICANT SHALL PROJECT A MINIMUM OF 36 PRIMARY PCI PROCEDURES  
243 | PER YEAR.

244 | (b) IF THE APPLICANT IS APPLYING FOR AN ELECTIVE PCI SERVICE WITHOUT ON-SITE  
245 | OHS, THE APPLICANT SHALL PROJECT A MINIMUM OF 200 PCI PROCEDURES PER YEAR.

246 |  
247 | (13) IF THE APPLICANT IS APPLYING FOR AN ELECTIVE PCI SERVICE WITHOUT ON-SITE  
248 | OHS, THE APPLICANT ALSO SHALL DEMONSTRATE THE FOLLOWING:

249 | (a) THE APPLICANT OPERATED A PRIMARY PCI SERVICE FOR AT LEAST ONE YEAR PRIOR  
250 | TO THE DATE OF APPLICATION.

251 | (b) THE APPLICANT SUBMITTED DATA TO A DATA REGISTRY ADMINISTERED BY THE  
252 | DEPARTMENT OR ITS DESIGNEE AND BEEN FOUND TO HAVE ACCEPTABLE PERFORMANCE AS  
253 | COMPARED TO THE REGISTRY BENCHMARKS FOR THE MOST RECENT 12 MONTHS PRIOR TO  
254 | THE DATE OF APPLICATION.

255 | (c) IF THE APPLICANT WAS NOT APPROVED AS A PRIMARY PCI SERVICE PRIOR TO (INSERT  
256 | EFFECTIVE DATE OF THESE STANDARDS), THEN, IN ADDITION, THE APPLICANT SHALL  
257 | DEMONSTRATE THAT THERE IS NO PCI OR OHS SERVICE WITHIN 60 RADIUS MILES OR 60  
258 | MINUTES TRAVEL TIME FROM THE PROPOSED SITE.

259 |  
260 | (14) IF THE APPLICANT IS CURRENTLY PROVIDING OHS SERVICES AND THERAPEUTIC  
261 | CARDIAC CATHETERIZATION SERVICES AND IS PROPOSING TO DISCONTINUE OHS SERVICES  
262 | AND THERAPEUTIC CARDIAC CATHETERIZATION SERVICES, THEN THE APPLICANT SHALL  
263 | APPLY TO INITIATE PRIMARY OR ELECTIVE PCI SERVICES WITHOUT ON-SITE OHS USING THIS

264 | SECTION. THE APPLICANT SHALL DEMONSTRATE ALL OF THE REQUIREMENTS IN THIS  
265 | SECTION EXCEPT FOR SUB-SECTION (13) AND IS SUBJECT TO ALL REQUIREMENTS IN SECTION  
266 | 10.

268 | **Section 45. Requirements to replace an existing cardiac catheterization service or laboratory**

269 |  
270 | Sec. 45. Replacing a cardiac catheterization laboratory means a change in the angiography x-ray  
271 | equipment or a relocation of the service to a new site. The term does not include a change in any of the  
272 | other equipment or software used in the laboratory. An applicant proposing to replace a cardiac  
273 | catheterization laboratory or service shall demonstrate the following as applicable to the proposed project:  
274 |

275 | (1) An applicant proposing to replace cardiac catheterization laboratory equipment shall demonstrate  
276 | the following:

277 | (a) The existing laboratory or laboratories to be replaced are fully depreciated according to generally  
278 | accepted accounting principles or demonstrates either of the following:

279 | (i) The existing angiography x-ray equipment to be replaced poses a threat to the safety of the  
280 | patients.

281 | (ii) The replacement angiography x-ray equipment offers technological improvements that enhance  
282 | quality of care, increases efficiency, and reduces operating costs.

283 | (b) The existing angiography x-ray equipment to be replaced will be removed from service on or  
284 | before beginning operation of the replacement equipment.

285 |  
286 | (2) An applicant proposing to replace a cardiac catheterization service to a new site shall  
287 | demonstrate the following:

288 | (a) The proposed project is part of an application to replace the entire hospital.

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

291 | (i) A minimum of 300 procedure equivalents in the category of adult diagnostic cardiac  
292 | catheterization procedures.

293 | (ii) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac  
294 | catheterization procedures.

295 | (iii) A minimum of 600 procedure equivalents in the category of pediatric cardiac catheterization  
296 | procedures.

297 | (iv) A minimum of 500 procedure equivalents for a hospital in a rural or micropolitan county with one  
298 | laboratory.

299 | (v) A minimum of 750 procedure equivalents for a hospital in a metropolitan county with one  
300 | laboratory.

301 | (vi) A minimum of 1,000 procedure equivalents per cardiac catheterization laboratory for a hospital  
302 | with two or more laboratories.

303 | (c) The existing cardiac catheterization service has been in operation for at least 36 months as of the  
304 | date the application has been submitted to the Department.

305 |  
306 | **Section 56. Requirements to expand a cardiac catheterization service**

307 |  
308 | Sec. 56. An applicant proposing to add a laboratory to an existing cardiac catheterization service shall  
309 | demonstrate the following:

310 |  
311 | (1) The applicant has performed the following during the most recent 12-month period preceding the  
312 | date the application was submitted to the Department as applicable to the proposed project:

313 | (a) A minimum of 300 procedure equivalents in the category of adult diagnostic cardiac  
314 | catheterization procedures.

315 | (b) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac  
316 | catheterization procedures.

317 (c) A minimum of 600 procedure equivalents in the category of pediatric cardiac catheterization  
318 procedures.

319  
320 (2) The applicant has performed a minimum of 1,400 procedure equivalents per existing and  
321 approved laboratories during the most recent 12-month period preceding the date the application was  
322 submitted to the Department.

323  
324 | **Section 67. Requirements to acquire a cardiac catheterization service**

325  
326 | Sec. 67. Acquiring a cardiac catheterization service and its laboratories means obtaining possession  
327 and control by contract, ownership, lease or other comparable arrangement or renewal of a lease for  
328 existing angiography x-ray equipment. An applicant proposing to acquire a cardiac catheterization  
329 service or renew a lease for equipment shall demonstrate the following as applicable to the proposed  
330 project:

331  
332 (1) An applicant proposing to acquire a cardiac catheterization service shall demonstrate the  
333 following:

334 (a) The proposed project is part of an application to acquire the entire hospital.

335 (b) An application for the first acquisition of an existing cardiac catheterization service after February  
336 27, 2012 shall not be required to be in compliance with the applicable volume requirements in ~~subsection~~  
337 ~~SECTION (e)10~~. The cardiac catheterization service shall be operating at the applicable volumes set  
338 forth in the project delivery requirements in the second 12 months of operation of the service by the  
339 applicant and annually thereafter.

340 (c) ~~FOR ANY APPLICATION PROPOSING TO ACQUIRE AN EXISTING CARDIAC~~  
341 ~~CATHETERIZATION SERVICE, EXCEPT THE FIRST APPLICATION APPROVED PURSUANT TO~~  
342 ~~SUBSECTION (B), AN APPLICANT SHALL BE REQUIRED TO DOCUMENT THAT THE CARDIAC~~  
343 ~~CATHETERIZATION SERVICE TO BE ACQUIRED IS OPERATING IN COMPLIANCE WITH THE~~  
344 ~~VOLUME REQUIREMENTS SET FORTH IN SECTION 10 OF THESE STANDARDS APPLICABLE TO~~  
345 ~~AN EXISTING CARDIAC CATHETERIZATION SERVICE ON THE DATE THE APPLICATION IS~~  
346 ~~SUBMITTED TO THE DEPARTMENT. The applicant has performed the following during the most recent~~  
347 ~~12-month period preceding the date the application was submitted to the Department as applicable to the~~  
348 ~~proposed project:~~

349 ~~—(i) A minimum of 300 procedure equivalents in the category of adult diagnostic cardiac~~  
350 ~~catheterization procedures.~~

351 ~~—(ii) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac~~  
352 ~~catheterization procedures.~~

353 ~~—(iii) A minimum of 600 procedure equivalents in the category of pediatric cardiac catheterization~~  
354 ~~procedures.~~

355 ~~—(iv) A minimum of 500 procedure equivalents for a hospital in a rural or micropolitan county with one~~  
356 ~~laboratory.~~

357 ~~—(v) A minimum of 750 procedure equivalents for a hospital in a metropolitan county with one~~  
358 ~~laboratory.~~

359 ~~—(vi) A minimum of 1,000 procedure equivalents per cardiac catheterization laboratory for two or more~~  
360 ~~laboratories.~~

361  
362 (2) An applicant proposing to renew a lease for existing angiography x-ray equipment shall  
363 demonstrate the renewal of the lease is more cost effective than replacing the equipment.

364  
365 | **Section 78. Requirements for a hybrid operating room/cardiac catheterization laboratory (OR/CCL)**

366  
367 | Sec. 78. A hybrid OR/CCL means an operating room located on a sterile corridor and equipped with an  
368 angiography system permitting minimally invasive procedures of the heart and blood vessels with full

369 anesthesia capabilities. An applicant proposing to add one or more hybrid OR/CCLs at an existing cardiac  
370 catheterization service shall demonstrate each of the following:

- 371
- 372 | (1) The applicant operates an ~~open heart surgery~~OHS service which is in full compliance with the  
373 | current CON Review Standards for ~~Open Heart Surgery~~OHS Services.
- 374
- 375 | (2) The applicant operates a therapeutic cardiac catheterization program which is in full compliance  
376 | with section 45(2) of these standards.
- 377
- 378 | (3) If the hybrid OR/CCL(s) represents an increase in the number of cardiac catheterization laboratories  
379 | at the facility, the applicant is in compliance with Section ~~5-6~~6 of these standards.
- 380
- 381 | (4) If the hybrid OR/CCL(s) represents conversion of an existing cardiac catheterization laboratory(s),  
382 | the applicant is in compliance with the provisions of Section 45, if applicable.
- 383
- 384 | (5) The applicant meets the applicable requirements of the CON Review Standards for Surgical  
385 | Services.
- 386
- 387 | (6) Each case performed in a hybrid OR/CCL shall be included either in the surgical volume or the  
388 | therapeutic cardiac catheterization volume of the facility. No case shall be counted more than once.
- 389
- 390 | (7) For each hybrid OR/CCL, a facility shall have 0.5 excluded from its inventory of cardiac  
391 | catheterization laboratories for the purposes of computing the procedure equivalents per room. A facility  
392 | will not be limited to the number of hybrid ORCCLs within a single licensed facility.
- 393

394 | **Section 89. Requirement for Medicaid participation**

395

396 | Sec. 89. An applicant shall provide verification of Medicaid participation at the time the application is  
397 | submitted to the Department. An applicant that is initiating a new service or is a new provider not  
398 | currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the  
399 | Department within six (6) months from the offering of services if a CON is approved.

400

401 | **Section 910. Project delivery requirements and terms of approval for all applicants**

402

403 | Sec. 910. An applicant shall agree that, if approved, the cardiac catheterization service and all  
404 | existing and approved laboratories shall be delivered in compliance with the following terms of approval:

405

- 406 | (1) Compliance with these standards.
- 407
- 408 | (2) Compliance with the following quality assurance standards:
- 409 | (a) Cardiac catheterization procedures shall be performed in a cardiac catheterization laboratory  
410 | located within a hospital, and have within, or immediately available to the room, dedicated emergency  
411 | equipment to manage cardiovascular emergencies.
- 412 | (b) The service shall be staffed with sufficient medical, nursing, technical and other personnel to  
413 | permit regular scheduled hours of operation and continuous 24-hour on-call availability.
- 414 | (c) The medical staff and governing body shall receive and review at least annual reports describing  
415 | the activities of the cardiac catheterization service including complication rates, morbidity and mortality,  
416 | success rates and the number of procedures performed.
- 417 | (d) Each physician credentialed by a hospital to perform adult therapeutic cardiac catheterization  
418 | procedures shall perform, as the primary operator, a minimum of ~~75-50~~ adult therapeutic cardiac  
419 | catheterization procedures per year in the second 12 months after being credentialed to and annually  
420 | thereafter. The annual case load for a physician means adult therapeutic cardiac catheterization  
421 | procedures performed by that physician in any combination of hospitals.

422 (e) Each physician credentialed by a hospital to perform pediatric ~~diagnostic~~ cardiac catheterizations  
423 shall perform, as the primary operator, a minimum of 50 pediatric ~~diagnostic~~ cardiac catheterization  
424 procedures per year in the second 12 months after being credentialed and annually thereafter. The  
425 annual case load for a physician means pediatric ~~diagnostic~~ cardiac catheterization procedures  
426 performed by that physician in any combination of hospitals.

427 ~~—(f) Each physician credentialed by a hospital to perform pediatric therapeutic cardiac~~  
428 ~~catheterizations shall perform, as a primary operator, a minimum of 25 pediatric therapeutic cardiac~~  
429 ~~catheterizations per year in the second 12 months after being credentialed and annually thereafter. The~~  
430 ~~annual case load for a physician means pediatric therapeutic cardiac catheterization procedures~~  
431 ~~performed by that physician in any combination of hospitals~~

432 (gf) An adult diagnostic cardiac catheterization service shall have a minimum of two appropriately  
433 trained physicians on its active hospital staff. The Department may accept other evidence or shall  
434 consider it appropriate training if the staff physicians:

- 435 (i) are trained consistent with the recommendations of the American College of Cardiology;
- 436 (ii) are credentialed by the hospital to perform adult diagnostic cardiac catheterizations; and
- 437 (iii) have each performed a minimum of 100 adult diagnostic cardiac catheterizations in the preceding  
438 12 months.

439 (hg) An adult therapeutic cardiac catheterization service shall have a minimum of two appropriately  
440 trained physicians on its active hospital staff. The Department may accept other evidence or shall  
441 consider it appropriate training if the staff physicians:

- 442 (i) are trained consistent with the recommendations of the American College of Cardiology;
- 443 (ii) are credentialed by the hospital to perform adult therapeutic cardiac catheterizations; and
- 444 (iii) have each performed a minimum of ~~75-50~~ adult therapeutic cardiac catheterization procedures in  
445 the preceding 12 months.

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

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

452 (i) A PEDIATRIC CARDIAC CATHETERIZATION SERVICE SHALL MAINTAIN A QUALITY  
453 ASSURANCE PLAN AS OUTLINED IN THE MOST CURRENT ACCF/SCAI GUIDELINES.

454 (j) A cardiac catheterization service shall be directed by an appropriately trained physician. The  
455 Department shall consider appropriate training of the director if the physician is board certified in  
456 cardiology, cardiovascular radiology or cardiology, adult or pediatric, as applicable. The director of an  
457 adult cardiac catheterization service shall have performed at least ~~200-100~~ catheterizations per year  
458 during each of the five preceding years. The Department may accept other evidence that the director is  
459 appropriately trained.

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

462 (l) THE APPLICANT HOSPITAL PROVIDING THERAPEUTIC CARDIAC CATHETERIZATION  
463 SERVICES, PRIMARY PCI SERVICES WITHOUT ON-SITE OHS SERVICE, OR ELECTIVE PCI  
464 SERVICES WITHOUT ON-SITE OHS SERVICE SHALL PARTICIPATE WITH A DATA REGISTRY  
465 ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE THAT MONITORS QUALITY AND RISK  
466 ADJUSTED OUTCOMES.

467  
468 (3) Compliance with the following access to care requirements:

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

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

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

475 (d) The operation of and referral of patients to the cardiac catheterization service shall be in  
476 conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.1621; MSA 14.15  
477 (16221).

478

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

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

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

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

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

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

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

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

489 (vii) 36 adult primary PCI cases for a primary PCI service WITHOUT ON-SITE OHS SERVICE.

490 (viii) 200 ADULT PCI PROCEDURES FOR AN ELECTIVE PCI SERVICE WITHOUT ON-SITE OHS  
491 SERVICE.

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

496 (c) The APPLICANT hospital PROVIDING THERAPEUTIC CARDIAC CATHETERIZATION  
497 SERVICES, PRIMARY PCI SERVICES WITHOUT ON-SITE OHS SERVICE, OR ELECTIVE PCI  
498 SERVICES WITHOUT ON-SITE OHS SERVICE shall participate in a ~~quality improvement~~ data registry  
499 administered by the Department or its designee AS A MEANS TO MEASURE QUALITY AND RISK  
500 ADJUSTED OUTCOMES WITHIN CARDIAC CATHETERIZATION SERVICES. The DEPARTMENT OR  
501 ITS DESIGNEE SHALL REQUIRE THAT THE APPLICANT hospital ~~shall~~ submit summary reports as  
502 ~~required~~ SPECIFIED by the Department. The APPLICANT hospital shall provide the required data in a  
503 format established by the Department or its designee. The APPLICANT hospital ~~is~~ SHALL BE liable for  
504 the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes  
505 and assure quality. The APPLICANT hospital ~~must~~ SHALL become a member of the data registry  
506 SPECIFIED BY THE DEPARTMENT upon initiation of the service and continue to participate annually  
507 thereafter for the life of that service.

508 (d) THE APPLICANT HOSPITAL SHALL PROVIDE THE DEPARTMENT WITH TIMELY NOTICE OF  
509 THE PROPOSED PROJECT IMPLEMENTATION CONSISTENT WITH APPLICABLE STATUTE AND  
510 PROMULGATED RULES.

511

512 (5) Compliance with the following primary AND ELECTIVE PCI requirements FOR HOSPITALS  
513 PROVIDING THERAPEUTIC CARDIAC CATHETERIZATION SERVICES, PRIMARY PCI SERVICES  
514 WITHOUT ON-SITE OHS SERVICE, OR ELECTIVE PCI SERVICES WITHOUT ON-SITE OHS  
515 SERVICE, if applicable:

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

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

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

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

523 (d) The APPLICANT hospital shall participate in a data registry, administered by the Department or  
524 its designee AS A MEANS TO MEASURE QUALITY AND RISK ADJUSTED OUTCOMES WITHIN PCI  
525 SERVICES BY SERVICE LEVEL. The Department or its designee shall require that the applicant  
526 HOSPITAL submit ~~data on~~ all consecutive ~~cases of primary~~ PCI CASES PERFORMED WITHIN THE  
527 HOSPITAL AND MEET DATA SUBMISSION TIMELINESS REQUIRMENTS AND THRESHOLD

528 REQUIREMENTS FOR PCI DATA SUBMISSION, ACCURACY AND COMPLETENESS ESTABLISHED  
529 BY DATA REGISTRY ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE, as is necessary to  
530 comprehensively assess and provide comparative analyses of case selection, processes and outcome of  
531 care, and trend in efficiency. The applicant HOSPITAL shall provide the required data in a format  
532 established by the Department or its designee. The applicant HOSPITAL shall be liable for the cost of  
533 data submission and on-site reviews in order for the Department to verify and monitor volumes and  
534 assure quality. THE APPLICANT HOSPITAL SHALL BECOME A MEMBER OF THE DATA REGISTRY  
535 SPECIFIED BY THE DEPARTMENT UPON INITIATION OF THE SERVICE AND CONTINUE TO  
536 PARTICIPATE ANNUALLY THEREAFTER FOR THE LIFE OF THAT SERVICE. AT A MINIMUM, THE  
537 APPLICANT HOSPITAL SHALL REPORT THE FOLLOWING:  
538 (i) THE NUMBER OF PATIENTS TREATED WITH AND WITHOUT STEMI,  
539 (ii) THE PROPORTION OF PCI PATIENTS WITH EMERGENCY CABG OR REQUIRED  
540 EMERGENT TRANSFER,  
541 (iii) RISK AND RELIABILITY ADJUSTED PATIENT MORTALITY FOR ALL PCI PATIENTS AND A  
542 SUBSET OF PATIENTS WITH STEMI,  
543 (iv) PCI APPROPRIATE USE IN ELECTIVE NON-ACUTE MI CASES, AND  
544 (v) RATES OF AD-HOC MULTI-VESSEL PCI PROCEDURES IN THE SAME SESSION,  
545 (e) THE APPLICANT HOSPITAL SHALL MAINTAIN A PHYSICIAN POINT OF CONTACT FOR THE  
546 DATA REGISTRY.  
547 (f) CATH LAB FACILITY REQUIREMENTS AND COLLABORATIVE CARDIOLOGISTS-HEART  
548 SURGEON RELATIONSHIP REQUIREMENTS SHALL CONFORM TO ALL SCAI/ACC GUIDELINES  
549 FOR PCI INCLUDING THE SCAI/ACC/AHA EXPERT CONSENSUS DOCUMENT. THE APPLICANT  
550 HOSPITAL SHALL BE LIABLE FOR THE COST OF DEMONSTRATING COMPLIANCE WITH THESE  
551 CRITERIA.  
552 (g) THE DEPARTMENT SHALL USE THESE THRESHOLDS AND METRICS IN EVALUATING  
553 COMPLIANCE: PERFORMANCE AT A LEVEL ABOVE THE 50TH PERCENTILE OF THE STATEWIDE  
554 PERFORMANCE ON EACH METRIC LISTED UNDER SUBSECTION (d)(ii) – (v) OR ANOTHER LEVEL  
555 PROVIDED BY THE DATA REGISTRY DESIGNEE AND ACCEPTED BY THE DEPARTMENT.  
556 (h) THE DEPARTMENT SHALL NOTIFY THOSE HOSPITALS WHO FAIL TO MEET ANY OF THE  
557 MINIMALLY ACCEPTABLE OBJECTIVE QUALITY METRIC THRESHOLDS INCLUDING THOSE  
558 UNDER SUBSECTION (d)(ii) – (v). THE DEPARTMENT SHALL REQUIRE THESE HOSPITALS TO:  
559 (i) SUBMIT A CORRECTIVE ACTION PLAN WITHIN ONE MONTH OF NOTIFICATION AND  
560 (ii) DEMONSTRATE THAT PERFORMANCE HAS IMPROVED TO MEET OR EXCEED ALL  
561 APPLICABLE OBJECTIVE QUALITY METRIC THRESHOLDS, INCLUDING THOSE UNDER  
562 SUBSECTION (d)(ii) – (v), WITHIN 12 MONTHS OF NOTIFICATION.  
563 (i) THE APPLICANT HOSPITAL INITIATING ELECTIVE PCI WITHOUT ON-SITE OHS SERVICES  
564 SHALL HAVE ACCREDITATION FOR CARDIOVASCULAR EXCELLENCE (ACE) ACCREDITATION OR  
565 AN EQUIVALENT BODY PERFORM AN ON-SITE REVIEW WITHIN 3, 6, AND 12 MONTHS AFTER  
566 IMPLEMENTATION. THE APPLICANT HOSPITAL SHALL SUBMIT THE SUMMARY REPORTS OF  
567 THE ON-SITE REVIEW TO THE DEPARTMENT.  
568  
569 (6) NOTHING IN THIS SECTION PROHIBITS THE DEPARTMENT FROM TAKING COMPLIANCE  
570 ACTION UNDER MCL 333.22247.  
571  
572 (7) THE AGREEMENTS AND ASSURANCES REQUIRED BY THIS SECTION SHALL BE IN THE  
573 FORM OF A CERTIFICATION AGREED TO BY THE APPLICANT OR ITS AUTHORIZED AGENT.  
574

575 **Section 4011. Methodology for computing cardiac catheterization equivalents**  
576

577 | Sec. 4011. The following shall be used in calculating procedure equivalents and evaluating utilization  
578 of a cardiac catheterization service and its laboratories:  
579

Procedure Type	Procedure equivalent	
	Adult	Pediatric
Diagnostic cardiac catheterization/peripheral sessions	1.5	2.7
Therapeutic cardiac catheterization/peripheral sessions	2.7	4.0
Complex percutaneous valvular sessions*	4.0	7.0

\* Complex percutaneous valvular sessions includes, but is not limited to, procedures performed percutaneously or with surgical assistance to repair or replace aortic, mitral and pulmonary valves such as transcatheter aortic valvular implantation (Tavi) procedures. These sessions can only be performed at hospitals approved with ~~open heart surgery~~OHS services.

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**Section 4112. Documentation of projections**

**Sec. 4112. An applicant required to project volumes shall demonstrate the following as applicable to the proposed project:**

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

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

(3) AN APPLICANT PROPOSING TO INITIATE AN ELECTIVE PCI SERVICE WITHOUT ON-SITE OHS SERVICES SHALL DEMONSTRATE AND CERTIFY THAT THE HOSPITAL SHALL TREAT 200 OR MORE PATIENTS WITH PCI ANNUALLY USING DATA DURING THE MOST RECENT 12-MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT AS FOLLOWS:

(a) ALL PRIMARY PCIS PERFORMED AT THE APPLICANT HOSPITAL.

(b) ALL INPATIENTS TRANSFERRED FROM THE APPLICANT HOSPITAL TO ANOTHER HOSPITAL FOR PCI.

(c) 90% OF PATIENTS WHO RECEIVED DIAGNOSTIC CARDIAC CATHETERIZATIONS AT THE APPLICANT HOSPITAL AND RECEIVED AN ELECTIVE PCI AT ANOTHER HOSPITAL WITHIN 30 DAYS OF THE DIAGNOSTIC CATHETERIZATION (BASED ON PHYSICIAN COMMITMENTS).

(d) 50% OF THE ELECTIVE PCI PROCEDURES PERFORMED BY THE COMMITTING PHYSICIAN AT ANOTHER HOSPITAL WITHIN 120 RADIUS MILES OR 120 MINUTES TRAVEL TIME FROM THE APPLICANT HOSPITAL FOR PATIENTS WHO DID NOT RECEIVE DIAGNOSTIC CARDIAC CATHETERIZATION AT THE APPLICANT HOSPITAL (BASED ON PHYSICIAN COMMITMENTS).

(e) AN APPLICANT WITH CURRENT OHS SERVICES AND THERAPEUTIC CARDIAC CATHETERIZATION SERVICES THAT IS PROPOSING TO DISCONTINUE OHS SERVICES AND THERAPEUTIC CARDIAC CATHETERIZATION SERVICES AND IS APPLYING TO INITIATE PRIMARY OR ELECTIVE PCI SERVICES WITHOUT ON-SITE OHS SERVICES MAY COUNT ALL PRIMARY AND ELECTIVE PCI AT THE APPLICANT HOSPITAL WITHIN THE MOST RECENT 12-MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT.

**Section 4213. Comparative reviews; Effect on prior CON Review Standards**

622 | Sec. ~~1213~~. Proposed projects reviewed under these standards shall not be subject to comparative  
623 | review. These CON Review Standards supercede and replace the CON Review Standards for Cardiac  
624 | Catheterization Services approved by the CON Commission on ~~December 15, 2014~~MARCH 18, 2014  
625 | and effective on ~~February 27, 2012~~JUNE 2, 2014.  
626

627  
628  
629 Rural Michigan counties are as follows:

630			
631	Alcona	<del>Hillsdale</del>	Oceana
632	Alger	Huron	Ogemaw
633	Antrim	Iosco	Ontonagon
634	Arenac	Iron	Osceola
635	Baraga	Lake	Oscoda
636	Charlevoix	Luce	Otsego
637	Cheboygan	Mackinac	Presque Isle
638	Clare	Manistee	Roscommon
639	Crawford	<del>Mason</del>	Sanilac
640	Emmet	<del>Montcalm</del>	Schoolcraft
641	Gladwin	Montmorency	Tuscola
642	Gogebic	<u>NEWAYGO</u>	

643  
644 Micropolitan statistical area Michigan counties are as follows:

645			
646	Allegan	<u>HILLSDALE</u>	<u>MASON</u>
647	Alpena	Houghton	Mecosta
648	Benzie	<u>IONIA</u>	Menominee
649	Branch	Isabella	<del>Midland</del>
650	Chippewa	Kalkaska	Missaukee
651	Delta	Keweenaw	St. Joseph
652	Dickinson	Leelanau	Shiawassee
653	Grand Traverse	Lenawee	Wexford
654	Gratiot	Marquette	

655  
656 Metropolitan statistical area Michigan counties are as follows:

657			
658	Barry	<del>onia</del>	<u>MONTCALM</u> <del>Newaygo</del>
659	Bay	Jackson	Muskegon
660	Berrien	Kalamazoo	Oakland
661	Calhoun	Kent	Ottawa
662	Cass	Lapeer	Saginaw
663	Clinton	Livingston	St. Clair
664	Eaton	Macomb	Van Buren
665	Genesee	<u>MIDLAND</u>	Washtenaw
666	Ingham	Monroe	Wayne

667  
668 Source:

669  
670 | ~~65-75~~ F.R., p. ~~82238-37245~~ (~~December 27~~JUNE 28, 2000~~2010~~)  
671 Statistical Policy Office  
672 Office of Information and Regulatory Affairs  
673 United States Office of Management and Budget

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**APPENDIX B**

**ICD-9-CM TO ICD-10-CM Code Translation**

<b>ICD-9 Code</b>	<b>Description</b>	<b>ICD-10 Code</b>	<b>Description</b>
426.7	Anomalous Atrioventricular Excitation	I45.6	Pre-Excitation Syndrome
427	Cardiac Dysrhythmias	I47.0-I47.9	Paroxysmal Tachycardia
		I48.0-I48.92	Atrial Fibrillation and Flutter
		I49.01-I49.9	Other Cardiac Arrhythmias
		R00.1	Bradycardia, Unspecified
745.0 through 747.99	Bulbus Cordis Anomalies and Anomalies of Cardiac Septal Closure, Other Congenital Anomalies of Heart, and other Congenital Anomalies of Circulatory System	P29.3	Persistent Fetal Circulation
		Q20.0-Q28.9	Congenital Malformations of the Circulatory System

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"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.

"ICD-10-CM Code" means the disease codes and nomenclature found in the International Classification of Diseases - 10th Revision - Clinical Modification, National Center for Health Statistics.