

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 (ENDOASCULAR 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.

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

383 384 **Section 6. Requirements to expand a cardiac catheterization service**

385
386 Sec. 6. An applicant HOSPITAL proposing to add a laboratory to an existing cardiac catheterization
387 service shall demonstrate the following:

388
389 (1) The applicant HOSPITAL has performed the following during the most recent 12-month period
390 preceding the date the application was submitted to the Department as applicable to the proposed
391 project:

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

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

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

398
399 (2) The applicant HOSPITAL has performed a minimum of 1,400 procedure equivalents per existing
400 and approved laboratories during the most recent 12-month period preceding the date the application was
401 submitted to the Department.

402 403 **Section 7. Requirements to acquire a cardiac catheterization service**

404
405 Sec. 7. Acquiring a cardiac catheterization service and its laboratories means obtaining possession
406 and control by contract, ownership, lease or other comparable arrangement or renewal of a lease for
407 existing angiography x-ray equipment. An applicant HOSPITAL proposing to acquire a cardiac
408 catheterization service or renew a lease for equipment shall demonstrate the following as applicable to
409 the proposed project:

410
411 (1) An applicant HOSPITAL proposing to acquire a cardiac catheterization service shall demonstrate
412 the following:

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

414 (b) An application for the first acquisition of an existing cardiac catheterization service after February
415 27, 2012 shall not be required to be in compliance with the applicable volume requirements in Section 10.
416 The cardiac catheterization service shall be operating at the applicable volumes set forth in the project
417 delivery requirements in the second 12 months of operation of the service by the applicant HOSPITAL
418 and annually thereafter.

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

424
425 (2) An applicant HOSPITAL proposing to renew a lease for existing angiography x-ray equipment
426 shall demonstrate the renewal of the lease is more cost effective than replacing the equipment.

427 428 **Section 8. Requirements for a hybrid operating room/cardiac catheterization laboratory (OR/CCL)**

429
430
431
432
433
434
435
436
437
438
439
440
441
442
443
444
445
446
447
448
449
450
451
452
453
454
455
456
457
458
459
460
461
462
463
464
465
466
467
468
469
470
471
472
473
474
475
476
477
478
479
480
481
482

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

- (1) The applicant HOSPITAL operates an OHS service which is in full compliance with the current CON Review Standards for OHS Services.
- (2) The applicant operates a therapeutic cardiac catheterization program which is in full compliance with section S 53(2) AND 10(4) of these standards.
- (3) If the hybrid OR/CCL(s) represents an increase in the number of cardiac catheterization laboratories at the facility, the applicant HOSPITAL is in compliance with Section 6 of these standards.
- (4) If the hybrid OR/CCL(s) represents conversion of an existing cardiac catheterization laboratory(s), the applicant HOSPITAL is in compliance with the provisions of Section 5, if applicable.
- (5) The applicant HOSPITAL meets the applicable requirements of the CON Review Standards for Surgical Services.
- (6) Each case performed in a hybrid OR/CCL shall be included either in the surgical volume or the therapeutic cardiac catheterization volume of the facility. No case shall be counted more than once.
- (7) For each hybrid OR/CCL, a facility shall have 0.5 excluded from its inventory of cardiac catheterization laboratories for the purposes of computing the procedure equivalents per room. A facility will not be limited to the number of hybrid OR/CCLs within a single licensed facility.

Section 9. Requirement for Medicaid participation

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

Section 10. Project delivery requirements and terms of approval for all applicants

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

- (1) Compliance with these standards.
- (2) Compliance with the following quality assurance standards:
 - (a) Cardiac catheterization procedures shall be performed in a cardiac catheterization laboratory located within a hospital, and have within, or immediately available to the room, dedicated emergency equipment to manage cardiovascular emergencies.
 - (b) The service shall be staffed with sufficient medical, nursing, technical and other personnel to permit regular scheduled hours of operation and continuous 24-hour on-call availability.
 - (c) The medical staff and governing body shall receive and review at least annual reports describing the activities of the cardiac catheterization service including complication rates, morbidity and mortality, success rates and the number of procedures performed.
 - (d) EACH PHYSICIAN CREDENTIALLED BY A HOSPITAL TO PERFORM DIAGNOSTIC LEFT-HEART CATHETERIZATION AND/OR CORONARY ANGIOGRAPHY MUST PERFORM, AS THE

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

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

528 (ef) Each physician credentialed by a hospital to perform pediatric/CONGENITAL cardiac
529 catheterizations shall perform, as the primary operator, a ~~N minimum~~ AVERAGE of AT LEAST 50
530 pediatric/CONGENITAL cardiac catheterization ~~procedures-SESSIONS~~ per year AVERAGED OVER THE
531 MOST RECENT 2 YEARS STARTING in the second 12 months after being credentialed. THIS TWO
532 YEAR AVERAGE WILL BE EVALUATED ON A ROLLING BASIS ~~and~~ annually thereafter. The annual
533 case load for a physician means pediatric/CONGENITAL cardiac catheterization ~~procedures-SESSIONS~~
534 performed by that physician in any combination of hospitals. PHYSICIANS FALLING BELOW THIS
535 VOLUME REQUIREMENT MUST BE PLACED ON A FOCUSED PROFESSIONAL PRACTICE
536 EVALUATION (FPPE) PLAN, WHICH MUST INCLUDE AN INDEPENDENT REVIEW OF ALL CARDIAC

537 CATHETERIZATION SESSIONS BY AN APPROPRIATE DESIGNEE, TO ENSURE QUALITY
538 OUTCOMES ARE MAINTAINED. IN THE EVENT A PHYSICIAN DOES NOT PERFORM CARDIAC
539 CATHETERIZATION PROCEDURES ON A TEMPORARY OR PERMANENT BASIS FOR A PERIOD OF
540 3 MONTHS OR MORE, THE PHYSICIAN THERAPEUTIC PROCEDURE VOLUME WILL BE
541 ANNUALIZED ON THE 24 MONTH PERIOD PRECEDING THE ABSENCE.

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

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

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

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

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

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

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

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

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

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

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

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

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

587 (c) The service shall not deny cardiac catheterization services to any individual based on ability to
588 pay or source of payment.
589

590 (d) The operation of and referral of patients to the cardiac catheterization service shall be in
591 conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.1621; MSA 14.15
592 (16221).

593

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

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

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

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

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

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

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

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

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

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

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

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

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

623

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

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

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

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

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

643 (i) the number of patients treated with and without STEMI,

- 644 (ii) the proportion of PCI patients with emergency CABG or required emergent transfer,
 645 (iii) risk and reliability adjusted patient mortality for all PCI patients and a subset of patients with
 646 STEMI,
 647 (iv) PCI appropriate use in elective non-acute MI cases, and
 648 (v) rates of ad-hoc multi-vessel PCI procedures in the same session.
 649 (e) The applicant hospital shall maintain a physician point of contact for the data registry.

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

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

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

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

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

668
 669 (6) Nothing in this section prohibits the Department from taking compliance action under MCL
 670 333.22247.

671
 672 (7) The agreements and assurances required by this section shall be in the form of a certification
 673 agreed to by the applicant **HOSPITAL** or its authorized agent.

674
 675 **Section 11. Methodology for computing cardiac catheterization equivalents**
 676

677 Sec. 11. The following shall be used in calculating procedure equivalents and evaluating utilization of
 678 a cardiac catheterization service and its laboratories:
 679

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), DIAGNOSTIC ELECTROPHYSIOLOGY STUDY, ANGIOGRAPHY IN THE PERIPHERAL ARTERIAL OR VENOUS CIRCULATION	1.5	2.7
Therapeutic cardiac	PCI, PERICARDIOCENTESIS, PACEMAKER	2.7	4.0

Procedure Type	DESCRIPTION	Procedure equivalent	
		Adult	Pediatric
catheterization/peripheral sessions	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		
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).			

680
681
682
683
684
685
686
687
688
689
690
691
692
693
694
695
696

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

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

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

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

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

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

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

714

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

716

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

721

722
723
724
725
726
727
728
729
730
731
732
733
734
735
736
737
738
739
740
741
742
743
744
745
746
747
748
749
750
751
752
753
754
755
756
757
758
759
760
761
762
763
764
765
766
767
768
769

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	
Graiot	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.