

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 AND HAS DIAGNOSTIC CARDIAC
40 CATHETERIZATION CON APPROVAL.

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

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

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

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

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

54 (i) PCI FOR CHRONIC TOTAL OCCLUSION

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

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

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

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

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

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

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

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

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

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

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

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

98 (ls) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C. 1396 to
99 1396g and 1396i to 1396u.

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

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

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

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

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

128 (py) "Procedure equivalent" means a unit of measure that reflects the relative average length of time
129 one patient spends in one session in a CARDIAC CATHETERIZATION laboratory based on the type of
130 procedures being performed. IF A DIAGNOSTIC AND THERAPEUTIC PROCEDURE IS PERFORMED
131 IN THE SAME SESSION, THE HIGHER PROCEDURE EQUIVALENT WEIGHTING WILL BE USED TO
132 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 SESSION" MAY INCLUDE: PCI (ELECTIVE,
148 EMERGENT), PERICARDIOCENTESIS, PERMANENT PACEMAKER IMPLANTATION, ICD
149 IMPLANTATION (ENDOVASCULAR OR SUBCUTANEOUS), PACEMAKER OR ICD GENERATOR
150 CHANGE, PACEMAKER OR ICD LEAD REVISION, CARDIAC ABLATION, AND/OR STRUCTURAL
151 HEART PROCEDURE. THIS ALSO INCLUDES IMPLANTATION OF A CIRCULATORY SUPPORT
152 DEVICE SUCH AS IABP, IMPELLA, ECMO OR TANDEMHEART WHERE THIS IS THE ONLY
153 THERAPEUTIC PROCEDURE. WHEN PCI IS PERFORMED IN MORE THAN ONE CORONARY
154 ARTERY DURING THE SAME SETTING, THIS IS COUNTED AS ONE SESSION.

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

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

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

169
170 (2) Terms defined in the Code have the same meanings when used in these standards.
171

172 Section 3. Requirements to initiate cardiac catheterization services 173

174 Sec. 3. An applicant **HOSPITAL** proposing to initiate cardiac catheterization services shall
175 demonstrate the following, as applicable to the proposed project.
176

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

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

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

189 (c) An applicant **HOSPITAL** proposing to initiate a diagnostic cardiac catheterization service with two
190 or more laboratories shall project a minimum of 1,000 procedure equivalents per laboratory that includes
191 300 procedure equivalents in the category of diagnostic cardiac catheterization procedures based on data
192 from the most recent 12-month period preceding the date the application was submitted to the
193 Department.
194

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

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

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

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

208 (d) The applicant **HOSPITAL** shall project a minimum of 300 procedure equivalents in the category of
209 adult therapeutic cardiac catheterizations based on data from the most recent 12-month period preceding
210 the date the application was submitted to the Department.
211

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

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

231
232 **Section 4. Requirements to initiate primary or elective PCI Services without on-site OHS services**
233

234 **Sec. 4.** An applicant **HOSPITAL** proposing to initiate primary or elective PCI services without on-site
235 OHS services shall demonstrate the following:
236

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

323
324 (14) If the applicant HOSPITAL is currently providing OHS services and therapeutic cardiac
325 catheterization services and is proposing to discontinue OHS services and therapeutic cardiac
326 catheterization services, then the applicant HOSPITAL shall apply to initiate primary or elective PCI
327 services without on-site OHS using this section. The applicant HOSPITAL shall demonstrate all of the
328 requirements in this section except for subsection (13) and is subject to all requirements in Section 10.
329

330 Section 5. Requirements to replace an existing cardiac catheterization service or laboratory 331

332 Sec. 5. Replacing a cardiac catheterization laboratory means a change in the angiography x-ray
333 equipment or a relocation of the service to a new site. The term does not include a change in any of the
334 other equipment or software used in the laboratory. An applicant HOSPITAL proposing to replace a
335 cardiac catheterization laboratory or service shall demonstrate the following as applicable to the proposed
336 project:
337

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

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

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

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

346 (b) The existing angiography x-ray equipment to be replaced will be removed from service on or
347 before beginning operation of the replacement equipment.
348

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

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

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

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

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

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

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

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

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

367 (c) The existing cardiac catheterization service has been in operation for at least 36 months as of the
368 date the application has been submitted to the Department.
369

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

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

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

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

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

388 389 **Section 6. Requirements to expand a cardiac catheterization service**

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

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

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

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

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

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

407 408 **Section 7. Requirements to acquire a cardiac catheterization service**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

462 **Section 9. Requirement for Medicaid participation** 463

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

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

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

475 (1) Compliance with these standards.
476

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

587
588 (3) Compliance with the following access to care requirements:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

673
 674 (6) Nothing in this section prohibits the Department from taking compliance action under MCL
 675 333.22247.

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

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

681
 682 Sec. 11. The following shall be used in calculating procedure equivalents and evaluating utilization of
 683 a cardiac catheterization service and its laboratories:
 684

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

Procedure Type	DESCRIPTION	Procedure equivalent	
		Adult	Pediatric
	DIAGNOSTIC ELECTROPHYSIOLOGY STUDY, ANGIOGRAPHY IN THE PERIPHERAL ARTERIAL OR VENOUS CIRCULATION		
Therapeutic cardiac catheterization/peripheral sessions	PCI, PERICARDIOCENTESIS, PACEMAKER IMPLANTATION, ICD IMPLANTATION (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.

(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

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

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

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

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

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

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

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

719

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

721

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

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Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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