

1 MICHIGAN DEPARTMENT OF COMMUNITY HEALTH  
2  
3 CERTIFICATE OF NEED (CON) REVIEW STANDARDS  
4 FOR CARDIAC CATHETERIZATION SERVICES  
5

6 (By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of  
7 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being  
8 sections 333.22215, 24.207 and 24.208 of the Michigan Compiled Laws.)  
9

10 **Section 1. Applicability**

11  
12 Sec. 1. (1) These standards are requirements for approval OF THE INITIATION, REPLACEMENT,  
13 EXPANSION, OR ACQUISITION OF CARDIAC CATHETERIZATION SERVICES, and THE delivery of  
14 THESE services under Part 222 of the Code. PURSUANT TO PART 222 OF THE CODE, cardiac  
15 catheterization services are A covered clinical service. The Department shall use THESE STANDARDS  
16 in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws  
17 AND Section 22225(2)(c) of the Code, being Section 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) "Cardiac catheterization laboratory" or "laboratory" means an individual radiological room  
23 equipped with a variety of x-ray machines and devices such as electronic image intensifiers, high speed  
24 film changers and digital subtraction units to assist in performing diagnostic or therapeutic cardiac  
25 catheterizations or electrophysiology studies.

26 (B) "Cardiac catheterization procedure" means any cardiac procedure, including diagnostic,  
27 therapeutic, and electrophysiology studies, performed on a patient during a single session in a laboratory.  
28 Cardiac catheterization is a medical diagnostic or therapeutic procedure during which a catheter is  
29 inserted into a vein or artery in a patient; subsequently the free end of the catheter is manipulated by a  
30 physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays  
31 and an electronic image intensifier are used as aides in placing the catheter tip in the desired position.  
32 When the catheter is in place, the physician is able to perform various diagnostic studies and/or  
33 therapeutic procedures in the heart. THIS TERM DOES not include "float catheters" THAT are performed  
34 at the bedside or in settings outside the laboratory OR THE IMPLANTATION OF CARDIAC  
35 PERMANENT PACEMAKERS AND IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICD)  
36 DEVICES THAT ARE PERFORMED IN AN INTERVENTIONAL RADIOLOGY LABORATORY OR  
37 OPERATING ROOM.

38 (C) "Cardiac catheterization service" means the provision of one or more of the following types of  
39 procedures: adult diagnostic cardiac catheterizations; pediatric diagnostic cardiac catheterizations; adult  
40 therapeutic cardiac catheterizations; and pediatric therapeutic cardiac catheterizations.

41 (D) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to  
42 Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

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

45 (F) "Department" means the Michigan Department of Community Health (MDCH).

46 (G) "Diagnostic cardiac catheterization service" means providing diagnostic cardiac catheterization  
47 PROCEDURES on an organized, regular basis in a laboratory TO DIAGNOSE ANATOMICAL AND/OR  
48 PHYSIOLOGICAL PROBLEMS IN THE HEART. PROCEDURES include the intra coronary  
49 administration of drugs; left heart catheterization; right heart catheterization; coronary angiography;  
50 diagnostic electrophysiology studies; and cardiac biopsies (echo-guided or fluoroscopic). A hospital that  
51 provides pediatric diagnostic cardiac catheterization services MAY ALSO PERFORM BALLOON ATRIAL  
52 SEPTOSTOMY PROCEDURES. A hospital that PROVIDES DIAGNOSTIC cardiac catheterization

53 services MAY ALSO PERFORM IMPLANTATIONS OF CARDIAC PERMANENT PACEMAKERS AND  
54 ICD DEVICES.

55 (H) "ELECTIVE PERCUTANEOUS CORONARY INTERVENTION (PCI) SERVICE" MEANS  
56 PROVIDING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND  
57 CORONARY STENT IMPLANTATION ON AN ORGANIZED, REGULAR BASIS IN A LABORATORY AT  
58 A HOSPITAL WITHOUT ON-SITE OPEN HEART SURGICAL SERVICES. THE TERM DOES NOT  
59 INCLUDE TRANSCATHETER VALVE, OTHER STRUCTURAL HEART DISEASE PROCEDURES, OR  
60 LEFT SIDED ARRHYTHMIA THERAPEUTIC PROCEDURES. A HOSPITAL THAT PROVIDES  
61 ELECTIVE PCI SERVICES MAY ALSO PERFORM IMPLANTATIONS OF CARDIAC PERMANENT  
62 PACEMAKERS, ICD DEVICES, AND RIGHT SIDED CATHETER ABLATION PROCEDURES.  
63 STRUCTURAL HEART DISEASE PROCEDURES CAN ONLY BE PERFORMED WITHIN A HOSPITAL  
64 THAT HAS ON-SITE OPEN HEART SURGICAL SERVICES.

65 (I) "Electrophysiology study" means a study of the electrical conduction activity of the heart and  
66 characterization of atrial and ventricular arrhythmias obtained by means of a cardiac catheterization  
67 procedure. The term also includes the implantation of permanent pacemakers and ICD DEVICES.

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

69 (K) "ICD-9-CM code" means the disease codes and nomenclature found in the International  
70 Classification of Diseases - 9th Revision - Clinical Modification, prepared by the Commission on  
71 Professional and Hospital Activities for the U.S. National Center for Health Statistics.

72 (L) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6  
73 and 1396r-8 to 1396v.

74 (M) "Pediatric cardiac catheterization service" means PROVIDING cardiac catheterization services on  
75 an organized, regular basis to infants and children ages 18 and below, except for electrophysiology  
76 studies THAT are offered and provided to infants and children ages 14 and below, and others with  
77 congenital heart disease as defined by the ICD-9-CM codes of 426.7 (ANOMALOUS  
78 ATRIOVENTRICULAR EXCITATION), 427.0 (CARDIAC DYSRHYTHMIAS), and 745.0 through 747.99  
79 (BULBUS CORDIS ANOMALIES AND ANOMALIES OF CARDIAC SEPTAL CLOSURE, OTHER  
80 CONGENITAL ANOMALIES OF HEART, AND OTHER CONGENITAL ANOMALIES OF CIRCULATORY  
81 SYSTEM).

82 (N) "Primary PCI" means a PCI performed ON AN acute myocardial infarction (AMI) patient with  
83 confirmed ST elevation or new left bundle branch block.

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

86 (P) "Therapeutic cardiac catheterization service" means providing therapeutic cardiac  
87 catheterizations on an organized, regular basis in a laboratory to treat and resolve anatomical and/or  
88 physiological problems in the heart. PROCEDURES include PCI, PTCA, atherectomy, stent, laser,  
89 cardiac valvuloplasty, balloon atrial septostomy, catheter ablation, cardiac permanent pacemaker, ICD  
90 device implantations, TRANSCATHETER VALVE, OTHER STRUCTURAL HEART DISEASE  
91 PROCEDURES, AND LEFT SIDED ARRHYTHMIA THERAPEUTIC PROCEDURES. The term does  
92 not include the intra coronary administration of drugs where that is the only therapeutic intervention.

93  
94 (2) Terms defined in the Code have the same meanings when used in these standards.  
95

### 96 **Section 3. Requirements to initiate cardiac catheterization services**

97  
98 Sec. 3. AN APPLICANT PROPOSING TO INITIATE CARDIAC CATHETERIZATION SERVICES  
99 SHALL DEMONSTRATE THE FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT.

100  
101 (1) An applicant proposing to initiate an adult diagnostic cardiac catheterization service shall  
102 DEMONSTRATE the following, as applicable TO THE PROPOSED PROJECT:

103 (A) THE APPLICANT IS APPLYING TO INITIATE PRIMARY PCI, ELECTIVE PCI, OR  
104 THERAPEUTIC CARDIAC CATHETERIZATION SERVICES.

105 (B) THE APPLICANT SHALL DEMONSTRATE THE FOLLOWING, AS APPLICABLE TO THE  
106 PROPOSED PROJECT:

107 (I) AN APPLICANT PROPOSING TO INITIATE WITH A SINGLE LABORATORY IN A rural or  
108 micropolitan statistical area county SHALL PROJECT a minimum of 500 procedure equivalents including  
109 300 procedure equivalents in the category of diagnostic cardiac catheterization PROCEDURES BASED  
110 ON DATA FROM THE MOST RECENT 12-MONTH PERIOD PRECEDING THE DATE THE  
111 APPLICATION WAS SUBMITTED TO THE DEPARTMENT.

112 (II) AN APPLICANT PROPOSING TO INITIATE WITH A SINGLE LABORATORY in a metropolitan  
113 statistical area county SHALL PROJECT a minimum of 750 procedure equivalents THAT includes 300  
114 procedure equivalents in the category of diagnostic cardiac catheterization PROCEDURES BASED ON  
115 DATA FROM THE MOST RECENT 12-MONTH PERIOD PRECEDING THE DATE THE APPLICATION  
116 WAS SUBMITTED TO THE DEPARTMENT.

117 (III) An applicant proposing to initiate WITH TWO or more laboratories shall project a minimum of  
118 1,000 procedure equivalents per laboratory THAT INCLUDES 300 PROCEDURE EQUIVALENTS IN THE  
119 CATEGORY OF DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES BASED ON DATA  
120 FROM THE MOST RECENT 12-month PERIOD PRECEDING THE DATE THE APPLICATION WAS  
121 SUBMITTED TO THE DEPARTMENT.

122  
123 (2) An applicant proposing to INITIATE AN ADULT therapeutic cardiac catheterization SERVICE  
124 shall demonstrate the following:

125 (a) THE applicant provides, IS APPROVED TO PROVIDE, or has APPLIED to provide adult  
126 diagnostic cardiac catheterization services AT THE HOSPITAL. THE APPLICANT MUST BE  
127 APPROVED FOR ADULT DIAGNOSTIC CARDIAC CATHETERIZATION SERVICES IN ORDER TO BE  
128 APPROVED FOR ADULT THERAPEUTIC CARDIAC CATHETERIZATION SERVICES.

129 (b) AN APPLICANT OPERATING AN ADULT DIAGNOSTIC CARDIAC CATHETERIZATION  
130 SERVICE HAS PERFORMED A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY  
131 OF ADULT DIAGNOSTIC CARDIAC CATHETERIZATIONS DURING THE MOST RECENT 12-MONTH  
132 PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT IF  
133 THE SERVICE HAS BEEN IN OPERATION MORE THAN 24 MONTHS.

134 (C) THE applicant HAS APPLIED TO provide adult open heart surgery services AT the hospital. The  
135 APPLICANT MUST BE APPROVED FOR AN ADULT OPEN HEART SURGERY SERVICE IN ORDER  
136 TO BE APPROVED FOR AN ADULT therapeutic cardiac catheterization SERVICE.

137 (D) THE applicant shall project a minimum of 300 procedure equivalents in the category of adult  
138 therapeutic cardiac catheterizations BASED ON DATA FROM THE MOST RECENT 12-MONTH PERIOD  
139 PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT.

140  
141 (3) An applicant proposing to initiate a pediatric cardiac catheterization service SHALL  
142 DEMONSTRATE THE FOLLOWING:

143 (A) THE APPLICANT HAS A board certified pediatric cardiologist with training in pediatric  
144 catheterization procedures to direct the pediatric catheterization laboratory.

145 (B) THE APPLICANT HAS standardized equipment as DEFINED IN THE MOST CURRENT  
146 AMERICAN ACADEMY OF PEDIATRICS (AAP) Guidelines FOR PEDIATRIC CARDIOVASCULAR  
147 CENTERS.

148 (C) THE APPLICANT HAS on-site ICU as outlined in THE MOST CURRENT AAP guidelines  
149 ABOVE.

150 (D) THE APPLICANT HAS APPLIED TO PROVIDE pediatric open heart surgery SERVICES AT THE  
151 HOSPITAL. THE APPLICANT MUST BE APPROVED FOR A PEDIATRIC OPEN HEART SURGERY  
152 SERVICE IN ORDER TO BE APPROVED FOR PEDIATRIC CARDIAC CATHETERIZATION SERVICES.

153 (E) THE applicant shall project a minimum of 600 procedure equivalents in the category of pediatric  
154 cardiac catheterizations BASED ON DATA FROM THE MOST RECENT 12-MONTH PERIOD  
155 PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT.

156

- 157 (4) An applicant proposing to initiate primary PCI service without on-site open heart surgery services  
158 shall demonstrate the following:
- 159 (a) The applicant OPERATES AN adult diagnostic cardiac catheterization service THAT HAS  
160 performed a minimum of 500 procedure EQUIVALENTS THAT INCLUDES 400 PROCEDURE  
161 EQUIVALENTS IN THE CATEGORY OF CARDIAC CATHETERIZATION PROCEDURES during the  
162 most recent 12 months preceding the date the application was submitted to the Department.
- 163 (b) The APPLICANT HAS AT LEAST TWO interventional cardiologists to perform the primary PCI  
164 PROCEDURES AND EACH CARDIOLOGIST HAS performed at least 75 PCI SESSIONS annually as the  
165 primary operator during the most recent 24-month PERIOD preceding the date the application was  
166 submitted to the Department.
- 167 (c) The nursing and technical catheterization laboratory staff: are experienced in handling acutely ill  
168 patients and comfortable with interventional equipment; have acquired experience in dedicated  
169 interventional laboratories at an open heart surgery HOSPITAL; and participate in an un-interrupted 24-  
170 hour, 365-day call schedule. Competency SHALL be documented annually.
- 171 (d) The laboratory OR LABORATORIES ARE equipped with optimal imaging systems, resuscitative  
172 equipment, AND intra-aortic balloon pump (IABP) support, and stocked with a broad array of  
173 interventional equipment.
- 174 (e) The cardiac care unit nurses are adept in hemodynamic monitoring and IABP management.  
175 Competency SHALL be documented annually.
- 176 (f) A written agreement with an open heart surgery HOSPITAL that includes ALL OF THE  
177 FOLLOWING:
- 178 (i) Involvement in credentialing criteria and recommendations for physicians approved to perform  
179 primary PCI PROCEDURES.
- 180 (ii) Provision for ongoing cross-training for professional and technical staff involved in the provision of  
181 primary PCI to ensure familiarity with interventional equipment. Competency SHALL be documented  
182 annually.
- 183 (iii) Provision for ongoing cross training for emergency department, catheterization laboratory, and  
184 critical care unit staff to ensure experience in handling the high acuity status of primary PCI patient  
185 candidates. Competency SHALL be documented annually.
- 186 (iv) Regularly held joint cardiology/cardiac surgery conferences to include review of all primary PCI  
187 cases.
- 188 (v) Development and ongoing review of patient selection criteria for primary PCI patients and  
189 implementation of those criteria.
- 190 (vi) A mechanism to provide for appropriate patient transfers between facilities and an agreed plan for  
191 prompt care.
- 192 (vii) Written protocols, signed by the applicant and the open heart surgery HOSPITAL, for the  
193 immediate transfer, within 1 hour from THE cardiac catheterization laboratory to evaluation on site in the  
194 open heart surgERY HOSPITAL, of patients requiring surgical evaluation and/or intervention 365 days a  
195 year. The protocols shall be reviewed AND tested on a quarterly basis.
- 196 (viii) Consultation on facilities, equipment, staffing, ancillary services, and policies and procedures for  
197 the provision of interventional procedures.
- 198 (g) A written protocol must be established and maintained for case selection for the performance of  
199 primary PCI.
- 200 (h) A system to ensure prompt and efficient identification of potential primary PCI patients and rapid  
201 transfer from the emergency department to the CARDIAC catheterization laboratory must be developed  
202 and maintained so that door-to-balloon targets are met.
- 203 (i) At least two physicians credentialed to perform primary PCI must commit to functioning as a  
204 coordinated group willing and able to provide this service at the hospital on a 24-hour per day, 365 day  
205 per year call schedule, with ability to be on-site and available to operate within 30 minutes of identifying  
206 the need for primary PCI. These physicians must be credentialed at the facility and actively collaborate  
207 with administrative and clinical staff in establishing and implementing protocols, call schedules, and  
208 quality assurance procedures pertaining to primary PCI designed to meet the requirements for this  
209 certification and in keeping with the current guidelines for the provision of primary PCI promulgated by the  
210 American College of Cardiology and American Heart Association.

211 (J) THE applicant shall project a minimum of 36 primary PCI CASES BASED ON DATA FROM THE  
212 MOST RECENT 12-month PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO  
213 THE DEPARTMENT.  
214

215 (5) AN APPLICANT PROPOSING TO INITIATE AN ELECTIVE PCI SERVICE WITHOUT ON-SITE  
216 OPEN HEART SURGERY SERVICES SHALL DEMONSTRATE THE FOLLOWING:

217 (A) THE APPLICANT PROVIDES, IS APPROVED TO PROVIDE, OR HAS APPLIED TO PROVIDE  
218 ADULT DIAGNOSTIC CARDIAC CATHETERIZATION SERVICES AT THE HOSPITAL. THE  
219 APPLICANT MUST BE APPROVED FOR ADULT DIAGNOSTIC CARDIAC CATHETERIZATION  
220 SERVICES IN ORDER TO BE APPROVED FOR ELECTIVE PCI SERVICES.

221 (B) THE APPLICANT HAS AT LEAST TWO INTERVENTIONAL CARDIOLOGISTS TO PERFORM  
222 PCI PROCEDURES AT THE HOSPITAL THAT MEET THE FOLLOWING:

223 (I) BOARD CERTIFIED IN INTERVENTIONAL CARDIOLOGY.

224 (II) INDIVIDUAL OUTCOMES ARE COMPARABLE TO NATIONAL OUTCOMES.

225 (III) PERFORMED AT LEAST 300 PCI SESSIONS SINCE FELLOWSHIP.

226 (IV) PERFORMED AT LEAST 100 PCI SESSIONS DURING THE MOST RECENT 24-MONTH  
227 PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT.

228 (C) A WRITTEN AGREEMENT WITH AN OPEN HEART SURGERY HOSPITAL THAT INCLUDES:

229 (I) SIGNATURES BY SENIOR EXECUTIVES FROM THE APPLICANT HOSPITAL AND THE  
230 HOSPITAL WITH OPEN HEART SURGERY SERVICES.

231 (II) INVOLVEMENT IN THE CREDENTIALING CRITERIA AND RECOMMENDATIONS FOR  
232 PHYSICIANS APPROVED TO PERFORM PCI.

233 (III) PROVISION FOR ONGOING CROSS-TRAINING FOR PROFESSIONAL AND TECHNICAL  
234 STAFF INVOLVED IN THE PROVISION OF PCI TO ENSURE FAMILIARITY WITH INTERVENTIONAL  
235 EQUIPMENT. COMPETENCY SHALL BE DOCUMENTED ANNUALLY.

236 (IV) PROVISION FOR ONGOING CROSS TRAINING FOR EMERGENCY DEPARTMENT,  
237 CATHETERIZATION LABORATORY AND CRITICAL CARE UNIT STAFF TO ENSURE EXPERIENCE  
238 IN HANDLING THE HIGH ACUITY STATUS OF PCI PATIENT CANDIDATES. COMPETENCY SHALL  
239 BE DOCUMENTED ANNUALLY.

240 (V) REGULARLY HELD JOINT CARDIOLOGY/CARDIAC SURGERY CONFERENCES (AT LEAST  
241 QUARTERLY) TO INCLUDE REVIEW OF ALL PCI CASES AND OUTCOMES;

242 (VI) DEVELOPMENT AND ONGOING REVIEW OF PATIENT SELECTION CRITERIA FOR PCI  
243 PATIENTS AND IMPLEMENTATION OF THOSE CRITERIA.

244 (VII) A MECHANISM TO PROVIDE FOR APPROPRIATE PATIENT TRANSFERS BETWEEN  
245 HOSPITALS AND AN AGREED PLAN FOR PROMPT CARE; WRITTEN PROTOCOLS, SIGNED BY  
246 THE APPLICANT AND THE OPEN HEART SURGICAL HOSPITAL, MUST BE IN PLACE WITH  
247 PROVISIONS FOR IMMEDIATE AND EFFICIENT TRANSFER WITHIN ONE HOUR OF PATIENTS  
248 REQUIRING SURGICAL EVALUATION AND/OR INTERVENTION 24 HOURS PER DAY, 365 DAYS A  
249 YEAR. THE PROTOCOLS SHALL BE REVIEWED/TESTED ON A REGULAR, SEMI-ANNUAL BASIS.

250 (VIII) ABILITY TO TRANSFER IMAGES ELECTRONICALLY FOR THE CONCURRENT REVIEW OF  
251 CASES WITH THE OPEN HEART SURGERY HOSPITAL IF NEEDED.

252 (IX) CONSULTATION ON FACILITIES, EQUIPMENT, STAFFING, ANCILLARY SERVICES, AND  
253 POLICIES AND PROCEDURES FOR THE PROVISION OF INTERVENTIONAL PROCEDURES.

254 (D) THE APPLICANT AGREES TO THE FOLLOWING:

255 (I) A WRITTEN PROTOCOL MUST BE ESTABLISHED AND MAINTAINED FOR CASE  
256 SELECTION FOR THE PERFORMANCE OF PCI THAT IS CONSISTENT WITH CURRENT PRACTICE  
257 GUIDELINES SET FORTH BY THE AMERICAN COLLEGE OF CARDIOLOGY AND THE AMERICAN  
258 HEART ASSOCIATION, INCLUDING A RISK STRATIFICATION TOOL (STS OR SYNTAX) USED AND  
259 RECORDED TO INSURE APPROPRIATE TRIAGE TO CORONARY ARTERY BYPASS GRAFT  
260 SURGERY. EXCLUSIONS FOR ELECTIVE PCI SHOULD INCLUDE DECOMPENSATED HEART  
261 FAILURE WITHOUT ACUTE ISCHEMIA, RECENT STROKE, ADVANCED MALIGNANCY, KNOWN  
262 CLOTTING DISORDERS, EF LESS THAN 25%, LEFT MAIN DISEASE UNPROTECTED BY PRIOR  
263 SURGERY, LESIONS THAT JEOPARDIZE >50% OF MYOCARDIUM, DIFFUSE DISEASE AND

264 EXCESSIVE TORTUOSITY, DEGENERATED VEIN GRAFTS, SUBSTANTIAL THROMBUS,  
265 AGGRESSIVE MEASURES TO OPEN CHRONIC TOTAL OCCLUSIONS, AND INABILITY TO  
266 PROTECT MAJOR SIDE BRANCHES.

267 (II) ESTABLISH AND MAINTAIN WRITTEN POLICY AND PROCEDURES FOR TRAINING,  
268 STAFFING, AND PROGRAM REVIEW.

269 (III) THE NURSING AND TECHNICAL CATHETERIZATION STAFF ARE EXPERIENCED IN  
270 HANDLING ACUTELY ILL PATIENTS AND COMFORTABLE WITH INTERVENTIONAL EQUIPMENT;  
271 HAVE ACQUIRED EXPERIENCE IN DEDICATED INTERVENTIONAL LABORATORIES AT OPEN  
272 HEART SURGERY SERVICES OR AT PRIMARY PCI SERVICES; AND PARTICIPATE IN AN UN-  
273 INTERRUPTED 24-HOUR, 365-DAY CALL SCHEDULE. COMPETENCY SHALL BE DOCUMENTED  
274 ANNUALLY.

275 (IV) THE CATHETERIZATION LABORATORY IS EQUIPPED WITH IMAGING SYSTEMS,  
276 RESUSCITATIVE EQUIPMENT, INTRA-AORTIC BALLOON PUMP (IABP) SUPPORT, AND STOCKED  
277 WITH APPROPRIATE INTERVENTIONAL EQUIPMENT.

278 (V) THE CARDIAC CARE UNIT NURSES ARE ADEPT IN HEMODYNAMIC MONITORING AND  
279 IABP MANAGEMENT. COMPETENCY SHALL BE DOCUMENTED ANNUALLY.

280 (VI) ESTABLISH AND MAINTAIN A SYSTEM TO ENSURE PROMPT AND EFFICIENT  
281 IDENTIFICATION OF POTENTIAL PRIMARY PCI PATIENTS AND RAPID TRANSFER TO THE  
282 CATHETERIZATION LABORATORY SO THAT DOOR-TO-BALLOON TARGETS ARE MET.

283 (VII) AT LEAST TWO PHYSICIANS CREDENTIALLED TO PERFORM PRIMARY PCI MUST COMMIT  
284 TO FUNCTIONING AS A COORDINATED GROUP WILLING AND ABLE TO PROVIDE THIS SERVICE  
285 AT THE HOSPITAL ON A 24-HOUR PER DAY, 365 DAY PER YEAR CALL SCHEDULE, WITH ABILITY  
286 TO BE ON-SITE AND AVAILABLE TO OPERATE WITHIN 30 MINUTES OF IDENTIFYING THE NEED  
287 FOR PRIMARY PCI. THESE PHYSICIANS MUST BE CREDENTIALLED AT THE FACILITY AND  
288 ACTIVELY COLLABORATE WITH ADMINISTRATIVE AND CLINICAL STAFF IN ESTABLISHING AND  
289 IMPLEMENTING PROTOCOLS, CALL SCHEDULES, AND QUALITY ASSURANCE PROCEDURES  
290 PERTAINING TO PRIMARY PCI DESIGNED TO MEET THE REQUIREMENTS FOR THIS  
291 CERTIFICATION AND IN KEEPING WITH THE CURRENT GUIDELINES FOR THE PROVISION OF  
292 PRIMARY PCI PROMULGATED BY THE AMERICAN COLLEGE OF CARDIOLOGY AND AMERICAN  
293 HEART ASSOCIATION.

294 (E) THE APPLICANT SHALL DEMONSTRATE THE FOLLOWING, AS APPLICABLE TO THE  
295 PROPOSED PROJECT:

296 (I) AN APPLICANT WITHIN ONE HOUR DRIVE TIME OF AN EXISTING PCI OR OPEN HEART  
297 SURGERY HOSPITAL SHALL PROJECT A MINIMUM OF 350 PCI (PTCA AND CORONARY STENT)  
298 CASES BASED ON DATA FROM THE MOST RECENT 12-MONTH PERIOD PRECEDING THE DATE  
299 THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT. THE DEPARTMENT SHALL REVOKE  
300 A CON FOR A PROGRAM THAT PERFORMS LESS THAN 250 PCIS IN THE SECOND 12 MONTHS  
301 OF OPERATION, OR LESS THAN 350 PCIS IN THE THIRD 12 MONTHS OF OPERATION, AND/OR IS  
302 RECOMMENDED FOR REVOCATION BY THE ORGANIZATION IDENTIFIED IN SECTION 8(6)(C).

303 (II) AN APPLICANT MORE THAN ONE HOUR DRIVE TIME OF AN EXISTING PCI OR OPEN  
304 HEART SURGERY HOSPITAL SHALL PROJECT A MINIMUM OF 250 PCI (PTCA AND CORONARY  
305 STENT) CASES BASED ON DATA FROM THE MOST RECENT 12-MONTH PERIOD PRECEDING THE  
306 DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT. THE DEPARTMENT SHALL  
307 REVOKE A CON FOR A PROGRAM THAT PERFORMS LESS THAN 250 PCIS IN THE THIRD 12  
308 MONTHS OF OPERATIONS AND/OR IS RECOMMENDED FOR REVOCATION BY THE  
309 ORGANIZATION IDENTIFIED IN SECTION 8(6)(C).

310  
311 **Section 4. Requirements to replace AN EXISTING cardiac catheterization SERVICE OR laboratory**  
312

313 Sec. 4. REPLACING A CARDIAC CATHETERIZATION LABORATORY MEANS A CHANGE IN THE  
314 ANGIOGRAPHY X-RAY EQUIPMENT OR A RELOCATION OF THE SERVICE TO A NEW SITE. THE  
315 TERM DOES NOT INCLUDE A CHANGE IN ANY OF THE OTHER EQUIPMENT OR SOFTWARE  
316 USED IN THE LABORATORY. AN APPLICANT PROPOSING TO REPLACE A CARDIAC

317 CATHETERIZATION LABORATORY OR SERVICE SHALL DEMONSTRATE THE FOLLOWING, AS  
318 APPLICABLE TO THE PROPOSED PROJECT:

319 (1) AN APPLICANT PROPOSING TO REPLACE CARDIAC CATHETERIZATION LABORATORY  
320 EQUIPMENT SHALL DEMONSTRATE THE FOLLOWING:

321 (A) THE EXISTING LABORATORY OR LABORATORIES TO BE REPLACED ARE FULLY  
322 DEPRECIATED ACCORDING TO GENERALLY ACCEPTED ACCOUNTING PRINCIPLES OR  
323 DEMONSTRATES EITHER OF THE FOLLOWING:

324 (i) THE EXISTING ANGIOGRAPHY X-RAY EQUIPMENT TO BE REPLACED POSES A THREAT  
325 TO THE SAFETY OF THE PATIENTS.

326 (ii) THE REPLACEMENT ANGIOGRAPHY X-RAY EQUIPMENT OFFERS TECHNOLOGICAL  
327 IMPROVEMENTS THAT ENHANCE QUALITY OF CARE, INCREASES EFFICIENCY, AND REDUCES  
328 OPERATING COSTS.

329 (B) THE EXISTING ANGIOGRAPHY X-RAY EQUIPMENT TO BE REPLACED WILL BE REMOVED  
330 FROM SERVICE ON OR BEFORE BEGINNING OPERATION OF THE REPLACEMENT EQUIPMENT.

331  
332 (2) An applicant PROPOSING TO REPLACE A cardiac catheterization service TO A NEW SITE  
333 SHALL DEMONSTRATE the following:

334 (a) THE PROPOSED PROJECT IS PART OF AN APPLICATION TO REPLACE THE ENTIRE  
335 HOSPITAL.

336 (b) THE APPLICANT HAS PERFORMED THE FOLLOWING DURING THE MOST RECENT 12-  
337 MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE  
338 DEPARTMENT, AS APPLICABLE TO THE PROPOSED PROJECT:

339 (i) A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT  
340 DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES.

341 (ii) A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT  
342 THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES.

343 (iii) A MINIMUM OF 600 PROCEDURE EQUIVALENTS IN THE CATEGORY OF PEDIATRIC  
344 CARDIAC CATHETERIZATION PROCEDURES.

345 (iv) A MINIMUM OF 500 PROCEDURE EQUIVALENTS FOR A HOSPITAL IN A RURAL OR  
346 MICROPOLITAN COUNTY WITH ONE LABORATORY.

347 (v) A MINIMUM OF 750 PROCEDURE EQUIVALENTS FOR A HOSPITAL IN A METROPOLITAN  
348 COUNTY WITH ONE LABORATORY.

349 (vi) A MINIMUM OF 1,000 PROCEDURE EQUIVALENTS PER CARDIAC CATHETERIZATION  
350 LABORATORY FOR A HOSPITAL WITH TWO OR MORE LABORATORIES.

351 (C) THE EXISTING CARDIAC CATHETERIZATION SERVICE HAS BEEN IN OPERATION FOR AT  
352 LEAST 36 MONTHS AS OF THE DATE THE APPLICATION HAS BEEN SUBMITTED TO THE  
353 DEPARTMENT.

354

### 355 **Section 5. Requirements to expand a cardiac catheterization service**

356

357 Sec. 5. An applicant proposing to add a laboratory to an existing cardiac catheterization service shall  
358 demonstrate the following:

359

360 (1) THE APPLICANT HAS PERFORMED THE FOLLOWING DURING THE MOST RECENT 12-  
361 MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE  
362 DEPARTMENT, AS APPLICABLE TO THE PROPOSED PROJECT:

363 (A) A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT  
364 DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES.

365 (B) A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT  
366 THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES.

367 (C) A MINIMUM OF 600 PROCEDURE EQUIVALENTS IN THE CATEGORY OF PEDIATRIC  
368 CARDIAC CATHETERIZATION PROCEDURES.

369

370 (2) THE APPLICANT HAS PERFORMED A MINIMUM OF 1,400 procedure equivalents PER existing  
371 and APPROVED LABORATORIES DURING THE MOST RECENT 12-month PERIOD PRECEDING THE  
372 DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT.  
373

374 **Section 6. Requirements TO ACQUIRE a cardiac catheterization SERVICE**  
375

376 Sec. 6. ACQUIRING A CARDIAC CATHETERIZATION SERVICE AND ITS LABORATORIES  
377 MEANS OBTAINING POSSESSION AND CONTROL BY CONTRACT, OWNERSHIP, LEASE OR  
378 OTHER COMPARABLE ARRANGEMENT OR RENEWAL OF A LEASE FOR EXISTING  
379 ANGIOGRAPHY X-RAY EQUIPMENT. AN APPLICANT PROPOSING TO ACQUIRE A CARDIAC  
380 CATHETERIZATION SERVICE OR RENEW A LEASE FOR EQUIPMENT SHALL DEMONSTRATE THE  
381 FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT:  
382

383 (1) AN APPLICANT PROPOSING TO ACQUIRE A CARDIAC CATHETERIZATION SERVICE  
384 SHALL DEMONSTRATE THE FOLLOWING:

385 (A) THE PROPOSED PROJECT IS PART OF AN APPLICATION TO ACQUIRE THE ENTIRE  
386 HOSPITAL.

387 (B) AN APPLICATION FOR THE FIRST ACQUISITION OF AN EXISTING CARDIAC  
388 CATHETERIZATION SERVICE AFTER <INSERT EFFECTIVE DATE OF THESE STANDARDS> SHALL  
389 NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE APPLICABLE VOLUME REQUIREMENTS IN  
390 SUBDIVISION (C). THE CARDIAC CATHETERIZATION SERVICE SHALL BE OPERATING AT THE  
391 APPLICABLE VOLUMES SET FORTH IN THE PROJECT DELIVERY REQUIREMENTS IN THE  
392 SECOND 12 MONTHS OF OPERATION OF THE SERVICE BY THE APPLICANT AND ANNUALLY  
393 THEREAFTER.

394 (C) THE APPLICANT HAS PERFORMED THE FOLLOWING DURING THE MOST RECENT 12-  
395 MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE  
396 DEPARTMENT, AS APPLICABLE TO THE PROPOSED PROJECT :

397 (I) A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT  
398 DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES.

399 (II) A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT  
400 THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES.

401 (III) A MINIMUM OF 600 PROCEDURE EQUIVALENTS IN THE CATEGORY OF PEDIATRIC  
402 CARDIAC CATHETERIZATION PROCEDURES.

403 (IV) A MINIMUM OF 500 PROCEDURE EQUIVALENTS FOR A HOSPITAL IN A RURAL OR  
404 MICROPOLITAN COUNTY WITH ONE LABORATORY.

405 (V) A MINIMUM OF 750 PROCEDURE EQUIVALENTS FOR A HOSPITAL IN A METROPOLITAN  
406 COUNTY WITH ONE LABORATORY.

407 (VI) A MINIMUM OF 1,000 PROCEDURE EQUIVALENTS PER CARDIAC CATHETERIZATION  
408 LABORATORY FOR TWO OR MORE LABORATORIES.  
409

410 (2) AN APPLICANT PROPOSING TO RENEW A LEASE FOR EXISTING ANGIOGRAPHY X-RAY  
411 EQUIPMENT SHALL DEMONSTRATE THE RENEWAL OF THE LEASE IS MORE COST EFFECTIVE  
412 THAN REPLACING THE EQUIPMENT.  
413

414 **Section 7. REQUIREMENT FOR MEDICAID PARTICIPATION**  
415

416 Sec. 7. An applicant shall provide verification of Medicaid participation at the time the application is  
417 submitted to the Department. An applicant that is initiating a new service or is a new provider not  
418 currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the  
419 Department within six (6) months from the offering of services if a CON is approved.

420 **Section 8. Project delivery requirements AND terms of approval for all applicants**

421  
422 Sec. 8. An applicant shall agree that, if approved, the CARDIAC CATHETERIZATION SERVICE AND  
423 ALL EXISTING AND APPROVED LABORATORIES shall be delivered in compliance with the following  
424 terms of approval:

- 425  
426 (1) Compliance with these standards.
- 427  
428 (2) Compliance with the following quality assurance standards:
- 429 (A) Cardiac catheterization procedures shall be performed in a cardiac catheterization laboratory  
430 located within a hospital, and have within, or immediately available to the room, dedicated emergency  
431 equipment to manage cardiovascular emergencies.
- 432 (B) The service shall be staffed with sufficient medical, nursing, technical and other personnel to  
433 permit regular scheduled hours of operation and continuous 24-hour on-call availability.
- 434 (C) The medical staff and governing body shall receive and review at least annual reports describing  
435 the activities of the cardiac catheterization service including complication rates, morbidity and mortality,  
436 success rates and the number of procedures performed.
- 437 (D) Each physician credentialed by a hospital to perform adult therapeutic cardiac catheterization  
438 procedures shall perform, as the primary operator, a minimum of 75 adult therapeutic cardiac  
439 catheterization procedures per year in the second 12 months after being credentialed to and annually  
440 thereafter. The annual case load for a physician means adult therapeutic cardiac catheterization  
441 procedures performed by that physician in any combination of hospitals.
- 442 (E) Each physician credentialed by a hospital to perform pediatric diagnostic cardiac catheterizations  
443 shall perform, as the primary operator, a minimum of 50 pediatric diagnostic cardiac catheterization  
444 procedures per year in the second 12 months after being credentialed and annually thereafter. The  
445 annual case load for a physician means pediatric diagnostic cardiac catheterization procedures  
446 performed by that physician in any combination of hospitals
- 447 (F) Each physician credentialed by a hospital to perform pediatric therapeutic cardiac  
448 catheterizations shall perform, as a primary operator, a minimum of 25 pediatric therapeutic cardiac  
449 catheterizations per year in the second 12 months after being credentialed and annually thereafter. The  
450 annual case load for a physician means pediatric therapeutic cardiac catheterization procedures  
451 performed by that physician in any combination of hospitals
- 452 (G) An adult diagnostic cardiac catheterization service shall have a minimum of two appropriately  
453 trained physicians on its active hospital staff. The Department MAY ACCEPT OTHER evidence OR  
454 SHALL CONSIDER IT appropriate training if the staff physicians:
- 455 (I) are trained consistent with the recommendations of the American College of Cardiology;  
456 (II) are credentialed by the hospital to perform adult diagnostic cardiac catheterizations; and  
457 (III) have each performed a minimum of 100 adult diagnostic cardiac catheterizations in the preceding  
458 12 months.
- 459 (H) An adult therapeutic cardiac catheterization service shall have a minimum of two appropriately  
460 trained physicians on its active hospital staff. The Department MAY ACCEPT OTHER evidence OR  
461 SHALL CONSIDER IT appropriate training if the staff physicians:
- 462 (I) are trained consistent with the recommendations of the American College of Cardiology;  
463 (II) are credentialed by the hospital to perform adult therapeutic cardiac catheterizations; and  
464 (III) have each performed a minimum of 75 adult therapeutic cardiac catheterization procedures in the  
465 preceding 12 months.
- 466 (I) A pediatric cardiac catheterization service shall HAVE AN appropriately trained physician on ITS  
467 active hospital staff. The Department MAY ACCEPT OTHER evidence OR SHALL CONSIDER IT  
468 appropriate training if the staff physician:
- 469 (I) IS board certified or board eligible in pediatric cardiology by the American Board of Pediatrics;  
470 (II) IS credentialed by the hospital to perform pediatric cardiac catheterizations; and  
471 (III) HAS trained consistently with the recommendations of the American College of Cardiology.

472 (J) A cardiac catheterization service shall be directed by an appropriately trained physician. The  
473 Department shall consider appropriate training OF THE director if the physician is board certified in  
474 cardiology, cardiovascular radiology or cardiology, adult or pediatric, as applicable. The director of an  
475 adult cardiac catheterization service shall have performed at least 200 catheterizations per year during  
476 each of the FIVE preceding years. The Department may accept other evidence that the director is  
477 appropriately trained.

478 (K) A cardiac catheterization service shall be operated consistently with the recommendations of the  
479 American College of Cardiology.

480  
481 (3) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:

482 (A) The SERVICE shall accept referrals for cardiac catheterization-from all appropriately licensed  
483 practitioners.

484 (B) THE SERVICE shall participate in Medicaid at least 12 consecutive months within the first two  
485 years of operation and annually thereafter.

486 (C) THE SERVICE SHALL not deny cardiac catheterization services to any individual based on ability  
487 to pay or source of payment.

488 (D) THE OPERATION OF AND REFERRAL OF PATIENTS TO THE CARDIAC CATHETERIZATION  
489 SERVICE SHALL BE IN CONFORMANCE WITH 1978 PA 368, SEC. 16221, AS AMENDED BY 1986 PA  
490 319; MCL 333.1621; MSA 14.15 (16221).

491  
492 (4) Compliance with THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:

493 (A) THE SERVICE SHALL BE OPERATING AT OR ABOVE THE APPLICABLE VOLUMES IN THE  
494 SECOND 12 MONTHS OF OPERATION OF THE SERVICE, OR AN ADDITIONAL LABORATORY, AND  
495 ANNUALLY THEREAFTER:

496 (I) 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT DIAGNOSTIC CARDIAC  
497 CATHETERIZATION PROCEDURES.

498 (II) 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT THERAPEUTIC CARDIAC  
499 CATHETERIZATION PROCEDURES.

500 (III) 600 PROCEDURE EQUIVALENTS IN THE CATEGORY OF PEDIATRIC CARDIAC  
501 CATHETERIZATION PROCEDURES.

502 (IV) 500 PROCEDURE EQUIVALENTS FOR A HOSPITAL IN A RURAL OR MICROPOLITAN  
503 COUNTY WITH ONE LABORATORY.

504 (V) 750 PROCEDURE EQUIVALENTS FOR A HOSPITAL IN A METROPOLITAN COUNTY WITH  
505 ONE LABORATORY.

506 (VI) 1,000 PROCEDURE EQUIVALENTS PER CARDIAC CATHETERIZATION LABORATORY FOR  
507 TWO OR MORE LABORATORIES.

508 (VII) 36 ADULT PRIMARY PCI CASES FOR A PRIMARY PCI SERVICE.

509 (VIII) 350 ADULT PCI CASES FOR AN ELECTIVE PCI SERVICE WITHIN ONE-HOUR DRIVE TIME  
510 OF AN EXISTING HOSPITAL WITH AN OPEN HEART SURGICAL SERVICE.

511 (IX) 250 ADULT PCI CASES FOR AN ELECTIVE PCI SERVICE MORE THAN ONE-HOUR DRIVE  
512 TIME OF AN EXISTING HOSPITAL WITH AN OPEN HEART SURGICAL SERVICE.

513 (B) The HOSPITAL shall participate in a data collection network established and administered by the  
514 Department or its designee. Data may include, but is not limited to, annual budget and cost information,  
515 operating schedules, PATIENT demographics, morbidity and mortality information, AND payor. The  
516 Department may verify the data through on-site review of appropriate records.

517 (C) The HOSPITAL shall participate in a quality improvement data registry administered by the  
518 Department or its designee. The HOSPITAL SHALL submit summary reports as required by the  
519 Department. The HOSPITAL shall provide the required data in a format established by the Department or  
520 its designee. The HOSPITAL IS liable for the cost of data submission and on-site reviews in order for the  
521 Department to verify and monitor volumes and assure quality. THE HOSPITAL MUST become a member  
522 of the data registry upon initiation of the service and continue to participate annually thereafter FOR THE  
523 LIFE OF THAT SERVICE.

524

- 525 (5) COMPLIANCE WITH THE FOLLOWING PRIMARY PCI REQUIREMENTS, IF APPLICABLE:  
526 (A) THE requirements set forth in Section 3(4).  
527 (B) THE HOSPITAL shall immediately report to the Department any changes in the interventional  
528 cardiologists who perform the primary PCI procedures.  
529 (C) The HOSPITAL shall perform a minimum of 36 primary PCI procedures at the HOSPITAL in the  
530 preceding 12-month PERIOD OF OPERATION OF THE SERVICE and annually thereafter.  
531 (D) THE HOSPITAL SHALL MAINTAIN A 90-MINUTE DOOR-TO-BALLON TIME OR LESS IN AT  
532 LEAST 75% OF THE PRIMARY PCI SESSIONS.  
533 (E) The HOSPITAL shall participate in a data registry, administered by the Department or its  
534 designee. The Department or its designee shall require that the applicant submit data on all consecutive  
535 cases of primary PCI as is necessary to comprehensively assess and provide comparative analyses of  
536 case selection, processes and outcome of care, and trend in efficiency. The applicant shall provide the  
537 required data in a format established by the Department or its designee. The applicant shall be liable for  
538 the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes  
539 and assure quality.  
540
- 541 (6) COMPLIANCE WITH THE FOLLOWING ELECTIVE PCI REQUIREMENTS, IF APPLICABLE:  
542 (A) THE REQUIREMENTS SET FORTH IN SECTION 3(5).  
543 (B) THE HOSPITAL SHALL PARTICIPATE IN A BENCHMARKED PCI DATA REGISTRY  
544 DESIGNED BY THE DEPARTMENT THAT INCLUDES ALL THE FOLLOWING:  
545 (I) PATIENT AND CLINICAL DESCRIPTIONS.  
546 (II) MEASURES OF OUTCOMES.  
547 (III) MEASURE OF THE ACC APPROPRIATE USE OF THE PROCEDURE INCLUDING STS OR  
548 SYNTAX SCORE IN EACH PATIENT. THE DEPARTMENT SHALL REQUIRE THAT THE HOSPITAL  
549 SUBMIT DATA ON ALL PCI CASES IN A FORMAT ESTABLISHED BY THE DEPARTMENT. THE  
550 HOSPITAL SHALL BE LIABLE FOR COSTS OF DATA SUBMISSION. THE DEPARTMENT SHALL  
551 REQUIRE THAT THE HOSPITAL SUBMIT A SUMMARY REPORT ON AN ANNUAL BASIS THAT  
552 SHALL BE MADE AVAILABLE TO THE GENERAL PUBLIC.  
553 (C) THE HOSPITAL SHALL PARTICIPATE IN AN EXTERNAL IMPARTIAL OVERSIGHT BODY TO  
554 BE DESIGNATED BY THE DEPARTMENT. THE HOSPITAL SHALL BE LIABLE FOR THE COSTS OF  
555 PARTICIPATING IN THIS OVERSIGHT PROCESS AND MUST CONTINUE TO PARTICIPATE  
556 ANNUALLY THEREAFTER. THE OVERSIGHT BODY SHALL PRODUCE AN ANNUAL REPORT OF  
557 ALL PCI PROGRAM THAT WILL CONTAIN ALL THE FOLLOWING:  
558 (I) COMPLICATION RATES.  
559 (II) NUMBER OF PROCEDURES PERFORMED PER OPERATOR.  
560 (III) SUCCESS RATES.  
561 (IV) APPROPRIATE USE RATES.  
562 (V) PATIENT TRANSFER RATES.  
563 (VI) THE OVERSIGHT BODY SHALL REVIEW THE FINDINGS WITH EACH OF THE  
564 PARTICIPATING HOSPITALS AS A GROUP AND SHALL PROVIDE THOSE FINDINGS TO THE  
565 DEPARTMENT TO BE MADE AVAILABLE TO THE GENERAL PUBLIC. ALL ELECTIVE PCI  
566 SERVICES PERFORMING LESS THAN 250 PCI CASES PER YEAR IN ANY GIVEN YEAR MUST  
567 HAVE ALL CASES REVIEWED BY THIS OVERSIGHT BODY FOR APPROPRIATENESS AND  
568 OUTCOMES.  
569 (D) THE HOSPITAL SHALL INCLUDE IN THEIR CONSENT FOR PCI NOTIFICATION TO THE  
570 PATIENT THAT THE HOSPITAL DOES NOT PROVIDE ON-SITE OPEN HEART SURGICAL SERVICES  
571 AND THAT TRANSFER TO A HOSPITAL WITH OPEN HEART SURGICAL SERVICES MAY BE  
572 NECESSARY.  
573 (E) THE HOSPITAL SHALL ESTABLISH AN INTERNAL REVIEW BODY, INCLUDING AT A  
574 MINIMUM THE CHIEF MEDICAL OFFICER, DIRECTOR OF CARDIOVASCULAR SERVICES,  
575 DIRECTOR OF CARDIOVASCULAR SERVICES FOR THE HOSPITAL WITH OPEN HEART SURGICAL  
576 SERVICES (OR EQUIVALENT PHYSICIAN REPRESENTATIVES), THAT SHALL REVIEW AT LEAST  
577 ANNUAL REPORTS DESCRIBING THE ACTIVITIES OF THE CARDIAC CATHETERIZATION SERVICE

578 INCLUDING COMPLICATION RATES, MORBIDITY AND MORTALITY, SUCCESS RATES AND THE  
579 NUMBER OF PROCEDURES PERFORMED AND PROCEDURES REQUIRING TRANSFER.

580 (F) THE HOSPITAL SHALL EMPLOY APPROPRIATE DATA MANAGEMENT PERSONNEL TO  
581 INSURE TIMELY AND ACCURATE REPORTING TO THE REGISTRY AND REVIEWING BODIES  
582 STATED ABOVE.

583 (G) EACH PHYSICIAN CREDENTIALLED BY A HOSPITAL TO PERFORM PCI CASES SHALL  
584 PERFORM, AS THE PRIMARY OPERATOR, A MINIMUM OF 100 PCI CASES PER YEAR IN THE  
585 SECOND 12 MONTHS AFTER BEING CREDENTIALLED AND ANNUALLY THEREAFTER. THE  
586 ANNUAL CASE LOAD FOR A PHYSICIAN MEANS PCI CASES PERFORMED BY THAT PHYSICIAN IN  
587 ANY COMBINATION OF HOSPITALS.

588 (H) EACH PHYSICIAN MUST ALSO MAINTAIN THE FOLLOWING IN ORDER TO BE  
589 CREDENTIALLED:

590 (I) PARTICIPATION IN AN INSTITUTIONAL QUALITY IMPROVEMENT PROGRAM.

591 (II) BOARD CERTIFIED IN INTERVENTIONAL CARDIOLOGY.

592 (III) PERFORMED AT LEAST 300 PCI CASES TOTAL SINCE FELLOWSHIP.

593 (IV) AT LEAST 30 HOURS OF CONTINUING MEDICAL EDUCATION DIRECTED TOWARD  
594 INTERVENTIONAL CARDIOLOGY EVERY 24 MONTHS.

595 (I) THE MEDICAL DIRECTOR OF THE HOSPITAL SHALL PERFORM PCI PROCEDURES AT  
596 THE CONTRACTED HOSPITAL WITH OPEN HEART SURGICAL SERVICES AND SHALL ALSO  
597 PERFORM PCI PROCEDURES AT THE ELECTIVE PCI SERVICE HOSPITAL DURING EACH YEAR  
598 UNTIL THE HOSPITAL REACHES MINIMUM VOLUME.

599 (J) THE HOSPITAL SHALL ALWAYS HAVE IN PLACE A WRITTEN AGREEMENT MEETING ALL  
600 OF THE REQUIREMENTS OF THE WRITTEN AGREEMENT BETWEEN THE HOSPITAL AND THE  
601 HOSPITAL WITH THE OPEN HEART SURGICAL SERVICE AS LONG AS THE ELECTIVE PCI  
602 SERVICE DOES NOT HAVE ON-SITE OPEN HEART SURGICAL SERVICES, BUT MAY CHANGE THE  
603 CONTRACTED OPEN HEART SURGICAL HOSPITAL.

604

### 605 **Section 9. Methodology for computing cardiac catheterization equivalents**

606

607 Sec. 9. The following shall be used in calculating PROCEDURE EQUIVALENTS and evaluating  
608 utilization of a cardiac catheterization SERVICE AND ITS laboratories:

609

PROCEDURE TYPE	PROCEDURE EQUIVALENT	
	Adult	Pediatric
Diagnostic cardiac catheterization/PERIPHERAL SESSIONS	1.5	2.7
Therapeutic cardiac catheterization/PERIPHERAL SESSIONS	2.7	4.0
COMPLEX PERCUTANEOUS VALVULAR SESSIONS*	4.0	7.0

\* COMPLEX PERCUTANEOUS VALVULAR SESSIONS INCLUDES, BUT IS NOT LIMITED TO, PROCEDURES PERFORMED PERCUTANEOUSLY OR WITH SURGICAL ASSISTANCE TO REPAIR OR REPLACE AORTIC, MITRAL AND PULMONARY VALVES SUCH AS TRANSCATHETER AORTIC VALVULAR IMPLANTATION (TAVI) PROCEDURES. THESE SESSIONS CAN ONLY BE PERFORMED AT HOSPITALS APPROVED WITH OPEN HEART SURGERY SERVICES.

610

### 611 **Section 10. Documentation of projections**

612

613 Sec. 10. An applicant required to project volumes shall DEMONSTRATE THE FOLLOWING, AS  
614 APPLICABLE TO THE PROPOSED PROJECT:

615

616 (1) THE applicant shall specify how the volume projections were developed. Specification of the  
617 projections shall include a description of the data source(s) used AND assessment of the accuracy of the  
618 data. The Department shall determine if the projections are reasonable.

619  
620 (2) AN APPLICANT PROPOSING TO INITIATE A PRIMARY PCI SERVICE SHALL  
621 DEMONSTRATE AND CERTIFY THAT THE HOSPITAL TREATED OR TRANSFERRED 36 ST  
622 SEGMENT ELEVATION AMI CASES DURING THE MOST RECENT 12-MONTH PERIOD PRECEDING  
623 THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT. CASES MAY INCLUDE  
624 THROMBOLYTIC ELIGIBLE PATIENTS DOCUMENTED THROUGH PHARMACY RECORDS  
625 SHOWING THE NUMBER OF DOSES OF THROMBOLYTIC THERAPY ORDERED AND MEDICAL  
626 RECORDS OF EMERGENCY TRANSFERS OF AMI PATIENTS TO AN APPROPRIATE HOSPITAL  
627 FOR A PRIMARY PCI PROCEDURE.  
628

629 (3) AN APPLICANT PROPOSING TO INITIATE AN ELECTIVE PCI SERVICE SHALL  
630 DEMONSTRATE AND CERTIFY THE FOLLOWING:

631 (A) PHYSICIAN COMMITMENTS OF PCI CASES PERFORMED AT AN EXISTING CARDIAC  
632 CATHETERIZATION SERVICE IN THE SAME HEALTH SERVICE AREA.

633 (I) COMMITMENTS OF PCI CASES SHALL NOT REDUCE AN EXISTING CARDIAC  
634 CATHETERIZATION SERVICE BELOW ITS APPLICABLE VOLUME REQUIREMENT.

635 (II) COMMITMENTS OF PCI CASES DO NOT REPRESENT DUPLICATE CASES WITHIN THIS  
636 SUBSECTION.

637 (III) COMMITMENTS IDENTIFY THE FOLLOWING:

638 (A) THE NAME OF EACH PHYSICIAN THAT PERFORMED PCI CASES TO BE COMMITTED TO  
639 THE PROPOSED PROJECT.

640 (B) THE NUMBER OF PCI CASES THAT EACH PHYSICIAN PERFORMED DURING THE MOST  
641 RECENT 12 MONTHS VERIFIABLE BY THE DEPARTMENT.

642 (C) THE LOCATIONS AT WHICH THE COMMITTED PCI CASES WERE PERFORMED.

643 (D) A WRITTEN COMMITMENT FROM EACH PHYSICIAN THAT HE OR SHE WILL PERFORM AT  
644 LEAST THE VOLUME OF PCI CASES COMMITTED TO THE PROPOSED ELECTIVE PCI SERVICE  
645 FOR NO LESS THAN THREE YEARS SUBSEQUENT TO THE INITIATION OF THE SERVICE  
646 PROPOSED BY THE APPLICANT.

647 (E) THE NUMBER OF PCI CASES PERFORMED AT THE EXISTING CARDIAC  
648 CATHETERIZATION SERVICE FROM WHICH PCI CASES WILL BE TRANSFERRED DURING THE  
649 MOST RECENT 12- MONTH PERIOD VERIFIABLE BY THE DEPARTMENT FOR WHICH ANNUAL  
650 SURVEY DATA IS AVAILABLE.

651 (B) DOCUMENTATION OF EXISTING PATIENT TRANSFERS FROM THE APPLICANT HOSPITAL  
652 TO A PCI SERVICE OR OPEN HEART SURGERY HOSPITAL FOR PURPOSES OF RECEIVING A PCI  
653 PROCEDURE. IN DEMONSTRATING COMPLIANCE, AN APPLICANT SHALL PROVIDE THE  
654 FOLLOWING FOR EACH PATIENT TRANSFER IN THE MOST RECENT 12-MONTH PERIOD  
655 VERIFIABLE BY THE DEPARTMENT:

656 (I) UNIQUE PATIENT IDENTIFIER.

657 (II) ICD-9, OR EQUIVALENT, DIAGNOSIS CODE.

658 (III) HOSPITAL WHERE THE PATIENT WAS TRANSFERRED.

659 (IV) PHYSICIAN PATIENT TRANSFERRED TO.

660 (V) DATE OF PATIENT TRANSFER.

661 (C) EXISTING PCI CASES PERFORMED AT THE APPLICANT HOSPITAL IN THE MOST RECENT  
662 12 MONTHS VERIFIABLE BY THE DEPARTMENT.  
663

#### 664 **Section 11. Comparative reviews; Effect on prior CON Review Standards** 665

666 Sec. 11. PROPOSED projects reviewed under these standards shall not be subject to comparative  
667 review. These CON Review Standards supercede and replace the CON Review Standards for Cardiac  
668 Catheterization Services approved by the CON Commission on DECEMBER 11, 2007 and effective on  
669 FEBRUARY 25, 2008.

670				
671				
672	<b>HEALTH SERVICE AREAS</b>	<b>COUNTIES</b>		
673				
674	1 – SOUTHEAST	LIVINGSTON	MONROE	ST. CLAIR
675		MACOMB	OAKLAND	WASHTENAW
676		WAYNE		
677				
678	2 – MID-SOUTHERN	CLINTON	HILLSDALE	JACKSON
679		EATON	INGHAM	LENAWEE
680				
681	3 – SOUTHWEST	BARRY	CALHOUN	ST. JOSEPH
682		BERRIEN	CASS	VAN BUREN
683		BRANCH	KALAMAZOO	
684				
685	4 – WEST	ALLEGAN	MASON	NEWAYGO
686		IONIA	MECOSTA	OCEANA
687		KENT	MONTCALM	OSCEOLA
688		LAKE	MUSKEGON	OTTAWA
689				
690	5 - GLS	GENESEE	LAPEER	SHIAWASSEE
691				
692	6 – EAST	ARENAC	HURON	ROSCOMMON
693		BAY	IOSCO	SAGINAW
694		CLARE	ISABELLA	SANILAC
695		GLADWIN	MIDLAND	TUSCOLA
696		GRATIOT	OGEMAW	
697				
698	7 – NORTHERN LOWER	ALCONA	CRAWFORD	MISSAUKEE
699		ALPENA	EMMET	MONTMORENCY
700		ANTRIM	GRAND TRAVERSE	OSCODA
701		BENZIE	KALKASKA	OTSEGO
702		CHARLEVOIX	LEELANAU	PRESQUE ISLE
703		CHEBOYGAN	MANISTEE	WEXFORD
704				
705	8 – UPPER PENINSULA	ALGER	GOGEBIC	MACKINAC
706		BARAGA	HOUGHTON	MARQUETTE
707		CHIPPEWA	IRON	MENOMINEE
708		DELTA	KEWEENAW	ONTONAGON
709		DICKINSON	LUCE	SCHOOLCRAFT

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Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:  
65 F.R., p. 82238 (December 27, 2000)  
Statistical Policy Office  
Office of Information and Regulatory Affairs  
United States Office of Management and Budget