

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.)  
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10 **Section 1. Applicability**

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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.  
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19 **Section 2. Definitions**

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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 | PERFORMED ON AN ACUTE MYOCARDIAL INFARCTION (AMI) PATIENT WITH CONFIRMED ST  
54 | ELEVATION OR NEW LEFT BUNDLE BRANCH BLOCK ON A NON-EMERGENT BASIS.

55 | (hi) "Electrophysiology study" means a study of the electrical conduction activity of the heart and  
56 | characterization of atrial and ventricular arrhythmias obtained by means of a cardiac catheterization  
57 | procedure. The term also includes the implantation of permanent pacemakers and ICD devices.

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

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

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

68 | (lm) "Primary percutaneous coronary intervention (PCI)" means a PCI performed on an acute  
69 | myocardial infarction (AMI) patient with confirmed ST elevation or new left bundle branch block.

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

72 | (no) "Therapeutic cardiac catheterization service" means providing therapeutic cardiac  
73 | catheterizations on an organized, regular basis in a laboratory to treat and resolve anatomical and/or  
74 | physiological problems in the heart. Procedures include PCI, PTCA, atherectomy, stent, laser, cardiac  
75 | valvuloplasty, balloon atrial septostomy, catheter ablation, cardiac permanent pacemaker, ICD device  
76 | implantations, transcatheter valve, other structural heart disease procedures, percutaneous transluminal  
77 | coronary angioplasty (PTCA) and coronary stent implantation and left sided arrhythmia therapeutic  
78 | procedures. The term does not include the intra coronary administration of drugs where that is the only  
79 | therapeutic intervention.

80 |  
81 | (2) Terms defined in the Code have the same meanings when used in these standards.  
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### 83 | **Section 3. Requirements to initiate cardiac catheterization services**

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85 | Sec. 3. An applicant proposing to initiate cardiac catheterization services shall demonstrate the  
86 | following, as applicable to the proposed project.  
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88 | (1) An applicant proposing to initiate an adult diagnostic cardiac catheterization service shall  
89 | demonstrate the following as applicable to the proposed project:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(4) An applicant proposing to initiate primary AND ELECTIVE PCI serviceS without on-site open heart surgery services shall demonstrate the following:

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

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

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

- 157 (d) The laboratory or laboratories are equipped with optimal imaging systems, resuscitative  
158 equipment, and intra-aortic balloon pump (IABP) support, and stocked with a broad array of interventional  
159 equipment.
- 160 (e) The cardiac care unit nurses are adept in hemodynamic monitoring and IABP management.  
161 Competency shall be documented annually.
- 162 (f) A written agreement with an open heart surgery hospital that includes all of the following:
- 163 (i) Involvement in credentialing criteria and recommendations for physicians approved to perform  
164 ~~primary~~ PCI procedures.
- 165 (ii) Provision for ongoing cross-training for professional and technical staff involved in the provision of  
166 ~~primary~~ PCI to ensure familiarity with interventional equipment. Competency shall be documented  
167 annually.
- 168 (iii) Provision for ongoing cross training for emergency department, catheterization laboratory, and  
169 critical care unit staff to ensure experience in handling the high acuity status of ~~primary~~ PCI patient  
170 candidates. Competency shall be documented annually.
- 171 (iv) Regularly held joint cardiology/cardiac surgery conferences to include review of all ~~primary~~ PCI  
172 cases.
- 173 (v) Development and ongoing review of patient selection criteria for ~~primary~~ PCI patients and  
174 implementation of those criteria.
- 175 (vi) A mechanism to provide for appropriate patient transfers between facilities and an agreed plan for  
176 prompt care.
- 177 (vii) Written protocols, signed by the applicant and the open heart surgery hospital, for the immediate  
178 transfer, within 1 hour from the cardiac catheterization laboratory to evaluation on site in the open heart  
179 surgery hospital, of patients requiring surgical evaluation and/or intervention 365 days a year. The  
180 protocols shall be reviewed and tested on a quarterly basis.
- 181 (viii) Consultation on facilities, equipment, staffing, ancillary services, and policies and procedures for  
182 the provision of interventional procedures.
- 183 (g) A written protocol must be established and maintained for case selection for the performance of  
184 ~~primary~~ PCI.
- 185 (h) A system to ensure prompt and efficient identification of potential primary PCI patients and rapid  
186 transfer from the emergency department to the cardiac catheterization laboratory must be developed and  
187 maintained so that door-to-balloon targets are met.
- 188 (i) At least two physicians credentialed to perform ~~primary~~ PCI must commit to functioning as a  
189 coordinated group willing and able to provide this service at the hospital on a 24-hour per day, 365 day  
190 per year call schedule, with ability to be on-site and available to operate within 30 minutes of identifying  
191 the need for primary PCI. These physicians must be credentialed at the facility and actively collaborate  
192 with administrative and clinical staff in establishing and implementing protocols, call schedules, and  
193 quality assurance procedures pertaining to ~~primary~~ PCI designed to meet the requirements for this  
194 certification and in keeping with the current guidelines for the provision of ~~primary~~ PCI WITHOUT ON-  
195 SITE OPEN HEART SURGERY SERVICES promulgated by the American College of Cardiology and  
196 American Heart Association.
- 197 (j) The applicant shall project a minimum of 36-200 primary-ADULT PCI cases-PROCEDURES  
198 based on data from the most recent 12-month period preceding the date the application was submitted to  
199 the Department. IF THE APPLICANT WAS NOT APPROVED AS A PRIMARY PCI SERVICE PRIOR TO  
200 (INSERT EFFECTIVE DATE OF THESE STANDARDS), THEN THE APPLICANT SHALL  
201 DEMONSTRATE THAT THERE IS NO PRIMARY PCI OR OPEN HEART SURGERY SERVICE AT  
202 LEAST 60 RADIUS MILES OR 60 MINUTES TRAVEL TIME FROM ANY EXISTING ADULT  
203 THERAPEUTIC CARDIAC CATHETERIZATION SERVICE.
- 204 (k) THE APPLICANT HOSPITAL SHALL PARTICIPATE IN A DATA REGISTRY ADMINISTERED  
205 BY THE DEPARTMENT OR ITS DESIGNEE AS A MEANS TO MEASURE QUALITY AND RISK  
206 ADJUSTED OUTCOMES WITHIN PCI SERVICES WITHOUT ON-SITE OPEN HEART SURGERY  
207 SERVICES, AND THE APPLICANT HOSPITAL SHALL IDENTIFY A PHYSICIAN POINT OF CONTACT  
208 POINT FOR THE DATA REGISTRY.
- 209 (l) CATH LAB FACILITY REQUIREMENTS AND COLLABORATIVE CARDIOLOGISTS-HEART  
210 SURGEON RELATIONSHIP REQUIREMENTS WILL CONFORM WITH ALL SCAI/ACC GUIDELINES

211 | INCLUDING THE CONSENSUS DOCUMENT. THE APPLICANT HOSPITAL SHALL BE LIABLE FOR  
212 | THE COST OF DEMONSTRATING COMPLIANCE WITH THESE CRITERIA IN THEIR APPLICATION.  
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214 | **Section 4. Requirements to replace an existing cardiac catheterization service or laboratory**  
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216 | Sec. 4. Replacing a cardiac catheterization laboratory means a change in the angiography x-ray  
217 | equipment or a relocation of the service to a new site. The term does not include a change in any of the  
218 | other equipment or software used in the laboratory. An applicant proposing to replace a cardiac  
219 | catheterization laboratory or service shall demonstrate the following as applicable to the proposed project:  
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221 | (1) An applicant proposing to replace cardiac catheterization laboratory equipment shall demonstrate  
222 | the following:

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

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

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

229 | (b) The existing angiography x-ray equipment to be replaced will be removed from service on or  
230 | before beginning operation of the replacement equipment.  
231

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

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

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

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

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

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

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

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

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

249 | (c) The existing cardiac catheterization service has been in operation for at least 36 months as of the  
250 | date the application has been submitted to the Department.  
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252 | **Section 5. Requirements to expand a cardiac catheterization service**  
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254 | Sec. 5. An applicant proposing to add a laboratory to an existing cardiac catheterization service shall  
255 | demonstrate the following:  
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257 | (1) The applicant has performed the following during the most recent 12-month period preceding the  
258 | date the application was submitted to the Department as applicable to the proposed project:

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

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

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

265 (2) The applicant has performed a minimum of 1,400 procedure equivalents per existing and  
266 approved laboratories during the most recent 12-month period preceding the date the application was  
267 submitted to the Department.  
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## 269 **Section 6. Requirements to acquire a cardiac catheterization service**

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272 Sec. 6. Acquiring a cardiac catheterization service and its laboratories means obtaining possession  
273 and control by contract, ownership, lease or other comparable arrangement or renewal of a lease for  
274 existing angiography x-ray equipment. An applicant proposing to acquire a cardiac catheterization  
275 service or renew a lease for equipment shall demonstrate the following as applicable to the proposed  
276 project:  
277

278 (1) An applicant proposing to acquire a cardiac catheterization service shall demonstrate the  
279 following:

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

281 (b) An application for the first acquisition of an existing cardiac catheterization service after February  
282 27, 2012 shall not be required to be in compliance with the applicable volume requirements in ~~subsection~~  
283 ~~Section (c)9.~~ ~~—The cardiac catheterization service shall be operating at the applicable volumes set forth~~  
284 ~~in the project delivery requirements in the second 12 months of operation of the service by the applicant~~  
285 ~~and annually thereafter.~~

286 (c) ~~FOR ANY APPLICATION PROPOSING TO ACQUIRE AN EXISTING CARDIAC~~  
287 ~~CATHETERIZATION SERVICE, EXCEPT THE FIRST APPLICATION APPROVED PURSUANT TO~~  
288 ~~SUBSECTION (B), AN APPLICANT SHALL BE REQUIRED TO DOCUMENT THAT THE CARDIAC~~  
289 ~~CATHETERIZATION SERVICE TO BE ACQUIRED IS OPERATING IN COMPLIANCE WITH THE~~  
290 ~~VOLUME REQUIREMENTS SET FORTH IN SECTION 9 OF THESE STANDARDS APPLICABLE TO AN~~  
291 ~~EXISTING CARDIAC CATHETERIZATION SERVICE ON THE DATE THE APPLICATION IS~~  
292 ~~SUBMITTED TO THE DEPARTMENT. The applicant has performed the following during the most recent~~  
293 ~~12-month period preceding the date the application was submitted to the Department as applicable to the~~  
294 ~~proposed project :~~

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

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

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

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

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

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

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308 (2) An applicant proposing to renew a lease for existing angiography x-ray equipment shall  
309 demonstrate the renewal of the lease is more cost effective than replacing the equipment.  
310

## 311 **Section 7. Requirements for a hybrid operating room/cardiac catheterization laboratory (OR/CCL)**

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313 Sec. 7. A hybrid OR/CCL means an operating room located on a sterile corridor and equipped with an  
314 angiography system permitting minimally invasive procedures of the heart and blood vessels with full

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

- 317
- 318 (1) The applicant operates an open heart surgery service which is in full compliance with the current  
319 CON Review Standards for Open Heart Surgery Services.
- 320
- 321 (2) The applicant operates a therapeutic cardiac catheterization program which is in full compliance  
322 with section 4(2) of these standards.
- 323
- 324 (3) If the hybrid OR/CCL(s) represents an increase in the number of cardiac catheterization laboratories  
325 at the facility, the applicant is in compliance with Section 5 of these standards.
- 326
- 327 (4) If the hybrid OR/CCL(s) represents conversion of an existing cardiac catheterization laboratory(s),  
328 the applicant is in compliance with the provisions of Section 4, if applicable.
- 329
- 330 (5) The applicant meets the applicable requirements of the CON Review Standards for Surgical  
331 Services.
- 332
- 333 (6) Each case performed in a hybrid OR/CCL shall be included either in the surgical volume or the  
334 therapeutic cardiac catheterization volume of the facility. No case shall be counted more than once.
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- 336 (7) For each hybrid OR/CCL, a facility shall have 0.5 excluded from its inventory of cardiac  
337 catheterization laboratories for the purposes of computing the procedure equivalents per room. A facility  
338 will not be limited to the number of hybrid ORCCLs within a single licensed facility.
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#### 340 **Section 8. Requirement for Medicaid participation**

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342 Sec. 8. An applicant shall provide verification of Medicaid participation at the time the application is  
343 submitted to the Department. An applicant that is initiating a new service or is a new provider not  
344 currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the  
345 Department within six (6) months from the offering of services if a CON is approved.

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#### 347 **Section 9. Project delivery requirements and terms of approval for all applicants**

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349 Sec. 9. An applicant shall agree that, if approved, the cardiac catheterization service and all existing  
350 and approved laboratories shall be delivered in compliance with the following terms of approval:

- 351
- 352 (1) Compliance with these standards.
- 353
- 354 (2) Compliance with the following quality assurance standards:
- 355 (a) Cardiac catheterization procedures shall be performed in a cardiac catheterization laboratory  
356 located within a hospital, and have within, or immediately available to the room, dedicated emergency  
357 equipment to manage cardiovascular emergencies.
- 358 (b) The service shall be staffed with sufficient medical, nursing, technical and other personnel to  
359 permit regular scheduled hours of operation and continuous 24-hour on-call availability.
- 360 (c) The medical staff and governing body shall receive and review at least annual reports describing  
361 the activities of the cardiac catheterization service including complication rates, morbidity and mortality,  
362 success rates and the number of procedures performed.
- 363 (d) Each physician credentialed by a hospital to perform adult therapeutic cardiac catheterization  
364 | procedures shall perform, as the primary operator, a minimum of ~~75-50~~ adult therapeutic cardiac  
365 catheterization procedures per year in the second 12 months after being credentialed to and annually  
366 thereafter. The annual case load for a physician means adult therapeutic cardiac catheterization  
367 procedures performed by that physician in any combination of hospitals.

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

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

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

- 381 (i) are trained consistent with the recommendations of the American College of Cardiology;
- 382 (ii) are credentialed by the hospital to perform adult diagnostic cardiac catheterizations; and
- 383 (iii) have each performed a minimum of 100 adult diagnostic cardiac catheterizations in the preceding  
384 12 months.

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

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

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

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

398 (i) A PEDIATRIC CARDIAC CATHETERIZATION SERVICE SHALL MAINTAIN A QUALITY  
399 ASSURANCE PLAN AS OUTLINED IN THE ACCF/SCAI GUIDELINES.

400 (j) A cardiac catheterization service shall be directed by an appropriately trained physician. The  
401 Department shall consider appropriate training of the director if the physician is board certified in  
402 cardiology, cardiovascular radiology or cardiology, adult or pediatric, as applicable. The director of an  
403 adult cardiac catheterization service shall have performed at least 200 catheterizations per year during  
404 each of the five preceding years. The Department may accept other evidence that the director is  
405 appropriately trained.

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

408 (l) THE APPLICANT HOSPITAL FOR THERAPEUTIC OR PCI SERVICES SHALL PARTICIPATE  
409 WITH A DATA REGISTRY ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE THAT  
410 MONITORS QUALITY AND RISK ADJUSTED OUTCOMES.

- 411
- 412 (3) Compliance with the following access to care requirements:
- 413 (a) The service shall accept referrals for cardiac catheterization from all appropriately licensed  
414 practitioners.
  - 415 (b) The service shall participate in Medicaid at least 12 consecutive months within the first two years  
416 of operation and annually thereafter.
  - 417 (c) The service shall not deny cardiac catheterization services to any individual based on ability to  
418 pay or source of payment.

419 (d) The operation of and referral of patients to the cardiac catheterization service shall be in  
420 conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.1621; MSA 14.15  
421 (16221).

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

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

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

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

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

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

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

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

433 (vii) 36 adult primary PCI cases for a primary PCI service.

434 (viii) 200 ADULT PCI PROCEDURES FOR A COMBINED PRIMARY AND ELECTIVE PCI SERVICE.

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

439 (c) The APPLICANT hospital shall participate in a ~~quality improvement~~ data registry administered by  
440 the Department or its designee AS A MEANS TO MEASURE QUALITY AND RISK ADJUSTED  
441 OUTCOMES WITHIN CARDIAC CATHETERIZATION SERVICES. The DEPARTMENT OR ITS  
442 DESIGNEE SHALL REQUIRE THAT THE APPLICANT hospital ~~shall~~ submit summary reports as ~~required~~  
443 SPECIFIED by the Department. The APPLICANT hospital shall provide the required data in a format  
444 established by the Department or its designee. The APPLICANT hospital ~~is~~ SHALL BE liable for the cost  
445 of data submission and on-site reviews in order for the Department to verify and monitor volumes and  
446 assure quality. The APPLICANT hospital ~~must~~ SHALL become a member of the data registry  
447 SPECIFIED BY THE DEPARTMENT upon initiation of the service and continue to participate annually  
448 thereafter for the life of that service.

449 (d) THE APPLICANT HOSPITAL SHALL PROVIDE THE DEPARTMENT WITH TIMELY NOTICE OF  
450 THE PROPOSED PROJECT IMPLEMENTATION CONSISTENT WITH APPLICABLE STATUTE AND  
451 PROMULGATED RULES.

452

453 (5) Compliance with the following primary AND ELECTIVE PCI requirements FOR ALL CARDIAC  
454 CATHETERIZATION SERVICES, if applicable:

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

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

458 (c) FOR PRIMARY ONLY PCI SERVICES, The ~~The~~ hospital shall perform a minimum of 36 primary  
459 PCI procedures at the hospital in the ~~preceding~~ FIRST 12-month ~~S period~~ of operation of the service and  
460 annually thereafter.

461 (d) FOR A COMBINED PRIMARY AND ELECTIVE PCI SERVICE, THE HOSPITAL SHALL  
462 PERFORM A MINIMUM OF 200 ADULT PCI PROCEDURES AT THE HOSPITAL IN THE FIRST 12  
463 MONTHS OF OPERATION OF THE SERVICE AND ANNUALLY THEREAFTER.

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

466 (ef) The APPLICANT hospital shall participate in a data registry, administered by the Department or  
467 its designee AS A MEANS TO MEASURE QUALITY AND RISK ADJUSTED OUTCOMES WITHIN PCI  
468 SERVICES WITHOUT ON-SITE OPEN HEART SURGERY SERVICES. The Department or its designee  
469 shall require that the applicant HOSPITAL submit data on all consecutive cases of primary AND  
470 ELECTIVE PCI as is necessary to comprehensively assess and provide comparative analyses of case  
471 selection, processes and outcome of care, and trend in efficiency. The applicant HOSPITAL shall provide

472 | the required data in a format established by the Department or its designee. The applicant HOSPITAL  
473 | shall be liable for the cost of data submission and on-site reviews in order for the Department to verify  
474 | and monitor volumes and assure quality. THE APPLICANT HOSPITAL SHALL BECOME A MEMBER  
475 | OF THE DATA REGISTRY SPECIFIED BY THE DEPARTMENT UPON INITIATION OF THE SERVICE  
476 | AND CONTINUE TO PARTICIPATE ANNUALLY THEREAFTER FOR THE LIFE OF THAT SERVICE.  
477 | AT A MINIMUM, THE APPLICANT HOSPITAL SHALL REPORT THE FOLLOWING:  
478 | (i) THE NUMBER OF PATIENTS TREATED WITH AND WITHOUT STEMI,  
479 | (ii) THE PROPORTION OF PCI PATIENTS WITH EMERGENCY CABG OR REQUIRED  
480 | EMERGENT TRANSFER,  
481 | (iii) RISK AND RELIABILITY ADJUSTED PATIENT MORTALITY FOR BOTH STEMI AND NON-  
482 | STEMI PROCEDURES,  
483 | (iv) PCI APPROPRIATE USE IN ELECTIVE NON-ACUTE MI CASES, AND  
484 | (v) RATES OF AD-HOC MULTI-VESSEL PCI PROCEDURES IN THE SAME SESSION.  
485 | (g) THE APPLICANT HOSPITAL SHALL MAINTAIN A PHYSICIAN POINT OF CONTACT FOR THE  
486 | DATA REGISTRY.  
487 | (h) CATH LAB FACILITY REQUIREMENTS AND COLLABORATIVE CARDIOLOGISTS-HEART  
488 | SURGEON RELATIONSHIP REQUIREMENTS WILL CONFORM WITH ALL SCAI/ACC GUIDELINES  
489 | INCLUDING THE CONSENSUS DOCUMENT. THE APPLICANT HOSPITAL SHALL BE LIABLE FOR  
490 | THE COST OF DEMONSTRATING COMPLIANCE WITH THESE CRITERIA.  
491 | (i) THE DEPARTMENT SHALL USE THESE THRESHOLDS AND METRICS IN EVALUATING  
492 | COMPLIANCE: PERFORMANCE AT A LEVEL ABOVE 25% OF THE STATEWIDE AVERAGE ON  
493 | EACH METRIC LISTED UNDER SUBSECTION (f)(i) – (v).  
494 | (j) THE DEPARTMENT SHALL NOTIFY THOSE HOSPITALS WHO FAIL TO MEET ANY OF THE  
495 | MINIMALLY ACCEPTABLE OBJECTIVE QUALITY METRIC THRESHOLDS INCLUDING THOSE  
496 | UNDER SUBSECTION (f)(i) – (v). THE DEPARTMENT SHALL REQUIRE THESE HOSPITALS TO:  
497 | (i) SUBMIT A CORRECTIVE ACTION PLAN WITHIN THREE (3) MONTHS OF NOTIFICATION  
498 | AND  
499 | (ii) DEMONSTRATE THAT PERFORMANCE HAS IMPROVED TO MEET OR EXCEED ALL  
500 | APPLICABLE OBJECTIVE QUALITY METRIC THRESHOLDS, INCLUDING THOSE UNDER  
501 | SUBSECTION (f)(i) – (v), WITHIN TWELVE (12) MONTHS OF NOTIFICATION.  
502 |  
503 | (6) NOTHING IN THIS SECTION PROHIBITS THE DEPARTMENT FROM TAKING COMPLIANCE  
504 | ACTION UNDER MCL 333.22247.  
505 |

506 | **Section 10. Methodology for computing cardiac catheterization equivalents**

507 |  
508 | Sec. 10. The following shall be used in calculating procedure equivalents and evaluating utilization of  
509 | a cardiac catheterization service and its laboratories:  
510 |

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 services.

511 |  
512 | **Section 11. Documentation of projections**  
513 |

514       **Sec. 11. An applicant required to project volumes shall demonstrate the following as**  
515 **applicable to the proposed project:**

516  
517       (1) The applicant shall specify how the volume projections were developed. Specification of the  
518 projections shall include a description of the data source(s) used and assessment of the accuracy of the  
519 data. The Department shall determine if the projections are reasonable.

520  
521       (2) An applicant proposing to initiate a ~~primary~~ PCI service shall demonstrate and certify that the  
522 hospital treated or transferred ~~36-200 ST segment elevation AMI PCI~~ cases during the most recent 12-  
523 month period preceding the date the application was submitted to the Department. Cases may include  
524 thrombolytic eligible patients documented through pharmacy records showing the number of doses of  
525 thrombolytic therapy ordered and medical records of emergency transfers of AMI patients to an  
526 appropriate hospital for a ~~primary~~ PCI procedure.

527  
528       **Section 12. Comparative reviews; Effect on prior CON Review Standards**

529  
530       Sec. 12. Proposed projects reviewed under these standards shall not be subject to comparative  
531 review. These CON Review Standards supercede and replace the CON Review Standards for Cardiac  
532 Catheterization Services approved by the CON Commission on ~~December 15, 2014~~ MARCH 18, 2014  
533 and effective on ~~February 27, 2012~~ JUNE 2, 2014.

534

535  
536  
537 Rural Michigan counties are as follows:

538			
539	Alcona	<del>Hillsdale</del>	Oceana
540	Alger	Huron	Ogemaw
541	Antrim	Iosco	Ontonagon
542	Arenac	Iron	Osceola
543	Baraga	Lake	Oscoda
544	Charlevoix	Luce	Otsego
545	Cheboygan	Mackinac	Presque Isle
546	Clare	Manistee	Roscommon
547	Crawford	<del>Mason</del>	Sanilac
548	Emmet	<del>Montcalm</del>	Schoolcraft
549	Gladwin	Montmorency	Tuscola
550	Gogebic	<u>NEWAYGO</u>	

551  
552 Micropolitan statistical area Michigan counties are as follows:

553			
554	Allegan	<u>HILLSDALE</u>	<u>MASON</u>
555	Alpena	Houghton	Mecosta
556	Benzie	<u>IONIA</u>	Menominee
557	Branch	Isabella	<del>Midland</del>
558	Chippewa	Kalkaska	Missaukee
559	Delta	Keweenaw	St. Joseph
560	Dickinson	Leelanau	Shiawassee
561	Grand Traverse	Lenawee	Wexford
562	Gratiot	Marquette	

563  
564 Metropolitan statistical area Michigan counties are as follows:

565			
566	Barry	<del>onia</del>	<u>MONTCALM</u> <del>Newaygo</del>
567	Bay	Jackson	Muskegon
568	Berrien	Kalamazoo	Oakland
569	Calhoun	Kent	Ottawa
570	Cass	Lapeer	Saginaw
571	Clinton	Livingston	St. Clair
572	Eaton	Macomb	Van Buren
573	Genesee	<u>MIDLAND</u>	Washtenaw
574	Ingham	Monroe	Wayne

575  
576 Source:

577  
578 | 65-75 F.R., p. 82238-37245 (December 27, 2000)  
579 | Statistical Policy Office  
580 | Office of Information and Regulatory Affairs  
581 | United States Office of Management and Budget

582  
583  
584  
585

**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.