

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. *THIS LENGTH OF TIME MEANS THE PERIOD FROM WHEN THE
130 PATIENT ENTERS ("WHEELS IN") AND LEAVES ("WHEELS OUT") THE LABORATORY. IF A
131 DIAGNOSTIC AND THERAPEUTIC PROCEDURE IS PERFORMED IN THE SAME SESSION, THE
132 HIGHER PROCEDURE EQUIVALENT WEIGHTING WILL BE USED TO EVALUATE UTILIZATION.*

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

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

147 (bb) *"THERAPEUTIC CARDIAC CATHETERIZATION SERVICE WITHOUT ON-SITE SURGERY"
148 MEANS PROVIDING ELECTIVE PCI, PRIMARY PCI, PERMANENT PACEMAKER IMPLANTATION,
149 AND ICD IMPLANTATION. A HOSPITAL THAT PROVIDES ELECTIVE OR PRIMARY PCI WITHOUT
150 ON-SITE SURGERY MAY ALSO PERFORM RIGHT SIDED CARDIAC ABLATION PROCEDURES
151 INCLUDING RIGHT ATRIAL FLUTTER, AV REENTRY, AV NODE REENTRY, RIGHT ATRIAL
152 TACHYCARDIA, AND AV NODE ABLATION.*

153 ~~(cc)~~ "THERAPEUTIC CARDIAC CATHETERIZATION SESSION" MAY INCLUDE: PCI (ELECTIVE,
154 EMERGENT), PERICARDIOCENTESIS, PERMANENT PACEMAKER IMPLANTATION, ICD
155 IMPLANTATION (ENDOVASCULAR OR SUBCUTANEOUS), PACEMAKER OR ICD GENERATOR
156 CHANGE, PACEMAKER OR ICD LEAD REVISION, CARDIAC ABLATION, AND/OR STRUCTURAL
157 HEART PROCEDURE. THIS ALSO INCLUDES IMPLANTATION OF A CIRCULATORY SUPPORT
158 DEVICE SUCH AS IABP, IMPELLA, ECMO OR TANDEMHEART WHERE THIS IS THE ONLY
159 THERAPEUTIC PROCEDURE. WHEN PCI IS PERFORMED IN MORE THAN ONE CORONARY
160 ARTERY DURING THE SAME SETTING, THIS IS COUNTED AS ONE SESSION.

161 (dd) "THERAPEUTIC PERIPHERAL PROCEDURE" MEANS A THERAPEUTIC CATHETERIZATION
162 PROCEDURE TO RESOLVE ANATOMIC AND/OR PHYSIOLOGIC PROBLEMS IN THE ARTERIAL OR
163 VENOUS CIRCULATION (EXCLUDING THE HEART). PROCEDURES MAY INCLUDE
164 PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA), ATHERECTOMY, DRUG ELUTING
165 BALLOON, LASER, STENT IMPLANTATION, IVC FILTER IMPLANTATION OR RETRIEVAL,
166 CATHETER-DIRECTED ULTRASOUND/THROMBOLYSIS, AND THROMBECTOMY.

167 (ee) "THERAPEUTIC PERIPHERAL SESSION" MEANS A CONTINUOUS TIME PERIOD DURING
168 WHICH A PATIENT MAY UNDERGO ONE OR MORE THERAPEUTIC PERIPHERAL PROCEDURES IN
169 A CARDIAC CATHETERIZATION LABORATORY.

170 (ff) "THERAPEUTIC PEDIATRIC/CONGENITAL CARDIAC CATHETERIZATION SESSION" MAY
171 INCLUDE: STRUCTURAL HEART PROCEDURE (AS LISTED ABOVE), PULMONARY ARTERY
172 ANGIOPLASTY/STENT IMPLANTATION, PULMONARY VALVE PERFORATION,
173 ANGIOPLASTY/STENT IMPLANTATION FOR AORTIC COARCTATION, CARDIAC ABLATION,
174 PACEMAKER/ICD IMPLANTATION, AND PCI.

175
176 (2) Terms defined in the Code have the same meanings when used in these standards.
177

178 Section 3. Requirements to initiate cardiac catheterization services 179

180 Sec. 3. An applicant **HOSPITAL** proposing to initiate cardiac catheterization services shall
181 demonstrate the following, as applicable to the proposed project.
182

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

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

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

195 (c) An applicant **HOSPITAL** proposing to initiate a diagnostic cardiac catheterization service with two
196 or more laboratories shall project a minimum of 1,000 procedure equivalents per laboratory that includes
197 300 procedure equivalents in the category of diagnostic cardiac catheterization procedures based on data
198 from the most recent 12-month period preceding the date the application was submitted to the
199 Department.
200

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

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

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

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

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

217
218 (3) An applicant **HOSPITAL** proposing to initiate a pediatric/**CONGENITAL** cardiac catheterization
219 service shall demonstrate the following:

220 (a) The applicant **HOSPITAL** has a board certified pediatric cardiologist with training in
221 pediatric/**CONGENITAL** catheterization procedures to direct the pediatric catheterization laboratory.

222 (b) The applicant **HOSPITAL** has standardized biplane equipment as defined in the most current
223 American Academy of Pediatrics (AAP) and American College of Cardiology Foundation (ACCF)/Society
224 for Cardiovascular Angiography and Interventions (SCAI) guidelines for pediatric cardiovascular centers.

225 (c) The applicant **HOSPITAL** has on-site pediatric and neonatal ICU as outlined in the most current
226 AAP and ACCF/SCAI guidelines above.

227 (d) The applicant **HOSPITAL** has applied to provide pediatric OHS services at the hospital. The
228 applicant **HOSPITAL** must be approved for a pediatric OHS service in order to be approved for
229 pediatric/**CONGENITAL** cardiac catheterization services.

230 (e) The applicant **HOSPITAL** has on-site pediatric extracorporeal membrane oxygenation (ECMO)
231 capability as outlined in the most current ACCF/SCAI guidelines.

232 (f) A pediatric/**CONGENITAL** cardiac catheterization service shall have a quality assurance plan as
233 outlined in the most current ACCF/SCAI guidelines.

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

237 238 **Section 4. Requirements to initiate primary or elective PCI Services without on-site OHS services**

239
240 **Sec. 4.** An applicant **HOSPITAL** proposing to initiate primary or elective PCI services without on-site
241 OHS services shall demonstrate the following:

242
243 (1) The applicant **HOSPITAL** operates an adult diagnostic cardiac catheterization service that has
244 performed a minimum of 500 procedure equivalents that includes 400 procedure equivalents in the
245 category of cardiac catheterization procedures during the most recent 12 months preceding the date the
246 application was submitted to the Department.

247
248 (2) The applicant **HOSPITAL** has at least two interventional cardiologists to perform the PCI
249 procedures and each cardiologist has performed at least 50 PCI sessions annually as the primary
250 operator during the most recent 24-month period preceding the date the application was submitted to the
251 Department.

252
253 (3) The nursing and technical catheterization laboratory staff: are experienced in handling acutely ill
254 patients and comfortable with interventional equipment; have acquired experience in dedicated
255 interventional laboratories at an OHS hospital; and participate in an un-interrupted 24-hour, 365-day call
256 schedule. Competency shall be documented annually.

257
258 (4) The laboratory or laboratories are equipped with optimal imaging systems, resuscitative
259 equipment, and intra-aortic balloon pump (IABP) support, and stocked with a broad array of interventional
260 equipment.

261
262 (5) The cardiac care unit nurses are adept in hemodynamic monitoring and IABP management.
263 Competency shall be documented annually.

264
265 (6) A written agreement with an OHS hospital that includes all of the following:

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

- 268 (b) Provision for ongoing cross-training for professional and technical staff involved in the provision of
269 PCI to ensure familiarity with interventional equipment. Competency shall be documented annually.
- 270 (c) Provision for ongoing cross training for emergency department, catheterization laboratory, and
271 critical care unit staff to ensure experience in handling the high acuity status of PCI patient candidates.
272 Competency shall be documented annually.
- 273 (d) Regularly held joint cardiology/cardiac surgery conferences to include review of all PCI cases.
- 274 (e) Development and ongoing review of patient selection criteria for PCI patients and implementation
275 of those criteria.
- 276 (f) A mechanism to provide for appropriate patient transfers between facilities and an agreed plan for
277 prompt care.
- 278 (g) Written protocols, signed by the applicant HOSPITAL and the OHS hospital, for the immediate
279 transfer within 60 minutes travel time from the cardiac catheterization laboratory to evaluation on site in
280 the OHS hospital, of patients requiring surgical evaluation and/or intervention 365 days a year. If the
281 applicant HOSPITAL meets the requirements of subsection (13)(c), then the OHS hospital can be more
282 than 60 minutes travel time from the proposed site. The protocols shall be reviewed and tested on a
283 quarterly basis.
- 284 (h) Consultation on facilities, equipment, staffing, ancillary services, and policies and procedures for
285 the provision of interventional procedures.
- 286
- 287 (7) A written protocol must be established and maintained for case selection for the performance of
288 PCI.
- 289
- 290 (8) A system to ensure prompt and efficient identification of potential primary PCI patients and rapid
291 transfer from the emergency department to the cardiac catheterization laboratory must be developed and
292 maintained so that door-to-balloon targets are met.
- 293
- 294 (9) At least two physicians credentialed to perform PCI must commit to functioning as a coordinated
295 group willing and able to provide this service at the hospital on a 24-hour per day, 365 day per year call
296 schedule, with ability to be on-site and available to operate within 30 minutes of identifying the need for
297 primary PCI. These physicians must be credentialed at the facility and actively collaborate with
298 administrative and clinical staff in establishing and implementing protocols, call schedules, and quality
299 assurance procedures pertaining to PCI designed to meet the requirements for this certification and in
300 keeping with the current guidelines for the provision of PCI without on-site OHS services promulgated by
301 the American College of Cardiology and American Heart Association.
- 302
- 303 (10) The applicant hospital shall participate in a data registry administered by the Department or its
304 designee as a means to measure quality and risk adjusted outcomes within PCI services without on-site
305 OHS services, and the applicant hospital shall identify a physician point of contact for the data registry.
- 306
- 307 (11) Cath lab facility requirements and collaborative cardiologists-heart surgeon relationship
308 requirements shall conform to all SCAI/ACC Guidelines for PCI Services Without On-Site OHS including
309 the SCAI/ACC/AHA Expert Consensus Document. The applicant hospital shall be liable for the cost of
310 demonstrating compliance with these criteria in their application.
- 311
- 312 (12) The applicant HOSPITAL shall project the following based on data from the most recent 12-
313 month period preceding the date the application was submitted to the Department, as applicable.
- 314 (a) If the applicant HOSPITAL is applying for a primary PCI service without open heart surgery, the
315 applicant HOSPITAL shall project a minimum of 36 primary PCI procedures per year.
- 316 (b) If the applicant HOSPITAL is applying for an elective PCI service without on-site OHS, the
317 applicant HOSPITAL shall project a minimum of 200 PCI procedures per year.
- 318
- 319 (13) If the applicant HOSPITAL is applying for an elective PCI service without on-site OHS, the
320 applicant HOSPITAL also shall demonstrate the following:
- 321 (a) The applicant HOSPITAL operated a primary PCI service for at least one year prior to the date of
322 application.

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

326 (c) If the applicant HOSPITAL was not approved as a primary PCI service prior to September 14,
327 2015, then, in addition, the applicant HOSPITAL shall demonstrate that there is no PCI or OHS service
328 within 60 radius miles or 60 minutes travel time from the proposed site.

329
330 (14) If the applicant HOSPITAL is currently providing OHS services and therapeutic cardiac
331 catheterization services and is proposing to discontinue OHS services and therapeutic cardiac
332 catheterization services, then the applicant HOSPITAL shall apply to initiate primary or elective PCI
333 services without on-site OHS using this section. The applicant HOSPITAL shall demonstrate all of the
334 requirements in this section except for subsection (13) and is subject to all requirements in Section 10.
335

336 Section 5. Requirements to replace an existing cardiac catheterization service or laboratory 337

338 Sec. 5. Replacing a cardiac catheterization laboratory means a change in the angiography x-ray
339 equipment or a relocation of the service to a new site. The term does not include a change in any of the
340 other equipment or software used in the laboratory. An applicant HOSPITAL proposing to replace a
341 cardiac catheterization laboratory or service shall demonstrate the following as applicable to the proposed
342 project:
343

344 (1) An applicant HOSPITAL proposing to replace cardiac catheterization laboratory equipment shall
345 demonstrate the following:

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

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

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

352 (b) The existing angiography x-ray equipment to be replaced will be removed from service on or
353 before beginning operation of the replacement equipment.
354

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

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

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

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

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

365 (iii) A minimum of 600 procedure equivalents in the category of pediatric/CONGENITAL cardiac
366 catheterization procedures.

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

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

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

373 (c) The existing cardiac catheterization service has been in operation for at least 36 months as of the
374 date the application has been submitted to the Department.
375

376 (3) AN APPLICANT HOSPITAL PROPOSING TO REPLACE A CARDIAC CATHETERIZATION
377 SERVICE TO A NEW SITE SIMULTANEOUSLY WITH AN OPEN HEART SURGERY SERVICE SHALL
378 DEMONSTRATE THE FOLLOWING:

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

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

384 (c) THE PROPOSED NEW SITE IS THE SAME SITE WHERE THE EXISTING OHS SERVICE IS
385 TO BE LOCATED WHICH IS WITHIN THE SAME PLANNING AREA AS THE OHS SERVICE.

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

390 391 **Section 6. Requirements to expand a cardiac catheterization service**

392
393 **Sec. 6. An applicant HOSPITAL proposing to add a laboratory to an existing cardiac catheterization**
394 **service shall demonstrate the following:**

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

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

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

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

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

409 410 **Section 7. Requirements to acquire a cardiac catheterization service**

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

417
418 **(1) An applicant HOSPITAL proposing to acquire a cardiac catheterization service shall demonstrate**
419 **the following:**

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

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

426 (c) For any application proposing to acquire an existing cardiac catheterization service, except the
427 **first application approved pursuant to subsection (b), an applicant HOSPITAL shall be required to**
428 **document that the cardiac catheterization service to be acquired is operating in compliance with the**

429 volume requirements set forth in section 10 of these standards applicable to an existing cardiac
430 catheterization service on the date the application is submitted to the Department.

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

434
435 **Section 8. Requirements for a hybrid operating room/cardiac catheterization laboratory (OR/CCL)**
436

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

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

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

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

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

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

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

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

463
464 **Section 9. Requirement for Medicaid participation**
465

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

470
471 **Section 10. Project delivery requirements and terms of approval for all applicants**
472

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

476
477 (1) Compliance with these standards.

478
479 (2) Compliance with the following quality assurance standards:

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

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

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

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

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

535 (ef) Each physician credentialed by a hospital to perform pediatric/CONGENITAL cardiac
536 catheterizations shall perform, as the primary operator, a ~~N minimum~~ AVERAGE of AT LEAST 50

537 pediatric/CONGENITAL cardiac catheterization ~~procedures~~ SESSIONS per year AVERAGED OVER THE
538 MOST RECENT 2 YEARS STARTING in the second 12 months after being credentialed. THIS TWO
539 YEAR AVERAGE WILL BE EVALUATED ON A ROLLING BASIS and annually thereafter. The annual
540 case load for a physician means pediatric/CONGENITAL cardiac catheterization ~~procedures~~ SESSIONS
541 performed by that physician in any combination of hospitals. PHYSICIANS FALLING BELOW THIS
542 VOLUME REQUIREMENT MUST BE PLACED ON A FOCUSED PROFESSIONAL PRACTICE
543 EVALUATION (FPPE) PLAN, WHICH MUST INCLUDE AN INDEPENDENT REVIEW OF ALL CARDIAC
544 CATHETERIZATION SESSIONS BY AN APPROPRIATE DESIGNEE, TO ENSURE QUALITY
545 OUTCOMES ARE MAINTAINED. IN THE EVENT A PHYSICIAN DOES NOT PERFORM CARDIAC
546 CATHETERIZATION PROCEDURES ON A TEMPORARY OR PERMANENT BASIS FOR A PERIOD OF
547 3 MONTHS OR MORE, THE PHYSICIAN THERAPEUTIC PROCEDURE VOLUME WILL BE
548 ANNUALIZED ON THE 24 MONTH PERIOD PRECEDING THE ABSENCE.

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

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

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

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

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

- 572 (i) is board certified or board eligible in pediatric cardiology by the American Board of Pediatrics;
 - 573 (ii) is credentialed by the hospital to perform pediatric/CONGENITAL cardiac catheterizations; and
 - 574 (iii) has trained consistently with the recommendations of the American College of Cardiology.
- 575 (ij) A pediatric/CONGENITAL cardiac catheterization service shall maintain a quality assurance plan
576 as outlined in the most current ACCF/SCAI Guidelines.

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

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

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

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

CON Review Standards for Cardiac Catheterization Services

For CON Commission Proposed Action on March 27, 2018

Proposed Department language is shown in italics and highlighted in blue

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

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

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

597 (d) The operation of and referral of patients to the cardiac catheterization service shall be in
598 conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.1621; MSA 14.15
599 (16221).

600

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

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

604 (i) 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures.
605 (ii) 300 procedure equivalents in the category of adult therapeutic cardiac catheterization
606 procedures.
607 (iii) 600 procedure equivalents in the category of pediatric CONGENITAL cardiac catheterization
608 procedures.

609 (iv) 500 procedure equivalents for a hospital in a rural or micropolitan county with one laboratory.
610 (v) 750 procedure equivalents for a hospital in a metropolitan county with one laboratory.
611 (vi) 1,000 procedure equivalents per cardiac catheterization laboratory for two or more laboratories.
612 (vii) 36 adult primary PCI cases for a primary PCI service without on-site OHS service.
613 (viii) 200 adult PCI procedures for an elective PCI service without on-site OHS service.

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

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

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

630

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

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

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

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

639 (d) The applicant hospital shall participate in a data registry administered by the Department or its
640 designee as a means to measure quality and risk adjusted outcomes within PCI services by service level.
641 The Department or its designee shall require that the applicant hospital submit all consecutive PCI cases
642 performed within the hospital and meet data submission timeliness requirements and threshold
643 requirements for PCI data submission, accuracy and completeness established by a data registry
644 administered by the Department or its designee. The applicant hospital shall provide the required data in
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645 a format established by the Department or its designee. The applicant hospital shall be liable for the cost
 646 of data submission and on-site reviews in order for the Department to verify and monitor volumes and
 647 assure quality. The applicant hospital shall become a member of the data registry specified by the
 648 Department upon initiation of the service and continue to participate annually thereafter for the life of that
 649 service. At a minimum, the applicant hospital shall report the following:

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

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

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

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

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

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

675
 676 (6) Nothing in this section prohibits the Department from taking compliance action under MCL
 677 333.22247.

678
 679 (7) The agreements and assurances required by this section shall be in the form of a certification
 680 agreed to by the applicant **HOSPITAL** or its authorized agent.

681
 682 **Section 11. Methodology for computing cardiac catheterization equivalents**

683
 684 Sec. 11. The following shall be used in calculating procedure equivalents and evaluating utilization of
 685 a cardiac catheterization service and its laboratories:
 686

Procedure Type	DESCRIPTION	Procedure equivalent	
		Adult	Pediatric
Diagnostic cardiac catheterization ^[A1] /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	1.5	2.7

Procedure Type	DESCRIPTION	Procedure equivalent	
		Adult	Pediatric
	THERAPEUTIC PROCEDURE, CARDIAC BIOPSY, INTRA-CARDIAC ECHOCARDIOGRAPHY (ICE), DIAGNOSTIC ELECTROPHYSIOLOGY STUDY, ANGIOGRAPHY IN THE PERIPHERAL ARTERIAL OR VENOUS CIRCULATION		
Therapeutic cardiac catheterization ^[A2] /peripheral sessions	PCI, PERICARDIOCENTESIS, PACEMAKER IMPLANTATION, ICD IMPLANTATION (ENDOVASCULAR 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.

697 (2) An applicant **HOSPITAL** proposing to initiate a primary PCI service shall demonstrate and certify
698 that the hospital treated or transferred 36 ST segment elevation AMI cases during the most recent 12-
699 month period preceding the date the application was submitted to the Department. Cases may include
700 thrombolytic eligible patients documented through pharmacy records showing the number of doses of
701 thrombolytic therapy ordered and medical records of emergency transfers of AMI patients to an
702 appropriate hospital for a primary PCI procedure.
703

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

708 (a) All primary PCIs performed at the applicant hospital.
709 (b) All inpatients transferred from the applicant hospital to another hospital for PCI.
710 (c) 90% of patients who received diagnostic cardiac catheterizations at the applicant hospital and
711 received an elective PCI at another hospital within 30 days of the diagnostic catheterization (based on
712 physician commitments).

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

716 (e) An applicant **HOSPITAL** with current OHS services and therapeutic cardiac catheterization
717 services that is proposing to discontinue OHS services and therapeutic cardiac catheterization services
718 and is applying to initiate primary or elective PCI services without on-site OHS services may count all
719 primary and elective PCI at the applicant hospital within the most recent 12-month period preceding the
720 date the application was submitted to the Department.
721

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

723
724 Sec. 13. Proposed projects reviewed under these standards shall not be subject to comparative
725 review. These CON Review Standards supercede and replace the CON Review Standards for Cardiac
726 Catheterization Services approved by the CON Commission on ~~March 18, 2014~~ **JUNE 11, 2015** and
727 effective on ~~June 2, 2014~~ **SEPTEMBER 14, 2015**.
728

729

730

731 Rural Michigan counties are as follows:

732

733	Alcona	Gogebic	Ogemaw
734	Alger	Huron	Ontonagon
735	Antrim	Iosco	Osceola
736	Arenac	Iron	Oscoda
737	Baraga	Lake	Otsego
738	Charlevoix	Luce	Presque Isle
739	Cheboygan	Mackinac	Roscommon
740	Clare	Manistee	Sanilac
741	Crawford	Montmorency	Schoolcraft
742	Emmet	Newaygo	Tuscola
743	Gladwin	Oceana	

744

745

746 Micropolitan statistical area Michigan counties are as follows:

747

748	Allegan	Hillsdale	Mason
749	Alpena	Houghton	Mecosta
750	Benzie	Ionia	Menominee
751	Branch	Isabella	Missaukee
752	Chippewa	Kalkaska	St. Joseph
753	Delta	Keweenaw	Shiawassee
754	Dickinson	Leelanau	Wexford
755	Grand Traverse	Lenawee	
756	Graiot	Marquette	

757

758 Metropolitan statistical area Michigan counties are as follows:

759

760	Barry	Jackson	Muskegon
761	Bay	Kalamazoo	Oakland
762	Berrien	Kent	Ottawa
763	Calhoun	Lapeer	Saginaw
764	Cass	Livingston	St. Clair
765	Clinton	Macomb	Van Buren
766	Eaton	Midland	Washtenaw
767	Genesee	Monroe	Wayne
768	Ingham	Montcalm	

769

770 Source:

771

772 75 F.R., p. 37245 (June 28, 2010)

773 Statistical Policy Office

774 Office of Information and Regulatory Affairs

775 United States Office of Management and Budget

776

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.