

1 **MICHIGAN DEPARTMENT OF COMMUNITY HEALTH AND HUMAN SERVICES**

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) **"ADULT CARDIAC CATHETERIZATION SERVICE" MEANS PROVIDING CARDIAC**  
23 **CATHETERIZATION SERVICES ON AN ORGANIZED, REGULAR BASIS TO PATIENTS AGE 18 AND**  
24 **ABOVE, AND FOR ELECTROPHYSIOLOGY PROCEDURES TO PATIENTS AGE 15 AND OLDER.**

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

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

40 (ed) "Cardiac catheterization service" means the provision of one or more of the following types of  
41 procedures: adult diagnostic cardiac catheterizations; adult therapeutic cardiac catheterizations; and  
42 **pediatric/CONGENITAL cardiac catheterizations.**

43 (e) **"CARDIAC CATHETERIZATION SESSION" MEANS A CONTINUOUS TIME PERIOD DURING**  
44 **WHICH A PATIENT MAY UNDERGO ONE OR MORE DIAGNOSTIC OR THERAPEUTIC CARDIAC OR**  
45 **PERIPHERAL PROCEDURES IN A CARDIAC CATHETERIZATION LABORATORY. THE TERM**  
46 **SESSION APPLIES TO BOTH ADULT AND PEDIATRIC/CONGENITAL CATHETERIZATIONS.**

47 (ef) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to  
48 Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

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

51 (h) **"COMPLEX THERAPEUTIC SESSION" MEANS A CONTINUOUS TIME PERIOD DURING**  
52 **WHICH A PATIENT UNDERGOES ONE OR MORE OF THE FOLLOWING PROCEDURES:**

53 (i) **PCI FOR CHRONIC TOTAL OCCLUSION**

54 (ii) TAVR, MITRAL/PULMONARY/TRICUSPID VALVE REPAIR OR REPLACEMENT,  
55 PARAVALVULAR LEAK CLOSURE

56 (iii) ABLATION FOR ATRIAL FIBRILLATION (AF) OR VENTRICULAR TACHYCARDIA (VT),  
57 PACEMAKER OR ICD LEAD EXTRACTION

58 (fi) "Department" means the Michigan Department of ~~Community Health~~ AND HUMAN SERVICES  
59 (MDCHHS).

60 (j) "DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURE" INCLUDES RIGHT HEART  
61 CATHETERIZATION, LEFT HEART CATHETERIZATION, CORONARY ANGIOGRAPHY, CORONARY  
62 ARTERY BYPASS GRAFT ANGIOGRAPHY, INTRACORONARY ADMINISTRATION OF DRUGS,  
63 FRACTIONAL FLOW RESERVE (FFR), INTRA-CORONARY IMAGING SUCH AS INTRAVASCULAR  
64 ULTRASOUND (IVUS), OPTICAL COHERENCE TOMOGRAPHY (OCT), OR NEAR-INFRARED  
65 SPECTROSCOPY (NIRS) WHEN PERFORMED WITHOUT A THERAPEUTIC PROCEDURE, CARDIAC  
66 BIOPSY, INTRA-CARDIAC ECHOCARDIOGRAPHY, AND ELECTROPHYSIOLOGY STUDY.

67 (gk) "Diagnostic cardiac catheterization service" means providing diagnostic cardiac catheterization  
68 procedures on an organized, regular basis in a laboratory to diagnose anatomical and/or physiological  
69 problems in the heart. ~~Procedures include the intra-coronary administration of drugs; left heart~~  
70 ~~catheterization; right heart catheterization; coronary angiography; diagnostic electrophysiology studies;~~  
71 ~~and cardiac biopsies (echo-guided or fluoroscopic).~~ A hospital that provides diagnostic cardiac  
72 catheterization services may also perform ~~implantations of cardiac permanent pacemakers and ICD~~  
73 ~~devices~~ IMPLANTATION (THERAPEUTIC PROCEDURES).

74 (l) "DIAGNOSTIC CARDIAC CATHETERIZATION SESSION" MEANS A CONTINUOUS TIME  
75 PERIOD DURING WHICH A PATIENT MAY UNDERGO ONE OR MORE DIAGNOSTIC CARDIAC  
76 CATHETERIZATION PROCEDURES.

77 (m) "DIAGNOSTIC PERIPHERAL PROCEDURE" INCLUDES ANGIOGRAPHY OR HEMODYNAMIC  
78 MEASUREMENTS IN THE ARTERIAL OR VENOUS CIRCULATION (EXCLUDING THE HEART).

79 (n) "DIAGNOSTIC PERIPHERAL SESSION" MEANS A CONTINUOUS TIME PERIOD DURING  
80 WHICH A PATIENT MAY UNDERGO ONE OR MORE DIAGNOSTIC PERIPHERAL PROCEDURES IN  
81 A CARDIAC CATHETERIZATION LABORATORY.

82 (ho) "Elective percutaneous coronary intervention (PCI)" means a PCI procedure performed on a non-  
83 emergent basis.

84 (ip) "Elective PCI services without on-site open heart surgery (OHS)" means performing PCI,  
85 ~~percutaneous transluminal coronary angioplasty (PTCA), and coronary stent implantation on an~~  
86 organized, regular basis in a hospital having a diagnostic cardiac catheterization service and a primary  
87 PCI service but not having OHS on-site and adhering to patient selection as outlined in the  
88 SCAI/ACC/AHA Expert Consensus Document: 2014 Update on PCI Without On-Site Surgical Backup  
89 and published in ~~circulation~~ Circulation 2014, 129:2610-2626 and its update or further guideline changes.  
90 A HOSPITAL THAT PROVIDES ELECTIVE PCI WITHOUT ON-SITE OHS MAY ALSO PERFORM  
91 RIGHT-SIDED CARDIAC ABLATION PROCEDURES INCLUDING RIGHT ATRIAL FLUTTER, AV  
92 REENTRY, AV NODE REENTRY, RIGHT ATRIAL TACHYCARDIA, AND AV NODE ABLATION.

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

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

97 (ls) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C. 1396 to  
98 1396g and 1396i to 1396u.

99 (mt) "Pediatric/CONGENITAL cardiac catheterization service" means providing cardiac AND  
100 ELECTROPHYSIOLOGY catheterization services on an organized, regular basis to infants and children  
101 ages 18 and below, ~~except for electrophysiology studies that are offered and provided to infants and~~  
102 ~~children ages 14 and below, and others-~~ PATIENTS BORN with congenital heart disease as defined by  
103 the ICD-9-CM codes (See Appendix B for ICD-10-CM Codes) of 426.7 (anomalous atrioventricular  
104 excitation), 427.0 (cardiac dysrhythmias), and 745.0 through 747.99 (bulbus cordis anomalies and  
105 anomalies of cardiac septal closure, other congenital anomalies of heart, and other congenital anomalies  
106 of circulatory system).

107 (u) "PERCUTANEOUS CORONARY INTERVENTION" (PCI) MEANS A THERAPEUTIC CARDIAC  
108 CATHETERIZATION PROCEDURE TO RESOLVE ANATOMIC AND/OR PHYSIOLOGIC PROBLEMS IN  
109 THE CORONARY ARTERIES OF THE HEART. A PCI SESSION MAY INCLUDE SEVERAL  
110 PROCEDURES INCLUDING BALLOON ANGIOPLASTY, ATHERECTOMY, LASER, STENT  
111 IMPLANTATION AND THROMBECTOMY. THE TERM DOES NOT INCLUDE THE INTRACORONARY  
112 ADMINISTRATION OF DRUGS, FFR OR IVUS WHERE THESE ARE THE ONLY PROCEDURES  
113 PERFORMED.

114 (v) "PERIPHERAL CATHETERIZATION SESSION" MEANS A CONTINUOUS TIME PERIOD  
115 DURING WHICH A PATIENT MAY UNDERGO ONE OR MORE DIAGNOSTIC OR THERAPEUTIC  
116 PROCEDURES IN THE ARTERIAL OR VENOUS CIRCULATION (EXCLUDING THE HEART) WHEN  
117 PERFORMED IN A CARDIAC CATHETERIZATION LABORATORY.

118 (aw) "Primary percutaneous coronary intervention (PCI)" means a PCI performed on an EMERGENT  
119 BASIS ON A acute myocardial infarction (AMI) patient with confirmed ST-SEGMENT elevation, or new  
120 left bundle branch block on an emergent basis, ECG EVIDENCE OF TRUE POSTERIOR MI, OR  
121 CARDIOGENIC SHOCK.

122 (ex) "Primary PCI service without on-site OHS" means performing primary PCI on an emergent basis  
123 in a hospital having a diagnostic cardiac catheterization service. A HOSPITAL THAT PROVIDES  
124 PRIMARY PCI WITHOUT ON-SITE OHS MAY ALSO PERFORM RIGHT-SIDED CARDIAC ABLATION  
125 PROCEDURES INCLUDING RIGHT ATRIAL FLUTTER, AV REENTRY, AV NODE REENTRY, RIGHT  
126 ATRIAL TACHYCARDIA, AND AV NODE ABLATION.

127 (py) "Procedure equivalent" means a unit of measure that reflects the relative average length of time  
128 one patient spends in one session in a CARDIAC CATHETERIZATION laboratory based on the type of  
129 procedures being performed. IF A DIAGNOSTIC AND THERAPEUTIC PROCEDURE IS PERFORMED  
130 IN THE SAME SESSION, THE HIGHER PROCEDURE EQUIVALENT WEIGHTING WILL BE USED TO  
131 EVALUATE UTILIZATION.

132 (z) "STRUCTURAL HEART PROCEDURE" MEANS A THERAPEUTIC CARDIAC  
133 CATHETERIZATION PROCEDURE TO RESOLVE ANATOMIC AND/OR PHYSIOLOGIC PROBLEMS  
134 OF THE HEART VALVES OR CHAMBERS. PROCEDURES INCLUDE: BALLOON VALVULOPLASTY,  
135 BALLOON ATRIAL SEPTOSTOMY, TRANSCATHETER VALVE REPAIR, TRANSCATHETER VALVE  
136 IMPLANTATION, PARAVALULAR LEAK CLOSURE, LEFT ATRIAL APPENDAGE OCCLUSION,  
137 PFO/ASD/VSD/PDA CLOSURE, ALCOHOL ABLATION OF CARDIAC TISSUE, EMBOLIZATION OF  
138 CORONARY FISTULAE AND ABNORMAL VASCULAR CONNECTIONS IN THE HEART.

139 (qaa) "Therapeutic cardiac catheterization service" means providing therapeutic cardiac  
140 catheterizations on an organized, regular basis in a laboratory to treat and resolve anatomical and/or  
141 physiological problems in the heart. Procedures include PCI, PTCA, atherectomy, stent, laser, cardiac  
142 valvuloplasty, balloon atrial septostomy, catheter ablation, cardiac permanent pacemaker, ICD device  
143 implantations, transcatheter valve, other structural heart disease procedures, PTCA with coronary stent  
144 implantation and left sided arrhythmia therapeutic procedures. The term does not include the intra  
145 coronary administration of drugs where that is the only therapeutic intervention.

146 (bb) "THERAPEUTIC CARDIAC CATHETERIZATION SESSION" MAY INCLUDE: PCI (ELECTIVE,  
147 EMERGENT), PERICARDIOCENTESIS, PERMANENT PACEMAKER IMPLANTATION, ICD  
148 IMPLANTATION (ENDOVASCULAR OR SUBCUTANEOUS), PACEMAKER OR ICD GENERATOR  
149 CHANGE, PACEMAKER OR ICD LEAD REVISION, CARDIAC ABLATION, AND/OR STRUCTURAL  
150 HEART PROCEDURE. THIS ALSO INCLUDES IMPLANTATION OF A CIRCULATORY SUPPORT  
151 DEVICE SUCH AS IABP, IMPELLA, ECMO OR TANDEMHEART WHERE THIS IS THE ONLY  
152 THERAPEUTIC PROCEDURE. WHEN PCI IS PERFORMED IN MORE THAN ONE CORONARY  
153 ARTERY DURING THE SAME SETTING, THIS IS COUNTED AS ONE SESSION.

154 (cc) "THERAPEUTIC PERIPHERAL PROCEDURE" MEANS A THERAPEUTIC CATHETERIZATION  
155 PROCEDURE TO RESOLVE ANATOMIC AND/OR PHYSIOLOGIC PROBLEMS IN THE ARTERIAL OR  
156 VENOUS CIRCULATION (EXCLUDING THE HEART). PROCEDURES MAY INCLUDE  
157 PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA), ATHERECTOMY, DRUG ELUTING  
158 BALLOON, LASER, STENT IMPLANTATION, IVC FILTER IMPLANTATION OR RETRIEVAL,  
159 CATHETER-DIRECTED ULTRASOUND/THROMBOLYSIS, AND THROMBECTOMY.

160 (dd) "THERAPEUTIC PERIPHERAL SESSION" MEANS A CONTINUOUS TIME PERIOD DURING  
161 WHICH A PATIENT MAY UNDERGO ONE OR MORE THERAPEUTIC PERIPHERAL PROCEDURES IN  
162 A CARDIAC CATHETERIZATION LABORATORY.

163 (ee) "THERAPEUTIC PEDIATRIC/CONGENITAL CARDIAC CATHETERIZATION SESSION" MAY  
164 INCLUDE: STRUCTURAL HEART PROCEDURE (AS LISTED ABOVE), PULMONARY ARTERY  
165 ANGIOPLASTY/STENT IMPLANTATION, PULMONARY VALVE PERFORATION,  
166 ANGIOPLASTY/STENT IMPLANTATION FOR AORTIC COARCTATION, CARDIAC ABLATION,  
167 PACEMAKER/ICD IMPLANTATION, AND PCI.

168  
169 (2) Terms defined in the Code have the same meanings when used in these standards.  
170

### 171 Section 3. Requirements to initiate cardiac catheterization services 172

173 Sec. 3. An applicant **HOSPITAL** proposing to initiate cardiac catheterization services shall  
174 demonstrate the following, as applicable to the proposed project.  
175

176 (1) An applicant **HOSPITAL** proposing to initiate an adult diagnostic cardiac catheterization service  
177 shall demonstrate the following as applicable to the proposed project:

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

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

188 (c) An applicant **HOSPITAL** proposing to initiate a diagnostic cardiac catheterization service with two  
189 or more laboratories shall project a minimum of 1,000 procedure equivalents per laboratory that includes  
190 300 procedure equivalents in the category of diagnostic cardiac catheterization procedures based on data  
191 from the most recent 12-month period preceding the date the application was submitted to the  
192 Department.  
193

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

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

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

204 (c) The applicant **HOSPITAL** has applied to provide adult OHS services at the hospital. The  
205 applicant **HOSPITAL** must be approved for an adult OHS service in order to be approved for an adult  
206 therapeutic cardiac catheterization service.

207 (d) The applicant **HOSPITAL** shall project a minimum of 300 procedure equivalents in the category of  
208 adult therapeutic cardiac catheterizations based on data from the most recent 12-month period preceding  
209 the date the application was submitted to the Department.  
210

211 (3) An applicant **HOSPITAL** proposing to initiate a pediatric/**CONGENITAL** cardiac catheterization  
212 service shall demonstrate the following:

- 213 (a) The applicant **HOSPITAL** has a board certified pediatric cardiologist with training in  
214 pediatric/**CONGENITAL** catheterization procedures to direct the pediatric catheterization laboratory.  
215 (b) The applicant **HOSPITAL** has standardized biplane equipment as defined in the most current  
216 American Academy of Pediatrics (AAP) and American College of Cardiology Foundation (ACCF)/Society  
217 for Cardiovascular Angiography and Interventions (SCAI) guidelines for pediatric cardiovascular centers.  
218 (c) The applicant **HOSPITAL** has on-site pediatric and neonatal ICU as outlined in the most current  
219 AAP and ACCF/SCAI guidelines above.  
220 (d) The applicant **HOSPITAL** has applied to provide pediatric OHS services at the hospital. The  
221 applicant **HOSPITAL** must be approved for a pediatric OHS service in order to be approved for  
222 pediatric/**CONGENITAL** cardiac catheterization services.  
223 (e) The applicant **HOSPITAL** has on-site pediatric extracorporeal membrane oxygenation (ECMO)  
224 capability as outlined in the most current ACCF/SCAI guidelines.  
225 (f) A pediatric/**CONGENITAL** cardiac catheterization service shall have a quality assurance plan as  
226 outlined in the most current ACCF/SCAI guidelines.  
227 (g) The applicant **HOSPITAL** shall project a minimum of 600 procedure equivalents in the category of  
228 pediatric/**CONGENITAL** cardiac catheterizations based on data from the most recent 12-month period  
229 preceding the date the application was submitted to the Department.  
230

#### 231 **Section 4. Requirements to initiate primary or elective PCI Services without on-site OHS services**

232

233 **Sec. 4.** An applicant **HOSPITAL** proposing to initiate primary or elective PCI services without on-site  
234 OHS services shall demonstrate the following:  
235

236 (1) The applicant **HOSPITAL** operates an adult diagnostic cardiac catheterization service that has  
237 performed a minimum of 500 procedure equivalents that includes 400 procedure equivalents in the  
238 category of cardiac catheterization procedures during the most recent 12 months preceding the date the  
239 application was submitted to the Department.  
240

241 (2) The applicant **HOSPITAL** has at least two interventional cardiologists to perform the PCI  
242 procedures and each cardiologist has performed at least 50 PCI sessions annually as the primary  
243 operator during the most recent 24-month period preceding the date the application was submitted to the  
244 Department.  
245

246 (3) The nursing and technical catheterization laboratory staff: are experienced in handling acutely ill  
247 patients and comfortable with interventional equipment; have acquired experience in dedicated  
248 interventional laboratories at an OHS hospital; and participate in an un-interrupted 24-hour, 365-day call  
249 schedule. Competency shall be documented annually.  
250

251 (4) The laboratory or laboratories are equipped with optimal imaging systems, resuscitative  
252 equipment, and intra-aortic balloon pump (IABP) support, and stocked with a broad array of interventional  
253 equipment.  
254

255 (5) The cardiac care unit nurses are adept in hemodynamic monitoring and IABP management.  
256 Competency shall be documented annually.  
257

258 (6) A written agreement with an OHS hospital that includes all of the following:

259 (a) Involvement in credentialing criteria and recommendations for physicians approved to perform  
260 PCI procedures.

261 (b) Provision for ongoing cross-training for professional and technical staff involved in the provision of  
262 PCI to ensure familiarity with interventional equipment. Competency shall be documented annually.

263 (c) Provision for ongoing cross training for emergency department, catheterization laboratory, and  
264 critical care unit staff to ensure experience in handling the high acuity status of PCI patient candidates.  
265 Competency shall be documented annually.

266 (d) Regularly held joint cardiology/cardiac surgery conferences to include review of all PCI cases.



267 (e) Development and ongoing review of patient selection criteria for PCI patients and implementation  
268 of those criteria.

269 (f) A mechanism to provide for appropriate patient transfers between facilities and an agreed plan for  
270 prompt care.

271 (g) Written protocols, signed by the applicant HOSPITAL and the OHS hospital, for the immediate  
272 transfer within 60 minutes travel time from the cardiac catheterization laboratory to evaluation on site in  
273 the OHS hospital, of patients requiring surgical evaluation and/or intervention 365 days a year. If the  
274 applicant HOSPITAL meets the requirements of subsection (13)(c), then the OHS hospital can be more  
275 than 60 minutes travel time from the proposed site. The protocols shall be reviewed and tested on a  
276 quarterly basis.

277 (h) Consultation on facilities, equipment, staffing, ancillary services, and policies and procedures for  
278 the provision of interventional procedures.

279  
280 (7) A written protocol must be established and maintained for case selection for the performance of  
281 PCI.

282  
283 (8) A system to ensure prompt and efficient identification of potential primary PCI patients and rapid  
284 transfer from the emergency department to the cardiac catheterization laboratory must be developed and  
285 maintained so that door-to-balloon targets are met.

286  
287 (9) At least two physicians credentialed to perform PCI must commit to functioning as a coordinated  
288 group willing and able to provide this service at the hospital on a 24-hour per day, 365 day per year call  
289 schedule, with ability to be on-site and available to operate within 30 minutes of identifying the need for  
290 primary PCI. These physicians must be credentialed at the facility and actively collaborate with  
291 administrative and clinical staff in establishing and implementing protocols, call schedules, and quality  
292 assurance procedures pertaining to PCI designed to meet the requirements for this certification and in  
293 keeping with the current guidelines for the provision of PCI without on-site OHS services promulgated by  
294 the American College of Cardiology and American Heart Association.

295  
296 (10) The applicant hospital shall participate in a data registry administered by the Department or its  
297 designee as a means to measure quality and risk adjusted outcomes within PCI services without on-site  
298 OHS services, and the applicant hospital shall identify a physician point of contact for the data registry.

299  
300 (11) Cath lab facility requirements and collaborative cardiologists-heart surgeon relationship  
301 requirements shall conform to all SCAI/ACC Guidelines for PCI Services Without On-Site OHS including  
302 the SCAI/ACC/AHA Expert Consensus Document. The applicant hospital shall be liable for the cost of  
303 demonstrating compliance with these criteria in their application.

304  
305 (12) The applicant HOSPITAL shall project the following based on data from the most recent 12-  
306 month period preceding the date the application was submitted to the Department, as applicable.

307 (a) If the applicant HOSPITAL is applying for a primary PCI service without open heart surgery, the  
308 applicant HOSPITAL shall project a minimum of 36 primary PCI procedures per year.

309 (b) If the applicant HOSPITAL is applying for an elective PCI service without on-site OHS, the  
310 applicant HOSPITAL shall project a minimum of 200 PCI procedures per year.

311  
312 (13) If the applicant HOSPITAL is applying for an elective PCI service without on-site OHS, the  
313 applicant HOSPITAL also shall demonstrate the following:

314 (a) The applicant HOSPITAL operated a primary PCI service for at least one year prior to the date of  
315 application.

316 (b) The applicant HOSPITAL submitted data to a data registry administered by the Department or its  
317 designee and been found to have acceptable performance as compared to the registry benchmarks for  
318 the most recent 12 months prior to the date of application.

319 (c) If the applicant HOSPITAL was not approved as a primary PCI service prior to September 14,  
320 2015, then, in addition, the applicant HOSPITAL shall demonstrate that there is no PCI or OHS service  
321 within 60 radius miles or 60 minutes travel time from the proposed site.

322  
323 (14) If the applicant **HOSPITAL** is currently providing OHS services and therapeutic cardiac  
324 catheterization services and is proposing to discontinue OHS services and therapeutic cardiac  
325 catheterization services, then the applicant **HOSPITAL** shall apply to initiate primary or elective PCI  
326 services without on-site OHS using this section. The applicant **HOSPITAL** shall demonstrate all of the  
327 requirements in this section except for subsection (13) and is subject to all requirements in Section 10.  
328

### 329 **Section 5. Requirements to replace an existing cardiac catheterization service or laboratory**

330

331 Sec. 5. Replacing a cardiac catheterization laboratory means a change in the angiography x-ray  
332 equipment or a relocation of the service to a new site. The term does not include a change in any of the  
333 other equipment or software used in the laboratory. An applicant **HOSPITAL** proposing to replace a  
334 cardiac catheterization laboratory or service shall demonstrate the following as applicable to the proposed  
335 project:  
336

337 (1) An applicant **HOSPITAL** proposing to replace cardiac catheterization laboratory equipment shall  
338 demonstrate the following:

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

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

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

345 (b) The existing angiography x-ray equipment to be replaced will be removed from service on or  
346 before beginning operation of the replacement equipment.  
347

348 (2) An applicant **HOSPITAL** proposing to replace a cardiac catheterization service to a new site shall  
349 demonstrate the following:

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

351 (b) The applicant **HOSPITAL** has performed the following during the most recent 12-month period  
352 preceding the date the application was submitted to the Department as applicable to the proposed  
353 project:

354 (i) A minimum of 300 procedure equivalents in the category of adult diagnostic cardiac  
355 catheterization procedures.

356 (ii) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac  
357 catheterization procedures.

358 (iii) A minimum of 600 procedure equivalents in the category of pediatric/**CONGENITAL** cardiac  
359 catheterization procedures.

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

362 (v) A minimum of 750 procedure equivalents for a hospital in a metropolitan county with one  
363 laboratory.

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

366 (c) The existing cardiac catheterization service has been in operation for at least 36 months as of the  
367 date the application has been submitted to the Department.  
368

369 (3) **AN APPLICANT HOSPITAL PROPOSING TO REPLACE A CARDIAC CATHETERIZATION**  
370 **SERVICE TO A NEW SITE SIMULTANEOUSLY WITH AN OPEN HEART SURGERY SERVICE SHALL**  
371 **DEMONSTRATE THE FOLLOWING:**

372 (a) **THE EXISTING CARDIAC CATHETERIZATION SERVICE TO BE REPLACED HAS BEEN IN**  
373 **OPERATION FOR AT LEAST 36 MONTHS AS OF THE DATE AN APPLICATION IS SUBMITTED TO**  
374 **THE DEPARTMENT.**

375 (b) THE PROPOSED NEW SITE IS A HOSPITAL THAT IS OWNED BY, IS UNDER COMMON  
376 CONTROL OF, OR HAS A COMMON PARENT AS THE APPLICANT HOSPITAL.

377 (c) THE PROPOSED NEW SITE IS THE SAME SITE WHERE THE EXISTING OHS SERVICE IS  
378 TO BE LOCATED WHICH IS WITHIN THE SAME PLANNING AREA AS THE OHS SERVICE AND  
379 WITHIN 5 MILES OF THE EXISTING OHS AND CARDIAC CATHETERIZATION SERVICE IF LOCATED  
380 IN A METROPOLITAN STATISTICAL AREA COUNTY OR WITHIN 10 MILES OF THE EXISTING OHS  
381 AND CARDIAC CATHETERIZATION SERVICE IF LOCATED IN A RURAL OR MICROPOLITAN  
382 STATISTICAL AREA COUNTY.

383 (d) THE EXISTING CARDIAC CATHETERIZATION SERVICE TO BE RELOCATED PERFORMED  
384 AT LEAST THE APPLICABLE MINIMUM NUMBER OF CARDIAC CATHETERIZATION CASES SET  
385 FORTH IN SECTION 10 AS OF THE DATE AN APPLICATION IS DEEMED SUBMITTED BY THE  
386 DEPARTMENT.

### 387 388 **Section 6. Requirements to expand a cardiac catheterization service**

389  
390 Sec. 6. An applicant HOSPITAL proposing to add a laboratory to an existing cardiac catheterization  
391 service shall demonstrate the following:

392  
393 (1) The applicant HOSPITAL has performed the following during the most recent 12-month period  
394 preceding the date the application was submitted to the Department as applicable to the proposed  
395 project:

396 (a) A minimum of 300 procedure equivalents in the category of adult diagnostic cardiac  
397 catheterization procedures.

398 (b) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac  
399 catheterization procedures.

400 (c) A minimum of 600 procedure equivalents in the category of pediatric/CONGENITAL cardiac  
401 catheterization procedures.

402  
403 (2) The applicant HOSPITAL has performed a minimum of 1,400 procedure equivalents per existing  
404 and approved laboratories during the most recent 12-month period preceding the date the application was  
405 submitted to the Department.

### 406 407 **Section 7. Requirements to acquire a cardiac catheterization service**

408  
409 Sec. 7. Acquiring a cardiac catheterization service and its laboratories means obtaining possession  
410 and control by contract, ownership, lease or other comparable arrangement or renewal of a lease for  
411 existing angiography x-ray equipment. An applicant HOSPITAL proposing to acquire a cardiac  
412 catheterization service or renew a lease for equipment shall demonstrate the following as applicable to  
413 the proposed project:

414  
415 (1) An applicant HOSPITAL proposing to acquire a cardiac catheterization service shall demonstrate  
416 the following:

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

418 (b) An application for the first acquisition of an existing cardiac catheterization service after February  
419 27, 2012 shall not be required to be in compliance with the applicable volume requirements in Section 10.  
420 The cardiac catheterization service shall be operating at the applicable volumes set forth in the project  
421 delivery requirements in the second 12 months of operation of the service by the applicant HOSPITAL  
422 and annually thereafter.

423 (c) For any application proposing to acquire an existing cardiac catheterization service, except the  
424 first application approved pursuant to subsection (b), an applicant HOSPITAL shall be required to  
425 document that the cardiac catheterization service to be acquired is operating in compliance with the  
426 volume requirements set forth in section 10 of these standards applicable to an existing cardiac  
427 catheterization service on the date the application is submitted to the Department.



429 (2) An applicant **HOSPITAL** proposing to renew a lease for existing angiography x-ray equipment  
430 shall demonstrate the renewal of the lease is more cost effective than replacing the equipment.  
431

### 432 **Section 8. Requirements for a hybrid operating room/cardiac catheterization laboratory (OR/CCL)** 433

434 Sec. 8. A hybrid OR/CCL means an operating room located on a sterile corridor and equipped with an  
435 angiography system permitting minimally invasive procedures of the heart and blood vessels with full  
436 anesthesia capabilities. An applicant **HOSPITAL** proposing to add one or more hybrid OR/CCLs at an  
437 existing cardiac catheterization service shall demonstrate each of the following:  
438

439 (1) The applicant **HOSPITAL** operates an OHS service which is in full compliance with the current  
440 CON Review Standards for OHS Services.  
441

442 (2) The applicant operates a therapeutic cardiac catheterization program which is in full compliance  
443 with section **S 53(2) AND 10(4)** of these standards.  
444

445 (3) If the hybrid OR/CCL(s) represents an increase in the number of cardiac catheterization laboratories  
446 at the facility, the applicant **HOSPITAL** is in compliance with Section 6 of these standards.  
447

448 (4) If the hybrid OR/CCL(s) represents conversion of an existing cardiac catheterization laboratory(s),  
449 the applicant **HOSPITAL** is in compliance with the provisions of Section 5, if applicable.  
450

451 (5) The applicant **HOSPITAL** meets the applicable requirements of the CON Review Standards for  
452 Surgical Services.  
453

454 (6) Each case performed in a hybrid OR/CCL shall be included either in the surgical volume or the  
455 therapeutic cardiac catheterization volume of the facility. No case shall be counted more than once.  
456

457 (7) For each hybrid OR/CCL, a facility shall have 0.5 excluded from its inventory of cardiac  
458 catheterization laboratories for the purposes of computing the procedure equivalents per room. A facility  
459 will not be limited to the number of hybrid OR/CCLs within a single licensed facility.  
460

### 461 **Section 9. Requirement for Medicaid participation** 462

463 Sec. 9. An applicant **HOSPITAL** shall provide verification of Medicaid participation at the time the  
464 application is submitted to the Department. An applicant **HOSPITAL** that is initiating a new service or is a  
465 new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be  
466 provided to the Department within six (6) months from the offering of services if a CON is approved.  
467

### 468 **Section 10. Project delivery requirements and terms of approval for all applicants** 469

470 Sec. 10. An applicant **HOSPITAL** shall agree that, if approved, the cardiac catheterization service and  
471 all existing and approved laboratories shall be delivered in compliance with the following terms of  
472 approval:  
473

474 (1) Compliance with these standards.  
475

476 (2) Compliance with the following quality assurance standards:

477 (a) Cardiac catheterization procedures shall be performed in a cardiac catheterization laboratory  
478 located within a hospital, and have within, or immediately available to the room, dedicated emergency  
479 equipment to manage cardiovascular emergencies.

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

482 (c) The medical staff and governing body shall receive and review at least annual reports describing  
483 the activities of the cardiac catheterization service including complication rates, morbidity and mortality,  
484 success rates and the number of procedures performed.

485 (d) EACH PHYSICIAN CREDENTIALLED BY A HOSPITAL TO PERFORM DIAGNOSTIC LEFT-  
486 HEART CATHETERIZATION AND/OR CORONARY ANGIOGRAPHY MUST PERFORM, AS THE  
487 PRIMARY OPERATOR, AN AVERAGE OF AT LEAST 50 DIAGNOSTIC CARDIAC CATHETERIZATION  
488 SESSIONS INVOLVING A LEFT-HEART CATHETERIZATION OR CORONARY ANGIOGRAPHY PER  
489 YEAR AVERAGED OVER THE MOST RECENT 2 YEARS STARTING IN THE SECOND 12 MONTHS  
490 AFTER BEING CREDENTIALLED. THIS TWO YEAR AVERAGE WILL BE EVALUATED ON A ROLLING  
491 BASIS ANNUALLY THEREAFTER. THE ANNUAL CASE LOAD FOR A PHYSICIAN MEANS A  
492 CARDIAC CATHETERIZATION SESSION IN WHICH THAT PHYSICIAN PERFORMED, AS THE  
493 PRIMARY OPERATOR, AT LEAST ONE LEFT-HEART CATHETERIZATION OR CORONARY  
494 ANGIOGRAPHY, IN ANY COMBINATION OF HOSPITALS. PHYSICIANS FALLING BELOW THIS  
495 VOLUME REQUIREMENT MUST BE PLACED ON A FOCUSED PROFESSIONAL PRACTICE  
496 EVALUATION (FPPE) PLAN, WHICH MUST INCLUDE AN INDEPENDENT REVIEW OF ALL  
497 DIAGNOSTIC CARDIAC CATHETERIZATION SESSIONS BY AN APPROPRIATE DESIGNEE, TO  
498 ENSURE QUALITY OUTCOMES ARE MAINTAINED. IN THE EVENT A PHYSICIAN DOES NOT  
499 PERFORM CARDIAC CATHETERIZATION PROCEDURES ON A TEMPORARY OR PERMANENT  
500 BASIS FOR A PERIOD OF 3 MONTHS OR MORE, THE PHYSICIAN DIAGNOSTIC PROCEDURE  
501 VOLUME WILL BE ANNUALIZED ON THE 24 MONTH PERIOD PRECEDING THE ABSENCE. WHEN A  
502 DIAGNOSTIC CARDIAC CATHETERIZATION SESSION AND AD HOC THERAPEUTIC CARDIAC  
503 CATHETERIZATION SESSION ARE PERFORMED TOGETHER, DIAGNOSTIC AND THERAPEUTIC  
504 SESSIONS ARE COUNTED SEPARATELY FOR THE PURPOSES OF THIS SUBSECTION. IF A  
505 PHYSICIAN IS DOING RIGHT HEART ONLY PROCEDURES, THEN THEY ARE NOT REQUIRED TO  
506 MEET THIS VOLUME REQUIREMENT. PHYSICIANS WHO ARE CREDENTIALLED BY A HOSPITAL  
507 TO PERFORM ADULT THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES ARE NOT  
508 REQUIRED TO MEET THE VOLUME REQUIREMENT FOR DIAGNOSTIC CARDIAC  
509 CATHETERIZATION SESSIONS.

510 (e) Each physician credentialed by a hospital to perform adult therapeutic cardiac catheterization  
511 procedures shall perform, as the primary operator, a ~~N minimum~~ AVERAGE of AT LEAST 50 adult  
512 therapeutic cardiac catheterization ~~procedures-SESSIONS~~ per year AVERAGED OVER THE MOST  
513 RECENT TWO YEARS STARTING in the second 12 months after being credentialed. THIS TWO YEAR  
514 AVERAGE WILL BE EVALUATED ON A ROLLING BASIS ~~to and~~ annually thereafter. The annual case  
515 load for a physician means adult therapeutic cardiac catheterization ~~procedures-SESSIONS~~ performed by  
516 that physician in any combination of hospitals. PHYSICIANS FALLING BELOW THIS VOLUME  
517 REQUIREMENT MUST BE PLACED ON A FOCUSED PROFESSIONAL PRACTICE EVALUATION  
518 (FPPE) PLAN, WHICH MUST INCLUDE AN INDEPENDENT REVIEW OF ALL THERAPEUTIC  
519 CARDIAC CATHETERIZATION SESSIONS BY AN APPROPRIATE DESIGNEE, TO ENSURE QUALITY  
520 OUTCOMES ARE MAINTAINED. IN THE EVENT A PHYSICIAN DOES NOT PERFORM CARDIAC  
521 CATHETERIZATION PROCEDURES ON A TEMPORARY OR PERMANENT BASIS FOR A PERIOD OF  
522 3 MONTHS OR MORE, THE PHYSICIAN THERAPEUTIC PROCEDURE VOLUME WILL BE  
523 ANNUALIZED ON THE 24 MONTH PERIOD PRECEDING THE ABSENCE. WHEN A DIAGNOSTIC  
524 CARDIAC CATHETERIZATION SESSION AND AD HOC THERAPEUTIC CARDIAC  
525 CATHETERIZATION SESSION ARE PERFORMED TOGETHER, DIAGNOSTIC AND THERAPEUTIC  
526 SESSIONS ARE COUNTED SEPARATELY FOR THE PURPOSES OF THIS SUBSECTION (THIS  
527 INCLUDES INTERVENTIONAL CARDIOLOGISTS AND ELECTROPHYSIOLOGISTS). FOR  
528 INTERVENTIONAL CARDIOLOGISTS, THE THERAPEUTIC SESSION VOLUME EXCLUDES  
529 PACEMAKER AND ICD IMPLANTATION. FOR ELECTROPHYSIOLOGISTS, PACEMAKER AND ICD  
530 IMPLANTS PERFORMED IN AN OPERATING ROOM MAY ALSO BE COUNTED TOWARD THE  
531 PHYSICIAN THERAPEUTIC VOLUME.

532 (ef) Each physician credentialed by a hospital to perform pediatric/CONGENITAL cardiac  
533 catheterizations shall perform, as the primary operator, a ~~N minimum~~ AVERAGE of AT LEAST 50  
534 pediatric/CONGENITAL cardiac catheterization ~~procedures-SESSIONS~~ per year AVERAGED OVER THE  
535 MOST RECENT 2 YEARS STARTING in the second 12 months after being credentialed. THIS TWO

536 YEAR AVERAGE WILL BE EVALUATED ON A ROLLING BASIS and annually thereafter. The annual  
537 case load for a physician means pediatric/CONGENITAL cardiac catheterization procedures SESSIONS  
538 performed by that physician in any combination of hospitals. PHYSICIANS FALLING BELOW THIS  
539 VOLUME REQUIREMENT MUST BE PLACED ON A FOCUSED PROFESSIONAL PRACTICE  
540 EVALUATION (FPPE) PLAN, WHICH MUST INCLUDE AN INDEPENDENT REVIEW OF ALL CARDIAC  
541 CATHETERIZATION SESSIONS BY AN APPROPRIATE DESIGNEE, TO ENSURE QUALITY  
542 OUTCOMES ARE MAINTAINED. IN THE EVENT A PHYSICIAN DOES NOT PERFORM CARDIAC  
543 CATHETERIZATION PROCEDURES ON A TEMPORARY OR PERMANENT BASIS FOR A PERIOD OF  
544 3 MONTHS OR MORE, THE PHYSICIAN THERAPEUTIC PROCEDURE VOLUME WILL BE  
545 ANNUALIZED ON THE 24 MONTH PERIOD PRECEDING THE ABSENCE.

546 (fg) An adult diagnostic cardiac catheterization service shall have a minimum of two appropriately  
547 trained physicians on its active hospital staff MEETING THE FOLLOWING CRITERIA. The Department  
548 may accept other evidence or shall consider it appropriate training if the staff physicians:

549 (i) are trained consistent with the recommendations of the American College of Cardiology;  
550 (ii) are credentialed by the hospital to perform adult diagnostic cardiac catheterizations; and  
551 (iii) have each performed a minimum of 100 adult diagnostic cardiac catheterizations SESSIONS in  
552 the preceding 12 months. THE ANNUAL CASE LOAD FOR A PHYSICIAN MEANS A CARDIAC  
553 CATHETERIZATION SESSION IN WHICH THAT PHYSICIAN PERFORMED, AS THE PRIMARY  
554 OPERATOR, AT LEAST ONE DIAGNOSTIC CARDIAC CATHETERIZATION, IN ANY COMBINATION  
555 OF HOSPITALS.

556 (gh) An adult therapeutic cardiac catheterization service shall have a minimum of two appropriately  
557 trained physicians on its active hospital staff MEETING THE FOLLOWING CRITERIA. The Department  
558 may accept other evidence or shall consider it appropriate training if the staff physicians:

559 (i) are trained consistent with the recommendations of the American College of Cardiology;  
560 (ii) are credentialed by the hospital to perform adult therapeutic cardiac catheterizations; and  
561 (iii) have each performed a minimum of 50 adult therapeutic cardiac catheterization procedures  
562 SESSIONS in the preceding 12 months. THE ANNUAL CASE LOAD FOR A PHYSICIAN MEANS A  
563 CARDIAC CATHETERIZATION SESSION IN WHICH THAT PHYSICIAN PERFORMED, AS THE  
564 PRIMARY OPERATOR, AT LEAST ONE THERAPEUTIC CARDIAC CATHETERIZATION, IN ANY  
565 COMBINATION OF HOSPITALS.

566 (hi) A pediatric/CONGENITAL cardiac catheterization service shall have an appropriately trained AT  
567 LEAST ONE physician on its active hospital staff MEETING THE FOLLOWING CRITERIA. The  
568 Department may accept other evidence or shall consider it appropriate training if the staff physician:

569 (i) is board certified or board eligible in pediatric cardiology by the American Board of Pediatrics;  
570 (ii) is credentialed by the hospital to perform pediatric/CONGENITAL cardiac catheterizations; and  
571 (iii) has trained consistently with the recommendations of the American College of Cardiology.

572 (ij) A pediatric/CONGENITAL cardiac catheterization service shall maintain a quality assurance plan  
573 as outlined in the most current ACCF/SCAI Guidelines.

574 (jk) A cardiac catheterization service shall be directed by an appropriately trained physician. The  
575 Department shall consider appropriate training of the director if the physician is board certified in  
576 cardiology, cardiovascular radiology or cardiology, adult or pediatric, as applicable. The director of an  
577 adult cardiac catheterization service shall have performed at least 100 catheterizations per year during  
578 each of the five preceding years. The Department may accept other evidence that the director is  
579 appropriately trained.

580 (kl) A cardiac catheterization service shall be operated consistently with the recommendations of the  
581 American College of Cardiology.

582 (lm) The applicant hospital providing therapeutic cardiac catheterization services, primary PCI  
583 services without on-site OHS service, or elective PCI services without on-site OHS service shall  
584 participate with a data registry administered by the Department or its designee that monitors quality and  
585 risk adjusted outcomes.

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

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

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

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

594 (d) The operation of and referral of patients to the cardiac catheterization service shall be in  
595 conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.1621; MSA 14.15  
596 (16221).

597  
598 (4) Compliance with the following monitoring and reporting requirements:

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

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

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

604 (iii) 600 procedure equivalents in the category of pediatric/CONGENITAL cardiac catheterization  
605 procedures.

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

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

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

609 (vii) 36 adult primary PCI cases for a primary PCI service without on-site OHS service.

610 (viii) 200 adult PCI procedures for an elective PCI service without on-site OHS service.

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

615 (c) The applicant hospital providing therapeutic cardiac catheterization services, primary PCI  
616 services without on-site OHS service, or elective PCI services without on-site OHS service shall  
617 participate in a data registry administered by the Department or its designee as a means to measure  
618 quality and risk adjusted outcomes within cardiac catheterization services. The Department or its  
619 designee shall require that the applicant hospital submit summary reports as specified by the Department.  
620 The applicant hospital shall provide the required data in a format established by the Department or its  
621 designee. The applicant hospital shall be liable for the cost of data submission and on-site reviews in  
622 order for the Department to verify and monitor volumes and assure quality. The applicant hospital shall  
623 become a member of the data registry specified by the Department upon initiation of the service and  
624 continue to participate annually thereafter for the life of that service.

625 (d) the applicant hospital shall provide the department with timely notice of the proposed project  
626 implementation consistent with applicable statute and promulgated rules.

627  
628 (5) Compliance with the following primary and elective PCI requirements for hospitals providing  
629 therapeutic cardiac catheterization services, primary PCI services without on-site OHS service, or elective  
630 PCI services without on-site OHS service, if applicable:

631 (a) The requirements set forth in Section 4.

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

634 (c) The hospital shall maintain a 90-minute door-to-balloon time or less in at least 75% of the primary  
635 PCI sessions (EXCLUDING PATIENTS WITH CARDIOGENIC SHOCK).

636 (d) The applicant hospital shall participate in a data registry administered by the Department or its  
637 designee as a means to measure quality and risk adjusted outcomes within PCI services by service level.  
638 The Department or its designee shall require that the applicant hospital submit all consecutive PCI cases  
639 performed within the hospital and meet data submission timeliness requirements and threshold  
640 requirements for PCI data submission, accuracy and completeness established by a data registry  
641 administered by the Department or its designee. The applicant hospital shall provide the required data in  
642 a format established by the Department or its designee. The applicant hospital shall be liable for the cost  
643 of data submission and on-site reviews in order for the Department to verify and monitor volumes and  
CON Review Standards for Cardiac Catheterization Services CON-210



644 assure quality. The applicant hospital shall become a member of the data registry specified by the  
 645 Department upon initiation of the service and continue to participate annually thereafter for the life of that  
 646 service. At a minimum, the applicant hospital shall report the following:

- 647 (i) the number of patients treated with and without STEMI,
- 648 (ii) the proportion of PCI patients with emergency CABG or required emergent transfer,
- 649 (iii) risk and reliability adjusted patient mortality for all PCI patients and a subset of patients with  
 650 STEMI,
- 651 (iv) PCI appropriate use in elective non-acute MI cases, and
- 652 (v) rates of ad-hoc multi-vessel PCI procedures in the same session.
- 653 (e) The applicant hospital shall maintain a physician point of contact for the data registry.

654 (f) **FOR PRIMARY PCI SERVICES WITHOUT ON-SITE OHS SERVICE AND ELECTIVE PCI**  
 655 **SERVICES WITHOUT ON-SITE OHS SERVICE, Catheterization-catheterization lab facility requirements**  
 656 and collaborative cardiologists-heart surgeon relationship requirements shall conform to all SCAI/ACC  
 657 Guidelines for PCI including the SCAI/ACC/AHA Expert Consensus Document. The applicant hospital  
 658 shall be liable for the cost of demonstrating compliance with these criteria.

659 (g) The Department shall use these thresholds and metrics in evaluating compliance: performance  
 660 at a level above the 50th percentile of the statewide performance on each metric listed under subsection  
 661 (d)(ii) – (v) or another level provided by the data registry designee and accepted by the Department.

662 (h) The Department shall notify those hospitals who fail to meet any of the minimally acceptable  
 663 objective quality metric thresholds including those under subsection (d)(ii) – (v). The Department shall  
 664 require these hospitals to:

- 665 (i) submit a corrective action plan within one month of notification and
- 666 (ii) demonstrate that performance has improved to meet or exceed all applicable objective quality  
 667 metric thresholds, including those under subsection (d)(ii) – (v), within 12 months of notification.

668 (i) The applicant hospital initiating elective PCI without on-site OHS services shall have  
 669 Accreditation for Cardiovascular Excellence (ACE) accreditation or an equivalent body perform an on-site  
 670 review within 3, 6, and 12 months after implementation. The applicant hospital shall submit the summary  
 671 reports of the on-site review to the Department **AND MAINTAIN ON-GOING ACCREDITATION.**

672  
 673 (6) Nothing in this section prohibits the Department from taking compliance action under MCL  
 674 333.22247.

675  
 676 (7) The agreements and assurances required by this section shall be in the form of a certification  
 677 agreed to by the applicant **HOSPITAL** or its authorized agent.

678  
 679 **Section 11. Methodology for computing cardiac catheterization equivalents**

680  
 681 Sec. 11. The following shall be used in calculating procedure equivalents and evaluating utilization of  
 682 a cardiac catheterization service and its laboratories:  
 683

Procedure Type	DESCRIPTION	Procedure equivalent	
		Adult	Pediatric
Diagnostic cardiac catheterization/peripheral sessions	RIGHT HEART CATHETERIZATION, LEFT HEART CATHETERIZATION, CORONARY ANGIOGRAPHY, CORONARY ARTERY BYPASS GRAFT ANGIOGRAPHY, INTRACORONARY ADMINISTRATION OF DRUGS, FRACTIONAL FLOW RESERVE (FFR), INTRA-CORONARY IMAGING (INTRAVASCULAR ULTRASOUND (IVUS), OPTICAL COHERENCE TOMOGRAPHY (OCT)) WHEN PERFORMED WITHOUT A THERAPEUTIC PROCEDURE, CARDIAC BIOPSY, INTRA-CARDIAC ECHOCARDIOGRAPHY (ICE).	1.5	2.7



Procedure Type	DESCRIPTION	Procedure equivalent	
		Adult	Pediatric
	DIAGNOSTIC ELECTROPHYSIOLOGY STUDY, ANGIOGRAPHY IN THE PERIPHERAL ARTERIAL OR VENOUS CIRCULATION		
Therapeutic cardiac catheterization/peripheral sessions	PCI, PERICARDIOCENTESIS, PACEMAKER IMPLANTATION, ICD IMPLANTATION (ENDOASCULAR OR SUBCUTANEOUS), PACEMAKER/ICD GENERATOR CHANGE, PACEMAKER/ICD LEAD REVISION, CARDIAC ABLATION (EXCLUDING AF/VT), AND/OR STRUCTURAL HEART PROCEDURE (EXCLUDING THOSE LISTED BELOW), AND IABP, IMPELLA, ECMO, OR TANDEMHEART WHEN THIS IS THE ONLY THERAPEUTIC PROCEDURE	2.7	4.0
THERAPEUTIC PERIPHERAL SESSION	PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA), ATHERECTOMY, LASER, STENT IMPLANTATION, IVC FILTER IMPLANTATION OR RETRIEVAL, CATHETER-DIRECTED ULTRASOUND/THROMBOLYSIS, THROMBECTOMY	2.7	4.0
Complex percutaneous valvular THERAPEUTIC sessions*	PCI FOR CHRONIC TOTAL OCCLUSION (CTO), TAVR, MITRAL/PULMONARY/TRICUSPID VALVE REPAIR OR REPLACEMENT, PARAVALVULAR LEAK CLOSURE, ABLATION FOR ATRIAL FIBRILLATION (AF) OR VENTRICULAR TACHYCARDIA (VT), PACEMAKER OR ICD LEAD EXTRACTION	4.0	7.0
PROLONGED THERAPEUTIC SESSION	CARDIAC THERAPEUTIC SESSION >6 HOURS	6.0	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 OHS services. PROCEDURE EQUIVALENTS FROM PERIPHERAL DIAGNOSTIC AND THERAPEUTIC PROCEDURES COUNT TOWARD THE VOLUME REQUIREMENT FOR INITIATION OF CARDIAC CATHETERIZATION SERVICES (SECTION 3) AND EXPANSION OF A CARDIAC CATHETERIZATION SERVICE (SECTION 6).			

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**Section 12. Documentation of projections**

**Sec. 12. An applicant HOSPITAL required to project volumes shall demonstrate the following as applicable to the proposed project:**

(1) The applicant HOSPITAL 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 HOSPITAL 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

698 thrombolytic therapy ordered and medical records of emergency transfers of AMI patients to an  
699 appropriate hospital for a primary PCI procedure.

700  
701 (3) An applicant **HOSPITAL** proposing to initiate an elective PCI service without on-site OHS  
702 services shall demonstrate and certify that the hospital shall treat 200 or more patients with PCI annually  
703 using data during the most recent 12-month period preceding the date the application was submitted to  
704 the Department as follows:

705 (a) All primary PCIs performed at the applicant hospital.

706 (b) All inpatients transferred from the applicant hospital to another hospital for PCI.

707 (c) 90% of patients who received diagnostic cardiac catheterizations at the applicant hospital and  
708 received an elective PCI at another hospital within 30 days of the diagnostic catheterization (based on  
709 physician commitments).

710 (d) 50% of the elective PCI procedures performed by the committing physician at another hospital  
711 within 120 radius miles or 120 minutes travel time from the applicant hospital for patients who did not  
712 receive diagnostic cardiac catheterization at the applicant hospital (based on physician commitments).

713 (e) An applicant **HOSPITAL** with current OHS services and therapeutic cardiac catheterization  
714 services that is proposing to discontinue OHS services and therapeutic cardiac catheterization services  
715 and is applying to initiate primary or elective PCI services without on-site OHS services may count all  
716 primary and elective PCI at the applicant hospital within the most recent 12-month period preceding the  
717 date the application was submitted to the Department.

718

### 719 **Section 13. Comparative reviews; Effect on prior CON Review Standards**

720

721 Sec. 13. Proposed projects reviewed under these standards shall not be subject to comparative  
722 review. These CON Review Standards supercede and replace the CON Review Standards for Cardiac  
723 Catheterization Services approved by the CON Commission on ~~March 18, 2014~~ **JUNE 11, 2015** and  
724 effective on ~~June 2, 2014~~ **SEPTEMBER 14, 2015**.

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Rural Michigan counties are as follows:

Alcona	Gogebic	Ogemaw
Alger	Huron	Ontonagon
Antrim	Iosco	Osceola
Arenac	Iron	Oscoda
Baraga	Lake	Otsego
Charlevoix	Luce	Presque Isle
Cheboygan	Mackinac	Roscommon
Clare	Manistee	Sanilac
Crawford	Montmorency	Schoolcraft
Emmet	Newaygo	Tuscola
Gladwin	Oceana	

Micropolitan statistical area Michigan counties are as follows:

Allegan	Hillsdale	Mason
Alpena	Houghton	Mecosta
Benzie	Ionia	Menominee
Branch	Isabella	Missaukee
Chippewa	Kalkaska	St. Joseph
Delta	Keweenaw	Shiawassee
Dickinson	Leelanau	Wexford
Grand Traverse	Lenawee	
Gratiot	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	Jackson	Muskegon
Bay	Kalamazoo	Oakland
Berrien	Kent	Ottawa
Calhoun	Lapeer	Saginaw
Cass	Livingston	St. Clair
Clinton	Macomb	Van Buren
Eaton	Midland	Washtenaw
Genesee	Monroe	Wayne
Ingham	Montcalm	

Source:

75 F.R., p. 37245 (June 28, 2010)  
Statistical Policy Office  
Office of Information and Regulatory Affairs  
United States Office of Management and Budget

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

ICD-9 Code	Description	ICD-10 Code	Description
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

"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.