

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 ~~for all projects approved and Certificates of Need issued~~ under Part 222 of the Code
15 ~~which involve cardiac catheterization services.~~

16
17 ~~—(2)— PURSUANT TO PART 222 OF THE CODE, Cardiac cardiac catheterization services are A~~
18 ~~covered clinical services for purposes of Part 222 of the Code.~~

19
20 ~~—(3)—~~ The Department shall use ~~sections 3, 4, 5, 6, 7, 8, 9, 10, 11 and 14 as applicable,~~ THESE
21 STANDARDS in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan
22 Compiled Laws.

23
24 ~~—(4)—~~ The Department shall use ~~Section 12 and 13 in applying~~ AND Section 22225(2)(c) of the Code,
25 being Section 333.22225(2)(c) of the Michigan Compiled Laws.

26
27 ~~—(5)—~~ The Department shall use ~~Section 3(2), in applying Section 22215(1)(b) of the Code, being~~
28 ~~Section 333.22215(1)(b) of the Michigan Compiled Laws.~~

29
30 **Section 2. Definitions**

31
32 Sec. 2. (1) For purposes of these standards:

33 (a) ~~"Balloon atrial septostomy" means a procedure in which a balloon-tipped catheter is placed~~
34 ~~across the atrial septum and withdrawn to create an enlarged atrial opening.~~

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

39 (eB) "Cardiac catheterization procedure" means any cardiac procedure, including diagnostic,
40 therapeutic, and electrophysiology studies, ~~as applicable,~~ performed on a patient during a single session
41 in a ~~cardiac catheterization~~ laboratory. Cardiac catheterization is a medical diagnostic or therapeutic
42 procedure during which a catheter is inserted into a vein or artery in a patient; subsequently the free end
43 of the catheter is manipulated by a physician to travel along the course of the blood vessel into the
44 chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aides in placing
45 the catheter tip in the desired position. When the catheter is in place, the physician is able to perform
46 various diagnostic studies and/or therapeutic procedures in the heart. ~~Cardiac catheterization shall~~ THIS
47 TERM DOES not include "float catheters" ~~which~~ THAT are performed at the bedside or in settings outside
48 the ~~cardiac catheterization~~ laboratory OR THE IMPLANTATION OF CARDIAC PERMANENT
49 PACEMAKERS AND IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICD) DEVICES THAT ARE
50 PERFORMED IN AN INTERVENTIONAL RADIOLOGY LABORATORY OR OPERATING ROOM.

51 (dC) "Cardiac catheterization service" means the provision of one or more of the following types of
52 procedures ~~in compliance with Part 222 of the Code:~~ adult diagnostic cardiac catheterizations; pediatric

53 diagnostic cardiac catheterizations; adult therapeutic cardiac catheterizations; and pediatric therapeutic
54 cardiac catheterizations.

55 ~~—(e) "Central service coordinator" means the organizational entity that has operational responsibility
56 for a mobile cardiac catheterization network. It shall be a legal entity authorized to do business in
57 Michigan.~~

58 (fD) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to
59 Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

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

62 (hF) "Department" means the Michigan Department of Community Health (MDCH).

63 (iG) "Diagnostic cardiac catheterization service" means providing diagnostic ~~only~~ cardiac
64 catheterization PROCEDURES on an organized, regular basis, in a laboratory TO DIAGNOSE
65 ANATOMICAL AND/OR PHYSIOLOGICAL PROBLEMS IN THE HEART. The term PROCEDURES
66 includes, but is not limited to: the intra coronary administration of drugs; left heart catheterization; right
67 heart catheterization; coronary angiography; diagnostic electrophysiology studies; and cardiac biopsies
68 (echo-guided or fluoroscopic). ~~For purposes of these standards, the term also includes balloon atrial~~
69 ~~septostomy procedure in a~~ hospital that provides pediatric diagnostic cardiac catheterization services
70 MAY ALSO PERFORM BALLOON ATRIAL SEPTOSTOMY PROCEDURES. This term also includes
71 cardiac permanent pacemaker/ICD device implantations in a hospital that ~~does not provide~~
72 therapeutic PROVIDES DIAGNOSTIC cardiac catheterization services MAY ALSO PERFORM
73 IMPLANTATIONS OF CARDIAC PERMANENT PACEMAKERS AND ICD DEVICES.

74 (H) "ELECTIVE PERCUTANEOUS CORONARY INTERVENTION (PCI) SERVICE" MEANS
75 PROVIDING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND
76 CORONARY STENT IMPLANTATION ON AN ORGANIZED, REGULAR BASIS IN A LABORATORY AT
77 A HOSPITAL WITHOUT ON-SITE OPEN HEART SURGICAL SERVICES. THE TERM DOES NOT
78 INCLUDE TRANSCATHETER VALVE, OTHER STRUCTURAL HEART DISEASE PROCEDURES, OR
79 LEFT SIDED ARRHYTHMIA THERAPEUTIC PROCEDURES. A HOSPITAL THAT PROVIDES
80 ELECTIVE PCI SERVICES MAY ALSO PERFORM IMPLANTATIONS OF CARDIAC PERMANENT
81 PACEMAKERS, ICD DEVICES, AND RIGHT SIDED CATHETER ABLATION PROCEDURES.
82 STRUCTURAL HEART DISEASE PROCEDURES CAN ONLY BE PERFORMED WITHIN A HOSPITAL
83 THAT HAS ON-SITE OPEN HEART SURGICAL SERVICES.

84 (jI) "Electrophysiology study" means a study of the electrical conduction activity of the heart and
85 characterization of atrial and ventricular arrhythmias, obtained by means of a cardiac catheterization
86 procedure. The term also includes the implantation of permanent pacemakers and ICD
87 DEVICES defibrillators.

88 ~~—(k) "Expand a cardiac catheterization service" means either:~~

89 ~~—(i) an increase in the number of cardiac catheterization laboratories at a hospital; or~~

90 ~~—(ii) expanding the types of cardiac catheterization procedures authorized to be performed including~~
91 ~~adult or pediatric, diagnostic or therapeutic, at a hospital that currently performs cardiac catheterization~~
92 ~~procedures.~~

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

94 ~~—(m) "Host facility" means a hospital at which a mobile cardiac catheterization network is authorized to~~
95 ~~provide cardiac catheterization services.~~

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

99 ~~—(o) "Initiate a cardiac catheterization service" means to begin performing cardiac catheterization~~
100 ~~procedures at a hospital that does not perform cardiac catheterization procedures as of the date an~~
101 ~~application is submitted to the Department.~~

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

104 ~~—(q) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as~~
105 ~~that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by~~

~~the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.~~

~~—(r) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.~~

~~—(s) "Mobile cardiac catheterization network" means the provision of adult diagnostic-only cardiac catheterization services by a central service coordinator and two or more host hospitals.~~

~~—(t) "On-site open heart surgery services" means a facility that does have a CON to perform open heart surgery services and does perform open heart surgery services in the existing hospital.~~

~~(uM) "Pediatric cardiac catheterization service" means the offering and provision of PROVIDING cardiac catheterization services on an organized, regular basis to infants and children ages 18 and below, except for electrophysiology studies which-THAT are offered and provided to infants and children ages 14 and below, and others with congenital heart disease as defined by the ICD-9-CM codes of 426.7 (ANOMALOUS ATRIOVENTRICULAR EXCITATION), 427.0 (CARDIAC DYSRHYTHMIAS), and 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).~~

~~(vN) "Primary percutaneous coronary intervention (PCI)" means a PCI performed within 120 minutes for emergency ON AN acute myocardial infarction (AMI) patients seen in the emergency room (ER) with confirmed ST elevation or new left bundle branch block.~~

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

~~—(x) "Replace/upgrade" means any equipment change that involves a capital expenditure of \$500,000 or more in any consecutive 24-month period which results in the applicant operating the same number of cardiac catheterization laboratories before and after project completion.~~

~~—(y) "Rural county" means a county not located in a metropolitan statistical area or micropolitan statistical areas as those terms are defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.~~

~~(zP) "Therapeutic cardiac catheterization service" means providing therapeutic cardiac catheterizations on an organized, regular basis in a laboratory to treat and resolve anatomical and/or physiological problems in the heart. The term PROCEDURES includes, but is not limited to: percutaneous coronary intervention (PCI), percutaneous transluminal coronary angioplasty (PTCA), atherectomy, stent, laser, cardiac valvuloplasty, balloon atrial septostomy, or catheter ablation, and cardiac permanent pacemaker, ICD device implantations, TRANSCATHETER VALVE, OTHER STRUCTURAL HEART DISEASE PROCEDURES, AND LEFT SIDED ARRHYTHMIA THERAPEUTIC PROCEDURES. The term does not include the intra coronary administration of drugs where that is the only therapeutic intervention. OR THE IMPLANTATION OF ICD DEVICES AND PACEMAKERS THAT ARE DONE IN AN INTERVENTIONAL RADIOLOGY SUITE OR OPERATING ROOM.~~

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

Section 3. Requirements for approval – all applicants

~~—Sec. 3. (1) Cardiac catheterization procedures shall be performed in a cardiac catheterization laboratory located within a hospital, and have within, or immediately available to the room, dedicated emergency equipment to manage cardiovascular emergencies.~~

~~—(2) An applicant shall provide verification of Medicaid participation at the time the application is submitted to the Department. An applicant that is initiating a new service or is a new provider not~~

159 ~~currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the~~
160 ~~Department within six (6) months from the offering of services if a CON is approved.~~

161
162 **Section 4. Requirements for approval ~~— applicants proposing to initiate an adult diagnostic~~**
163 **cardiac catheterization service**
164

165 Sec. 43. AN APPLICANT PROPOSING TO INITIATE CARDIAC CATHETERIZATION SERVICES
166 SHALL DEMONSTRATE THE FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT.
167

168 ~~___(1) An applicant proposing to initiate an adult diagnostic cardiac catheterization service shall project a~~
169 ~~minimum of 300 procedure equivalents in the category of adult diagnostic cardiac catheterization will be~~
170 ~~performed in the second 12 months of operation after initiation of the adult diagnostic cardiac~~
171 ~~catheterization service, and annually thereafter.~~

172
173 ~~___(2) An applicant proposing to initiate an adult diagnostic cardiac catheterization service in a new~~
174 ~~single laboratory shall project DEMONSTRATE the following volume of procedure equivalents, as~~
175 ~~applicable, will be performed in the second 12 months of operation after initiation of the service, and~~
176 ~~annually thereafter. TO THE PROPOSED PROJECT:~~

177 ___(A) AN THE APPLICANT IS APPLYING TO INITIATE PRIMARY PCI, ELECTIVE PCI, OR
178 THERAPEUTIC CARDIAC CATHETERIZATION SERVICES.

179 ___(aB) For a hospital located AN THE APPLICANT SHALL DEMONSTRATE THE FOLLOWING, AS
180 APPLICABLE TO THE PROPOSED PROJECT:

181 ___(i) ~~IN FOR A~~AN APPLICANT PROPOSING TO INITIATE WITH A SINGLE LABORATORY IN A
182 rural or micropolitan statistical area county, SHALL PROJECT a minimum of 500 procedure equivalents
183 which shall include ~~SING~~including the 300 procedure equivalents in the category of adult diagnostic
184 cardiac catheterization ~~required under subsection (1)~~PROCEDURES BASED ON DATA FROM THE
185 MOST RECENT 12-MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED
186 TO THE DEPARTMENT.

187 (bii) For a hospital located AN APPLICANT PROPOSING TO INITIATE WITH A SINGLE
188 LABORATORY in a metropolitan statistical area county, SHALL PROJECT a minimum of 750 procedure
189 equivalents which shall ~~THAT~~ include ~~Sin~~cludes the 300 procedure equivalents in the category of adult
190 diagnostic cardiac catheterization ~~required under subsection (1)~~ PROCEDURES DURING ~~BASED ON~~
191 DATA FROM THE MOST RECENT 12-MONTH PERIOD PRECEDING THE DATE THE APPLICATION
192 WAS SUBMITTED TO THE DEPARTMENT FOR A SINGLE LABORATORY.

193
194 (~~3C~~iii) An applicant proposing to initiate ~~an adult diagnostic cardiac catheterization service in 2~~WITH
195 TWO or more laboratories shall project ~~that~~ a minimum of 1,000 procedure equivalents per laboratory
196 THAT INCLUDES 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF DIAGNOSTIC CARDIAC
197 CATHETERIZATION PROCEDURES ~~will be performed in~~DURING ~~BASED ON DATA FROM~~ the second
198 MOST RECENT 12-~~months of operation after initiation of the service, and annually thereafter.~~ months
199 of operation after initiation of the service, and annually thereafter. The
200 projected volume shall include the procedure equivalents required by subsection (1) PERIOD
201 PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT.

202 ___(2) An applicant proposing to perform ~~INITIATE AN ADULT~~ therapeutic cardiac catheterization
203 procedures SERVICE shall demonstrate both of the following:

204 ___(a) An ~~THE~~ applicant provides, IS APPROVED TO PROVIDE, or has CON approval ~~APPLIED to~~
205 provide ~~an adult diagnostic cardiac catheterization service~~ services AT THE HOSPITAL. THE
206 APPLICANT MUST BE APPROVED FOR ADULT DIAGNOSTIC CARDIAC CATHETERIZATION
207 SERVICES IN ORDER TO BE APPROVED FOR ADULT THERAPEUTIC CARDIAC
208 CATHETERIZATION SERVICES.

209 ___(b) ~~THE~~AN APPLICANT HAS OPERATING AN ADULT DIAGNOSTIC CARDIAC
210 CATHETERIZATION SERVICE HAS PERFORMED A MINIMUM OF 300 PROCEDURE EQUIVALENTS
211 IN THE CATEGORY OF ADULT DIAGNOSTIC CARDIAC CATHETERIZATIONS DURING THE MOST

212 RECENT 12-MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE
213 DEPARTMENT IF THE ADULT DIAGNOSTIC CARDIAC CATHETERIZATION SERVICE HAS BEEN IN
214 OPERATION MORE THAN 24 MONTHS.

215 (C) ~~An~~THE applicant HAS APPLIED TO provides or has CON approval to provide an adult open
216 heart surgery ~~services~~services within AT the hospital. in which ~~t~~The APPLICANT MUST BE APPROVED
217 FOR AN ADULT OPEN HEART SURGERY SERVICE IN ORDER TO BE APPROVED FOR AN ADULT
218 therapeutic cardiac catheterizations ~~are to be performed~~ SERVICE.

219
220 (D) ~~An~~THE applicant proposing to perform therapeutic cardiac catheterization procedures shall
221 project the following volume of procedure equivalents, as applicable, will be performed in the second 12
222 months of operation after initiation of the service, and annually thereafter:

223 ~~(a)~~ Aa minimum of 300 procedure equivalents in the category of adult therapeutic cardiac
224 catheterizations BASED ON DATA FROM THE MOST RECENT 12-MONTH PERIOD PRECEDING THE
225 DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT.

226
227 (3) An applicant proposing to initiate a pediatric cardiac catheterization service SHALL
228 DEMONSTRATE THE FOLLOWING:

229 (A) THE APPLICANT HAS THE APPLICANT DEMONSTRATES THAT IT HAS THE FOLLOWING:~~at~~
230 a hospital that will perform cardiac catheterization procedures is required to have each of the following as
231 outlined in the American Academy of Pediatrics (AAP), Guidelines for Pediatric Cardiovascular Centers
232 (March 2002):

233 ~~(a)~~ aAA board certified pediatric cardiologist with training in pediatric catheterization procedures to
234 direct the pediatric catheterization laboratory;

235 ~~(b)~~THE APPLICANT HAS ~~s~~Standardized equipment as outlined inDEFINED IN THE MOST
236 CURRENT AMERICAN ACADEMY OF PEDIATRICS (AAP) ~~g~~Guidelines publicationFOR PEDIATRIC
237 CARDIOVASCULAR CENTERS;

238 ~~(c)~~THE APPLICANT HAS ~~e~~On-site ICU as outlined in THE MOST CURRENT AAP guidelines
239 publicationABOVE; and.

240 ~~(d)~~BD) THE APPLICANT HAS APPLIED TO PROVIDE ~~on-site~~pediatric open heart surgery SERVICES
241 AT THE HOSPITAL. THE APPLICANT MUST BE APPROVED FOR A PEDIATRIC OPEN HEART
242 SURGERY SERVICE IN ORDER TO BE APPROVED FOR PEDIATRIC CARDIAC CATHETERIZATION
243 SERVICES.

244 (2GE) ~~An~~THE applicant proposing to initiate a pediatric cardiac catheterization service at a hospital that
245 currently performs cardiac catheterization procedures shall project that a minimum of 600 procedure
246 equivalents in the category of pediatric cardiac catheterizations BASED ON DATA will be performed in
247 the second 12 months of operation after initiation of the pediatric cardiac catheterization service, and
248 annually thereafterFROM THE MOST RECENT 12-MONTH PERIOD PRECEDING THE DATE THE
249 APPLICATION WAS SUBMITTED TO THE DEPARTMENT.

250
251 **Section 5. Requirements for approval ~~— applicants proposing to initiate an adult diagnostic~~**
252 **cardiac catheterization service with provision to perform primary PCI for patients experiencing**
253 **AMI (ST elevation or new left bundle branch block) without on-site open heart surgery services**
254

255 Sec. 5. ~~(14)~~ An applicant proposing to initiate primary PCI service without on-site open heart surgery
256 services shall ~~submit documentation demonstrating~~ ~~demonstratE~~demonstrate all of the following:

257 (a) The applicant's OPERATES AN adult diagnostic cardiac catheterization service THAT HAS
258 performed a minimum of 400-500 diagnostic procedures EQUIVALENTS THAT INCLUDES 400
259 PROCEDURE EQUIVALENTS IN THE CATEGORY OF CARDIAC CATHETERIZATION PROCEDURES
260 (excluding diagnostic electrophysiology studies and right heart catheterizations) during the most recent 12
261 months preceding the date the application was submitted to the Department. ~~Mobile cardiac~~
262 catheterization laboratories are not eligible to apply under Section 5.

263 (b) The APPLICANT HAS AT LEAST TWO interventional cardiologists (~~at least two~~) to perform the
264 primary PCI PROCEDURES AND ~~are experienced interventionalists who~~ THAT have EACH

265 | ~~CARDIOLOGIST HAS each~~ performed at least 75 ~~interventions-PCI SESSIONS EACH,~~ annually, as the
266 | primary operator ~~at an open heart surgery facility~~ during the most recent 24-month ~~PERIODs~~ preceding
267 | the date the application was submitted to the Department, ~~and annually thereafter.~~

268 | (c) The nursing and technical catheterization laboratory staff: are experienced in handling acutely ill
269 | patients and comfortable with interventional equipment; have acquired experience in dedicated
270 | interventional laboratories at an open heart surgery ~~facility~~HOSPITAL; and participate in an un-interrupted
271 | 24-hour, 365-day call schedule. Competency ~~should~~SHALL be documented annually.

272 | (d) The ~~catheterization~~ laboratory ~~OR LABORATORIES is ARE well-~~equipped, with optimal imaging
273 | systems, resuscitative equipment, ~~AND~~ intra-aortic balloon pump (IABP) support, and ~~must be well-~~
274 | stocked with a broad array of interventional equipment.

275 | (e) The cardiac care unit nurses are adept in hemodynamic monitoring and IABP management.
276 | Competency ~~should~~SHALL be documented annually.

277 | (f) A written agreement with an open heart surgery ~~facility~~-HOSPITAL that includes ~~ALL OF THE~~
278 | ~~FOLLOWING:~~

279 | (i) Involvement in credentialing criteria and recommendations for physicians approved to perform
280 | primary PCI ~~PROCEDURES;~~

281 | (ii) Provision for ongoing cross-training for professional and technical staff involved in the provision of
282 | primary PCI to ensure familiarity with interventional equipment; ~~and, competency~~ Competency
283 | ~~should~~SHALL be documented annually;

284 | (iii) Provision for ongoing cross training for emergency department, catheterization laboratory, and
285 | critical care unit staff to ensure experience in handling the high acuity status of primary PCI patient
286 | candidates; ~~and, competency~~ Competency ~~should~~SHALL be documented annually;

287 | (iv) Regularly held joint cardiology/cardiac surgery conferences to include review of all primary PCI
288 | cases;

289 | (v) Development and ongoing review of patient selection criteria for primary PCI patients and
290 | implementation of those criteria;

291 | (vi) A mechanism to provide for appropriate patient transfers between facilities and an agreed plan for
292 | prompt care;

293 | (vii) Written protocols, signed by the applicant and the open heart surgery ~~facility~~HOSPITAL, ~~must be~~
294 | ~~in place, with provisions~~ for the ~~implementation for~~ immediate ~~and efficient~~ transfer, (within 1 hour from
295 | ~~THE~~ cardiac catheterization laboratory to evaluation on site in the open heart ~~surgical~~-SURGERY
296 | ~~facility~~HOSPITAL), of patients requiring surgical evaluation and/or intervention 365 days a year, ~~the~~
297 | ~~The~~ protocols shall be reviewed ~~AND~~ tested on a ~~regular~~ (quarterly) basis; ~~and,~~

298 | (viii) Consultation on facilities, equipment, staffing, ancillary services, and policies and procedures for
299 | the provision of interventional procedures.

300 | (g) A written protocol must be established and maintained for case selection for the performance of
301 | primary PCI ~~that is consistent with current practice guidelines set forth by the American College of~~
302 | ~~Cardiology and the American Heart Association.~~

303 | (h) A system to ensure prompt and efficient identification of potential primary PCI patients and rapid
304 | transfer from the emergency department to the ~~CARDIAC~~ catheterization laboratory must be developed
305 | and maintained so that door-to-balloon targets are met.

306 | (i) ~~Because primary PCI must be available to emergency patients 24 hours per day, 365 days a~~
307 | ~~year, a~~At least two physicians credentialed to perform primary PCI must commit to functioning as a
308 | coordinated group willing and able to provide this service at the hospital on a 24-hour per day, 365 day
309 | per year call schedule, with ability to be on-site and available to operate within 30 minutes of identifying
310 | the need for primary PCI. These physicians must be credentialed at the facility and actively collaborate
311 | with administrative and clinical staff in establishing and implementing protocols, call schedules, and
312 | quality assurance procedures pertaining to primary PCI designed to meet the requirements for this
313 | certification and in keeping with the current guidelines for the provision of primary PCI promulgated by the
314 | American College of Cardiology and American Heart Association.

315 |
316 | (2J) ~~An~~ THE applicant shall project a minimum of ~~48-36~~ primary PCI ~~procedures-CASES BASED ON~~
317 | ~~DATA -will be performed in the second-FROM THE MOST 12-RECENT 12-months-of-operation-after~~
318 | ~~initiation-of-service, and annually thereafter~~ PERIOD PRECEDING THE DATE THE APPLICATION WAS
319 | ~~SUBMITTED TO THE DEPARTMENT. -Primary PCI volume shall be projected by documenting, as~~

320 outlined in Section 13, and certifying that the applicant treated or transferred enough ST segment
321 elevation AMI cases during the most recent 12 months preceding the date the application was submitted
322 to the Department to maintain 48 primary PCI cases annually. Factors that may be considered in
323 projecting primary PCI volume are the number of thrombolytic eligible patients per year seen in the
324 Emergency Department (as documented through hospital pharmacy records showing the number of
325 doses of thrombolytic therapy ordered for AMI in the Emergency Department) and/or documentation of
326 emergency transfers to an open heart surgery facility for primary PCI.
327

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

330 (A) THE APPLICANT PROVIDES, IS APPROVED TO PROVIDE, OR HAS APPLIED TO PROVIDE
331 ADULT DIAGNOSTIC CARDIAC CATHETERIZATION SERVICES AT THE HOSPITAL. THE
332 APPLICANT MUST BE APPROVED FOR ADULT DIAGNOSTIC CARDIAC CATHETERIZATION
333 SERVICES IN ORDER TO BE APPROVED FOR ELECTIVE PCI SERVICES.

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

336 (I) BOARD CERTIFIED IN INTERVENTIONAL CARDIOLOGY.

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

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

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

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

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

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

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

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

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

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

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

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

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

367 (D) THE APPLICANT AGREES TO THE FOLLOWING:

368 (I) A WRITTEN PROTOCOL MUST BE ESTABLISHED AND MAINTAINED FOR CASE
369 SELECTION FOR THE PERFORMANCE OF PCI THAT IS CONSISTENT WITH CURRENT PRACTICE
370 GUIDELINES SET FORTH BY THE AMERICAN COLLEGE OF CARDIOLOGY AND THE AMERICAN
371 HEART ASSOCIATION, INCLUDING A RISK STRATIFICATION TOOL (STS OR SYNTAX) USED AND
372 RECORDED TO INSURE APPROPRIATE TRIAGE TO CORONARY ARTERY BYPASS GRAFT

373 SURGERY. EXCLUSIONS FOR ELECTIVE PCI SHOULD INCLUDE DECOMPENSATED HEART
374 FAILURE WITHOUT ACUTE ISCHEMIA, RECENT STROKE, ADVANCED MALIGNANCY, KNOWN
375 CLOTTING DISORDERS, EF LESS THAN 25%, LEFT MAIN DISEASE UNPROTECTED BY PRIOR
376 SURGERY, LESIONS THAT JEOPARDIZE >50% OF MYOCARDIUM, DIFFUSE DISEASE AND
377 EXCESSIVE TORTUOSITY, DEGENERATED VEIN GRAFTS, SUBSTANTIAL THROMBUS,
378 AGGRESSIVE MEASURES TO OPEN CHRONIC TOTAL OCCLUSIONS, AND INABILITY TO
379 PROTECT MAJOR SIDE BRANCHES.
380 (II) ESTABLISH AND MAINTAIN WRITTEN POLICY AND PROCEDURES FOR TRAINING,
381 STAFFING, AND PROGRAM REVIEW.
382 (III) THE NURSING AND TECHNICAL CATHETERIZATION STAFF ARE EXPERIENCED IN
383 HANDLING ACUTELY ILL PATIENTS AND COMFORTABLE WITH INTERVENTIONAL EQUIPMENT;
384 HAVE ACQUIRED EXPERIENCE IN DEDICATED INTERVENTIONAL LABORATORIES AT OPEN
385 HEART SURGERY SERVICES OR AT PRIMARY PCI SERVICES; AND PARTICIPATE IN AN UN-
386 INTERRUPTED 24-HOUR, 365-DAY CALL SCHEDULE. COMPETENCY SHALL BE DOCUMENTED
387 ANNUALLY.
388 (IV) THE CATHETERIZATION LABORATORY IS EQUIPPED WITH IMAGING SYSTEMS,
389 RESUSCITATIVE EQUIPMENT, INTRA-AORTIC BALLOON PUMP (IABP) SUPPORT, AND STOCKED
390 WITH APPROPRIATE INTERVENTIONAL EQUIPMENT.
391 (V) THE CARDIAC CARE UNIT NURSES ARE ADEPT IN HEMODYNAMIC MONITORING AND
392 IABP MANAGEMENT. COMPETENCY SHALL BE DOCUMENTED ANNUALLY.
393 (VI) ESTABLISH AND MAINTAIN A SYSTEM TO ENSURE PROMPT AND EFFICIENT
394 IDENTIFICATION OF POTENTIAL PRIMARY PCI PATIENTS AND RAPID TRANSFER TO THE
395 CATHETERIZATION LABORATORY SO THAT DOOR-TO-BALLOON TARGETS ARE MET.
396 (VII) AT LEAST TWO PHYSICIANS CREDENTIALLED TO PERFORM PRIMARY PCI MUST COMMIT
397 TO FUNCTIONING AS A COORDINATED GROUP WILLING AND ABLE TO PROVIDE THIS SERVICE
398 AT THE HOSPITAL ON A 24-HOUR PER DAY, 365 DAY PER YEAR CALL SCHEDULE, WITH ABILITY
399 TO BE ON-SITE AND AVAILABLE TO OPERATE WITHIN 30 MINUTES OF IDENTIFYING THE NEED
400 FOR PRIMARY PCI. THESE PHYSICIANS MUST BE CREDENTIALLED AT THE FACILITY AND
401 ACTIVELY COLLABORATE WITH ADMINISTRATIVE AND CLINICAL STAFF IN ESTABLISHING AND
402 IMPLEMENTING PROTOCOLS, CALL SCHEDULES, AND QUALITY ASSURANCE PROCEDURES
403 PERTAINING TO PRIMARY PCI DESIGNED TO MEET THE REQUIREMENTS FOR THIS
404 CERTIFICATION AND IN KEEPING WITH THE CURRENT GUIDELINES FOR THE PROVISION OF
405 PRIMARY PCI PROMULGATED BY THE AMERICAN COLLEGE OF CARDIOLOGY AND AMERICAN
406 HEART ASSOCIATION.
407 (E) THE APPLICANT SHALL DEMONSTRATE THE FOLLOWING, AS APPLICABLE TO THE
408 PROPOSED PROJECT:
409 (I) AN APPLICANT WITHIN ONE HOUR DRIVE TIME OF AN EXISTING PCI OR OPEN HEART
410 SURGERY HOSPITAL SHALL PROJECT A MINIMUM OF 350 PCI (PTCA AND CORONARY STENT)
411 CASES BASED ON DATA FROM THE MOST RECENT 12-MONTH PERIOD PRECEDING THE DATE
412 THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT. THE DEPARTMENT SHALL REVOKE
413 A CON FOR A PROGRAM THAT PERFORMS LESS THAN 250 PCIS IN THE SECOND 12 MONTHS
414 OF OPERATION, OR LESS THAN 350 PCIS IN THE THIRD 12 MONTHS OF OPERATION, AND/OR IS
415 RECOMMENDED FOR REVOCATION BY THE ORGANIZATION IDENTIFIED IN SECTION 8(6)(C).
416 (II) AN APPLICANT MORE THAN ONE HOUR DRIVE TIME OF AN EXISTING PCI OR OPEN
417 HEART SURGERY HOSPITAL SHALL PROJECT A MINIMUM OF 250 PCI (PTCA AND CORONARY
418 STENT) CASES BASED ON DATA FROM THE MOST RECENT 12-MONTH PERIOD PRECEDING THE
419 DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT. THE DEPARTMENT SHALL
420 REVOKE A CON FOR A PROGRAM THAT PERFORMS LESS THAN 250 PCIS IN THE THIRD 12
421 MONTHS OF OPERATIONS AND/OR IS RECOMMENDED FOR REVOCATION BY THE
422 ORGANIZATION IDENTIFIED IN SECTION 8(6)(C).

423
424 **Section 7. Requirements for approval -- applicants proposing to initiate an adult therapeutic**
425 **cardiac catheterization service**

426
427 — Sec. 7. (1) An applicant proposing to perform therapeutic cardiac catheterization procedures shall
428 demonstrate both of the following:
429 — (a) An applicant provides or has CON approval to provide an adult diagnostic cardiac catheterization
430 service.
431 — (b) An applicant provides or has CON approval to provide an adult open heart surgery service within
432 the hospital in which the therapeutic cardiac catheterizations are to be performed.
433 — (c) Subsections (a) and (b) do not preclude an applicant from simultaneously applying for a
434 diagnostic and therapeutic cardiac catheterization service and an open heart surgery service.
435
436 — (2) An applicant proposing to perform therapeutic cardiac catheterization procedures shall project the
437 following volume of procedure equivalents, as applicable, will be performed in the second 12 months of
438 operation after initiation of the service, and annually thereafter:
439 — (a) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac
440 catheterizations.

441
442 **Section 84. Requirements for approval — applicants proposing to replace/upgrade AN EXISTING**
443 **cardiac catheterization laboratoriesSERVICE OR laboratorlaboratory**
444

445 Sec. 84. (1) An applicant, other than a hospital that provides only pediatric cardiac catheterization
446 services, proposing to replace/upgrade its only laboratory, shall demonstrate that it meets each of the
447 following, as applicable REPLACING A CARDIAC CATHETERIZATION LABORATORY MEANS A
448 CHANGE IN THE ANGIOGRAPHY X-RAY EQUIPMENT OR A RELOCATION OF THE SERVICE TO A
449 NEW SITE. THE TERM DOES NOT INCLUDE A CHANGE IN ANY OF THE OTHER EQUIPMENT OR
450 SOFTWARE USED IN THE LABORATORY. AN APPLICANT PROPOSING TO REPLACE A CARDIAC
451 CATHETERIZATION LABORATORY OR SERVICE SHALL DEMONSTRATE THE FOLLOWING, AS
452 APPLICABLE TO THE PROPOSED PROJECT.:

453
454 (a1) For a hospital located in a rural county: AN APPLICANT PROPOSING TO REPLACE CARDIAC
455 CATHETERIZATION LABORATORY EQUIPMENT SHALL DEMONSTRATE THE FOLLOWING:

456 (iA) A minimum of 500 procedures equivalents were performed in the applicant's cardiac
457 catheterization laboratory during the most recent 12 months of normal operation preceding the date the
458 application was submitted to the Department; and THE EXISTING LABORATORY OR LABORATORIES
459 TO BE REPLACED ARE FULLY DEPRECIATED ACCORDING TO GENERALLY ACCEPTED
460 ACCOUNTING PRINCIPLES OR DEMONSTRATES EITHER OF THE FOLLOWING:

461 (ii) A minimum of 500 procedure equivalents will be performed in the applicant's cardiac
462 catheterization laboratory in the first 12 months of operation after installation of the new equipment, and
463 annually thereafter. THE EXISTING ANGIOGRAPHY X-RAY EQUIPMENT TO BE REPLACED POSES A
464 THREAT TO THE SAFETY OF THE PATIENTS.

465 (b1) For a hospital located in a non-rural county: THE REPLACEMENT ANGIOGRAPHY X-RAY
466 EQUIPMENT OFFERS TECHNOLOGICAL IMPROVEMENTS THAT ENHANCE QUALITY OF CARE,
467 INCREASES EFFICIENCY, AND REDUCES OPERATING COSTS.

468 (iB) A minimum of 750 procedure equivalents was performed in the applicant's cardiac catheterization
469 laboratory during the most recent 12 months of normal operation preceding the date the application was
470 submitted to the Department; and THE EXISTING ANGIOGRAPHY X-RAY EQUIPMENT TO BE
471 REPLACED WILL BE REMOVED FROM SERVICE ON OR BEFORE BEGINNING OPERATION OF THE
472 REPLACEMENT EQUIPMENT.

473 — (ii) A minimum of 750 procedure equivalents will be performed in the applicant's cardiac
474 catheterization laboratory in the first 12 months of operation after installation of the new equipment, and
475 annually thereafter.

477 (2) ~~If a~~An applicant ~~is a hospital that provides only pediatric~~PROPOSING TO REPLACE A cardiac
478 catheterization services ~~proposes to replace/upgrade an existing cardiac catheterization laboratory, an~~
479 applicant shall demonstrate that it meets each of TO A NEW SITE SHALL DEMONSTRATE the following:
480 (a) ~~A minimum of 500 procedure equivalents was performed in the applicant's cardiac catheterization~~
481 ~~laboratory in the most recent 12 months of normal operation preceding the date the application was~~
482 ~~submitted to the Department; and~~ THE PROPOSED PROJECT IS PART OF AN APPLICATION TO
483 REPLACE THE ENTIRE HOSPITAL.
484 (b) ~~A minimum of 500 procedure equivalents will be performed in the applicant's cardiac~~
485 ~~catheterization laboratory in the first 12 months of operation after installation of the new equipment, and~~
486 ~~annually thereafter.~~ THE APPLICANT HAS PERFORMED THE FOLLOWING DURING THE MOST
487 RECENT 12-MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE
488 DEPARTMENT, AS APPLICABLE TO THE PROPOSED PROJECT:
489 (I) A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT
490 DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES.
491 (II) A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT
492 THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES.
493 (III) A MINIMUM OF 600 PROCEDURE EQUIVALENTS IN THE CATEGORY OF PEDIATRIC
494 CARDIAC CATHETERIZATION PROCEDURES.
495 (IV) A MINIMUM OF 500 PROCEDURE EQUIVALENTS FOR A HOSPITAL IN A RURAL OR
496 MICROPOLITAN COUNTY WITH ONE LABORATORY.
497 (V) A MINIMUM OF 750 PROCEDURE EQUIVALENTS FOR A HOSPITAL IN A METROPOLITAN
498 COUNTY WITH ONE LABORATORY.
499 (VI) A MINIMUM OF 1,000 PROCEDURE EQUIVALENTS PER CARDIAC CATHETERIZATION
500 LABORATORY FOR- A HOSPITAL WITH TWO OR MORE LABORATORIES.
501 (C) THE EXISTING CARDIAC CATHETERIZATION SERVICE HAS BEEN IN OPERATION FOR AT
502 LEAST 36 MONTHS AS OF THE DATE THE APPLICATION HAS BEEN SUBMITTED TO THE
503 DEPARTMENT.
504 ~~—(3) An applicant with 2 or more laboratories proposing to replace/upgrade any of its laboratories shall~~
505 ~~demonstrate that it meets each of the following, as applicable:~~
506 ~~—(a) An average of 1,000 procedure equivalents per room was performed in each existing cardiac~~
507 ~~catheterization laboratory in the hospital during the most recent 12 months of operation preceding the~~
508 ~~date the application was submitted to the Department, and~~
509 ~~—(b) A minimum of 1,000 procedure equivalents will be performed in each cardiac catheterization~~
510 ~~laboratory in the first 12 months of operation after installation of the new equipment, and annually~~
511 ~~thereafter.~~
512
513 ~~—(4) An applicant proposing to replace equipment shall demonstrate that the existing equipment to be~~
514 ~~replaced is fully depreciated according to generally accepted accounting principles, or can clearly~~
515 ~~demonstrate that the existing equipment poses a threat to the safety of the public, or offers significant~~
516 ~~technological improvements which enhance quality of care, increases efficiency, and/or reduces~~
517 ~~operating costs.~~
518
519 ~~—(5) If an application involves the replacement/upgrade of equipment used by a mobile cardiac~~
520 ~~catheterization network, an applicant shall demonstrate both of the following:~~
521 ~~—(a) At least 500 procedure equivalents were performed in the most recent 12 months of normal~~
522 ~~operation preceding the date the application was submitted to the Department; and~~
523 ~~—(b) A minimum of 500 procedure equivalents will be performed in the first 12 months of operation~~
524 ~~after installation of the new equipment, and annually thereafter.~~
525 ~~—(c) In evaluating compliance with subsections (a) and (b), the Department shall consider the~~
526 ~~combined utilization for all approved host facilities.~~
527
528 ~~—(6) In demonstrating compliance with the minimum volume requirements set forth in each applicable~~
529 ~~subsection of this section, an applicant shall demonstrate that the minimum volume requirement~~

530 applicable to the specific type of cardiac catheterization procedures offered by an applicant (adult,
531 pediatric, diagnostic or therapeutic) as set forth in Section 4(1), 6(2) or 7(2)(a), as applicable, have also
532 been met.
533

534 **Section 95. Requirements for approval -- applicants proposing to expand a cardiac**
535 **catheterization service by adding a laboratory**
536

537 Sec. 95. An applicant proposing to add a laboratory to an existing cardiac catheterization service shall
538 demonstrate both of the following:
539

540 (1) THE APPLICANT HAS PERFORMED THE FOLLOWING DURING THE MOST RECENT 12-
541 MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE
542 DEPARTMENT, AS APPLICABLE TO THE PROPOSED PROJECT ~~An average of 1,500 procedure~~
543 ~~equivalents per room per year was performed in each existing cardiac catheterization laboratory in the~~
544 ~~hospital during the most recent 12-month period preceding the date the application was submitted to the~~
545 ~~Department:~~

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

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

550 (C) A MINIMUM OF 600 PROCEDURE EQUIVALENTS IN THE CATEGORY OF PEDIATRIC
551 CARDIAC CATHETERIZATION PROCEDURES.
552

553 (2) THE APPLICANT HAS PERFORMED ~~An An average~~ A MINIMUM OF ~~of 1,000~~ 1,400 procedure
554 ~~equivalents will be performed in each cardiac catheterization laboratory (both PER existing and~~
555 ~~proposed~~ APPROVED) LABORATORIES DURING THE MOST RECENT ~~in the second 12-12-months of~~
556 ~~operation after initiating operation of the additional room, and annually thereafter~~ PERIOD PRECEDING
557 THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT.
558

559 **Section 106. Requirements for approval -- applicants for** TO ACQUIRE **a mobile cardiac**
560 **catheterization network** SERVICE
561

562 Sec. 106. ~~An application involving a mobile cardiac catheterization network shall demonstrate that it~~
563 ~~meets each of the following, as applicable:~~ ACQUIRING A CARDIAC CATHETERIZATION SERVICE
564 AND ITS LABORATORIES MEANS OBTAINING POSSESSION AND CONTROL BY CONTRACT,
565 OWNERSHIP, LEASE OR OTHER COMPARABLE ARRANGEMENT OR RENEWAL OF A LEASE FOR
566 EXISTING ANGIOGRAPHY X-RAY EQUIPMENT. AN APPLICANT PROPOSING TO ACQUIRE A
567 CARDIAC CATHETERIZATION SERVICE OR RENEW A LEASE FOR EQUIPMENT SHALL
568 DEMONSTRATE THE FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT:
569

570 (1) ~~An application will not result in an increase in the number of mobile cardiac catheterization~~
571 ~~networks with valid CON approval as of the effective date of these standards.~~ AN APPLICANT
572 PROPOSING TO ACQUIRE A CARDIAC CATHETERIZATION SERVICE SHALL DEMONSTRATE THE
573 FOLLOWING:
574

575 (2A) ~~An application will not result in an increase in the number of host facilities being served by a~~
576 ~~mobile cardiac catheterization network from the number of host facilities authorized to be served by that~~
577 ~~same network as of the effective date of these standards~~ THE PROPOSED PROJECT IS PART OF AN
578 APPLICATION TO ACQUIRE THE ENTIRE HOSPITAL.
579

580 (4)(3B) ~~An application does not involve the initiation of a mobile cardiac catheterization network not~~
581 ~~authorized by a valid CON as of the effective date of these standards~~ AN APPLICATION FOR THE FIRST
582 ACQUISITION OF AN EXISTING CARDIAC CATHETERIZATION SERVICE AFTER <INSERT

583 EFFECTIVE DATE OF THESE STANDARDS. SHALL NOT BE REQUIRED TO BE IN COMPLIANCE
 584 WITH THE APPLICABLE VOLUME REQUIREMENTS IN SUBDIVISION (C). THE CARDIAC
 585 CATHETERIZATION SERVICE SHALL BE OPERATING AT THE APPLICABLE VOLUMES SET FORTH
 586 IN THE PROJECT DELIVERY REQUIREMENTS IN THE SECOND 12 MONTHS OF OPERATION OF
 587 THE SERVICE BY THE APPLICANT AND ANNUALLY THEREAFTER.

589 (4C) THE APPLICANT HAS PERFORMED THE FOLLOWING DURING THE MOST RECENT 12-
 590 MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE
 591 DEPARTMENT, AS APPLICABLE TO THE PROPOSED PROJECT. ~~An application involving the provision~~
 592 ~~of mobile cardiac catheterization services shall demonstrate that cardiac catheterization procedures will~~
 593 ~~be performed within a hospital. The Department shall consider procedures performed in a mobile cardiac~~
 594 ~~catheterization unit as within a hospital if the mobile unit is or will be physically adjoined to the hospital by~~
 595 ~~means of a connector such that patients will not be transported outside the hospital in order to receive~~
 596 ~~cardiac catheterization services.;~~

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

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

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

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

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

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

609 _____
 610 (2) AN APPLICANT PROPOSING TO RENEW A LEASE FOR EXISTING ANGIOGRAPHY X-RAY
 611 EQUIPMENT SHALL DEMONSTRATE THE RENEWAL OF THE LEASE IS MORE COST EFFECTIVE
 612 THAN REPLACING THE EQUIPMENT.

613
 614 **Section 7. REQUIREMENT FOR MEDICAID PARTICIPATION**

615
 616 Sec. 7. An applicant shall provide verification of Medicaid participation at the time the application is
 617 submitted to the Department. An applicant that is initiating a new service or is a new provider not
 618 currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the
 619 Department within six (6) months from the offering of services if a CON is approved.

620
 621 **Section 11. Methodology for computing cardiac catheterization equivalents—procedures and**
 622 **weights**

623
 624 Sec. 11. (1) The following procedure equivalents shall be used in calculating and evaluating
 625 utilization of a cardiac catheterization laboratory:

PROCEDURE TYPE	PROCEDURE EQUIVALENT	
	Adult	Pediatric
Diagnostic cardiac catheterization	1.0	3.0
Therapeutic cardiac catheterization	1.5	3.0
Therapeutic, other (PFO/ASD/Valvuloplasty, LVAD)	2.5	3.5
Diagnostic, peripheral ⁴	1.0	2.0
Therapeutic, peripheral—Carotid, Subclavian, Renal, Iliac, Mesenteric	1.5	2.5

PROCEDURE TYPE	PROCEDURE EQUIVALENT	
	Adult	Pediatric
Therapeutic, peripheral—Superficial Femoral Artery	2.5	2.5
Therapeutic, peripheral—Infrapopliteal	3.0	3.0
Therapeutic, peripheral—Aorta	4.0	4.0
Diagnostic, electro-physiology (EP)	2.0	3.5
Therapeutic, EP—Permanent Pacemaker, ICD	2.5	5.0
Therapeutic, EP—Ablation Non-AF	3.0	5.0
Therapeutic, EP—Ablation AF or VT	4.0	6.0
Therapeutic, EP—Cardioversion	1.0	1.0
Other procedures (IVC Filter, Temporary Venous Pacemaker, IABP, other radiological procedures)	1.0	2.0
Multiple procedures within the same session (diagnostic and/or therapeutic)	The sum of procedure weights minus 0.5 for each procedure after the first procedure	The sum of procedure weights minus 0.5 for each procedure after the first procedure
⁴ Excludes selective common femoral angiography when performed as part of a diagnostic or therapeutic cardiac catheterization for a possible closure device.		

628
629 ~~—(2) For purposes of evaluating whether an applicant meets applicable volume requirements set forth~~
630 ~~in these standards, cardiac catheterization procedures per laboratory must be met exclusive of the intra-~~
631 ~~vascular catheterization procedures when considering expansion or replace/upgrade. The peripheral~~
632 ~~non-cardiac procedures shall count toward the total volume requirements for procedures, but the~~
633 ~~minimum volumes remain the same for initiation of cardiac catheterization services.~~
634 ~~—(a) Intra-vascular catheterization is a medical diagnostic or therapeutic procedure during which a~~
635 ~~catheter is inserted into an artery in a patient. Subsequently, the free end of the catheter is manipulated~~
636 ~~by a physician to travel along the course of a non-coronary artery. X-rays and an electronic image~~
637 ~~intensifier are used as aids in placing the catheter tip into the desired position. When the catheter is in~~
638 ~~place, the physician is able to perform various diagnostic studies and/or therapeutic procedures in the~~
639 ~~artery. Intra-vascular catheterization shall not include "float catheters" or "hemodynamic monitoring~~
640 ~~catheters" which are performed, and/or are used at the bedside for the purposes of monitoring or~~
641 ~~administering hemodynamic medication.~~

642
643 **Section 128. Project delivery requirements —AND terms of approval for all applicants**

644
645 Sec. 128. ~~(1)~~ An applicant shall agree that, if approved, the project CARDIAC CATHETERIZATION
646 SERVICE AND ALL EXISTING AND APPROVED LABORATORIES shall be delivered in compliance with
647 the following terms of CON-approval:

648
649
650 (a1) Compliance with these standards.

651
652 ~~—(b) Compliance with applicable operating standards.~~

653 (e2) Compliance with the following quality assurance standards:

654 (iA) The approved services shall be operating at the applicable required volumes within the time
655 periods specified in these standards, and annually thereafter Cardiac catheterization procedures shall be
656 performed in a cardiac catheterization laboratory located within a hospital, and have within, or
657 immediately available to the room, dedicated emergency equipment to manage cardiovascular
658 emergencies.

659 (iiB) The approved services shall be staffed with sufficient medical, nursing, technical and other
660 personnel to permit regular scheduled hours of operation and continuous 24-hour on-call availability.

661 (iiiC) The medical staff and governing body shall receive and review at least annual reports describing
662 the activities of the cardiac catheterization service including: complication rates ~~(including emergency~~
663 ~~surgical procedures);~~₁ morbidity and mortality ~~data;~~₁ success rates and the number of procedures
664 performed.

665 (ivD) Each physician credentialed by a hospital to perform adult therapeutic cardiac catheterization
666 procedures shall perform, as the primary operator, a minimum of 75 adult therapeutic cardiac
667 catheterization procedures per year in the second 12 months after being credentialed to perform
668 procedures at the applicant hospital, and annually thereafter. The annual case load for a physician
669 means adult therapeutic cardiac catheterization procedures performed by that physician in any hospital or
670 in any combination of hospitals. ~~The applicant shall be responsible for reporting to the Department, on an~~
671 ~~annual basis, the name and the number of adult therapeutic cardiac catheterization procedures~~
672 ~~performed by each physician credentialed to perform adult therapeutic cardiac catheterization~~
673 ~~procedures.~~

674 (vE) Each physician credentialed by a hospital to perform pediatric diagnostic cardiac catheterizations
675 shall perform, as the primary operator, a minimum of 50 pediatric diagnostic cardiac catheterization
676 procedures per year in the second 12 months after being credentialed to perform procedures at the
677 applicant hospital, and annually thereafter. The annual case load for a physician means pediatric
678 diagnostic cardiac catheterization procedures performed by that physician in any hospital or in any
679 combination of hospitals. ~~The applicant shall be responsible for reporting to the Department, on an~~

680 ~~annual basis, the name and the number of pediatric diagnostic cardiac catheterization procedures~~
681 ~~performed by each physician credentialed to perform pediatric diagnostic cardiac catheterization~~
682 ~~procedures.~~

683 (viF) Each physician credentialed by a hospital to perform pediatric therapeutic cardiac
684 catheterizations shall perform, as a primary operator, a minimum of 25 pediatric therapeutic cardiac
685 catheterizations per year in the second 12 months after being credentialed ~~to perform procedures at the~~
686 ~~applicant hospital,~~ and annually thereafter. The annual case load for a physician means pediatric
687 therapeutic cardiac catheterization procedures performed by that physician ~~in any hospital or~~ in any
688 combination of hospitals. ~~The applicant shall be responsible for reporting to the Department, on an~~
689 ~~annual basis, the name and the number of pediatric therapeutic cardiac catheterization procedures~~
690 ~~performed by each physician credentialed to perform pediatric therapeutic cardiac catheterization~~
691 ~~procedures.~~

692 ~~—(vii) For purposes of evaluating subdivisions (v) or (vi), a diagnostic cardiac catheterization followed~~
693 ~~by a therapeutic cardiac catheterization (including electrophysiology studies) in the same session shall be~~
694 ~~considered both 1 diagnostic procedure and 1 therapeutic procedure. Two physicians, one credentialed~~
695 ~~to perform diagnostic cardiac catheterizations and one credentialed to perform therapeutic cardiac~~
696 ~~catheterizations, each may be considered to have performed either 1 diagnostic or 1 therapeutic~~
697 ~~catheterization if both were involved in performing a diagnostic cardiac catheterization procedure followed~~
698 ~~by a therapeutic procedure in the same session.~~

699 (viiiG) An ~~applicant proposing to offer an~~ adult diagnostic cardiac catheterization service shall have a
700 minimum of two ~~(2)~~ appropriately trained physicians on its active hospital staff. ~~For purposes of~~
701 ~~evaluating this subsection, †The Department shall consider it prima facie~~ MAY ACCEPT OTHER evidence
702 OR SHALL CONSIDER -IT of appropriate training if the staff physicians:

- 703 (A) are trained consistent with the recommendations of the American College of Cardiology;
- 704 (BII) are credentialed by the hospital to perform adult diagnostic cardiac catheterizations; and
- 705 (CIII) have each performed a minimum of 100 adult diagnostic cardiac catheterizations in the preceding
706 12 months.

707 ~~—However, the applicant may submit and the Department may accept other evidence that the staff~~
708 ~~physicians performing adult diagnostic cardiac catheterizations are appropriately trained.~~

709 (ixH) An ~~applicant proposing to offer an~~ adult therapeutic cardiac catheterization service shall have a
710 minimum of two ~~(2)~~ appropriately trained physicians on its active hospital staff. ~~For purposes of~~
711 ~~evaluating this subsection, †The Department shall consider it prima facie~~ MAY ACCEPT OTHER evidence
712 OR SHALL CONSIDER of-IT appropriate training if the staff physicians:

- 713 (A) are trained consistent with the recommendations of the American College of Cardiology;
- 714 (BII) are credentialed by the hospital to perform adult therapeutic cardiac catheterizations; and
- 715 (CIII) have each performed a minimum of 75 adult therapeutic cardiac catheterization procedures in the
716 preceding 12 months.

717 ~~—However, the applicant may submit and the Department may accept other evidence that the staff~~
718 ~~physicians performing adult therapeutic cardiac catheterizations are appropriately trained.~~

719 (xI) An ~~applicant proposing to offer a~~ pediatric cardiac catheterization service shall ~~demonstrate~~
720 ~~an~~ HAVE AN appropriately trained physician(s) ~~shall be on the ITS~~ active hospital staff ~~to perform~~
721 ~~diagnostic or therapeutic, as applicable, pediatric cardiac catheterizations. For purposes of evaluating~~
722 ~~this subsection, †The Department shall consider it prima facie~~ MAY ACCEPT OTHER evidence ~~of OR~~
723 SHALL CONSIDER IT appropriate training if the staff physician(s) is:

- 724 (A) IS board certified or board eligible in pediatric cardiology by the American Board of Pediatrics;
- 725 (BII) IS credentialed by the hospital to perform ~~diagnostic or therapeutic, as applicable,~~ pediatric
726 cardiac catheterizations; and
- 727 (CIII) HAS trained consistently with the recommendations of the American College of Cardiology.

728 ~~—However, the applicant may submit and the Department may accept other evidence that the staff~~
729 ~~physician(s) performing pediatric cardiac catheterizations is appropriately trained.~~

730 (xiJ) A cardiac catheterization service shall be directed by an appropriately trained physician. ~~For~~
731 ~~purposes of evaluating this subsection, †The Department shall consider it prima facie~~ evidence of
732 appropriate training and experience of the cardiac catheterization service OF THE director if the physician

733 is board certified in cardiology, cardiovascular radiology or cardiology, adult or pediatric, as applicable.
734 The director of an adult cardiac catheterization service shall have performed at least 200 catheterizations
735 per year during each of the ~~5-FIVE~~ preceding years. ~~However, the applicant may submit and t~~The
736 Department may accept other evidence that the ~~cardiac catheterization service~~ director is appropriately
737 trained.

738 ~~(xiiiK)~~ ~~An approved~~ cardiac catheterization service shall be operated consistently with the
739 recommendations of the American College of Cardiology.

740
741 (3) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:

742 ~~(xiiiA)~~ ~~The CARDIAC CATHETERIZATION SERVICE shall accept referrals for cardiac catheterization~~
743 ~~services from all appropriately licensed health care practitioners.~~

744 ~~(B)~~ ~~An applicant~~THE CARDIAC CATHETERIZATION SERVICE shall participate in Medicaid at least
745 12 consecutive months within the first two years of operation and ~~continue to participate~~ annually
746 thereafter.

747 ~~(d)~~ ~~Compliance with the following terms of approval:~~

748 ~~(i)~~ ~~Equipment that is replaced shall be removed from the cardiac catheterization service.~~

749 ~~(ii)~~ ~~The applicant, to assure appropriate utilization by all segments of the Michigan population, shall:~~

750 ~~(AC)~~ ~~THE CARDIAC CATHETERIZATION SERVICE SHALL Not Notnot~~ deny cardiac catheterization
751 services to any individual based on ability to pay or source of payment;_

752 ~~(B)~~ ~~Provide cardiac catheterization services to all individuals based on the clinical indications of need~~
753 ~~for the service; and~~

754 ~~(CD)~~ ~~Maintain information by payor and non-paying sources to indicate the volume of care from each~~
755 ~~source provided annually~~THE OPERATION OF AND REFERRAL OF PATIENTS TO THE CARDIAC

756 CATHETERIZATION SERVICE SHALL BE IN CONFORMANCE WITH 1978 PA 368, SEC. 16221, AS
757 AMENDED BY 1986 PA 319; MCL 333.1621; MSA 14.15 (16221).

758
759 (4) Compliance with ~~selective contracting requirements shall not be construed as a violation of this~~
760 termTHE FOLLOWING MONITORING AND REPORTING REQUIREMENTS;:

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

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

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

768 (III) 600 PROCEDURE EQUIVALENTS IN THE CATEGORY OF PEDIATRIC CARDIAC
769 CATHETERIZATION PROCEDURES.

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

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

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

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

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

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

781 ~~(iiiB)~~ ~~The applicant~~ HOSPITAL shall participate in a data collection network established and
782 administered by the Department or its designee. ~~The d~~Data may include, but is not limited to, annual
783 budget and cost information, operating schedules, ~~and~~ PATIENT demographicSdemographics,
784 ~~diagnostic,~~ morbidity and mortality information, ~~as well as the volume of care provided to patients from~~
785 ~~all~~AND payor sources and other data requested by the Department or its designee and approved by the

786 ~~Commission. The applicant shall provide the required data on a separate basis for each separate and~~
787 ~~distinct site or unit as required by the Department, in a format established by the Department and in a~~
788 ~~mutually agreed upon media. The Department may elect to verify the data through on-site review of~~
789 ~~appropriate records.~~

790 ~~(ivC) The applicant HOSPITAL shall participate in a quality improvement data registry administered by~~
791 ~~the Department or its designee. The Department or its designee shall require that the~~
792 ~~applicant HOSPITAL SHALL submit a summary report Reports as required by the Department. The~~
793 ~~applicant HOSPITAL shall provide the required data in a format established by the Department or its~~
794 ~~designee. The applicant HOSPITAL shall be liable for the cost of data submission and on-site reviews~~
795 ~~in order for the Department to verify and monitor volumes and assure quality. An applicant shall THE~~
796 ~~HOSPITAL MUST become a member of the data registry upon initiation of the service and continue to~~
797 ~~participate annually thereafter FOR THE LIFE OF THAT SERVICE.~~

798 ~~—(v) The applicant shall provide the Department with a notice stating the date on which the first~~
799 ~~approved service is performed and such notice shall be submitted to the Department consistent with~~
800 ~~applicable statute and promulgated rules.~~

801 ~~—(vi) The applicant shall accept referrals for cardiac catheterization services from all appropriately~~
802 ~~licensed health care practitioners.~~

804 ~~—(2) The agreements and assurances required by this section shall be in the form of a certification~~
805 ~~agreed to by the applicant or its authorized agent.~~

807 **Section 13. Project delivery requirements—additional terms of approval for applicants approved**
808 **under Section 5**

809 —
810 ~~Sec. 13. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance with~~
811 ~~the following terms of CON approval:~~

812 ~~—(a5) COMPLIANCE WITH THE FOLLOWING PRIMARY PCI REQUIREMENTS, IF APPLICABLE:~~

813 ~~—(A) THE Compliance with requirements set forth in Section 3(4).~~

814 ~~An applicant shall agree that, if approved, the project shall be delivered in compliance with the following~~
815 ~~terms of CON approval:~~

816 ~~—(B) THE HOSPITAL S shall immediately report to the Department any changes in the interventional~~
817 ~~cardiologists who perform the primary PCI procedures.~~

818 ~~—(b1) —~~

819 ~~Compliance with requirements of the standards set forth in Section 53(14).~~

820 ~~(2BC) The applicant HOSPITAL shall have performed a minimum of 48-36 primary PCI procedures at~~
821 ~~the facility HOSPITAL in the preceding 12—months PERIOD OF OPERATION OF THE SERVICE and~~
822 ~~annually thereafter.~~

823 ~~—(D) THE HOSPITAL SHALL MAINTAIN A 90-MINUTE DOOR-TO-BALLON TIME OR LESS IN AT~~
824 ~~LEAST 75% OF THE PRIMARY PCI SESSIONS.~~

825 ~~(3E) The applicant HOSPITAL shall participate in a data registry, administered by the Department or~~
826 ~~its designee. The Department or its designee shall require that the applicant submit data on all~~
827 ~~consecutive cases of primary PCI as is necessary to comprehensively assess and provide comparative~~
828 ~~analyses of case selection, processes and outcome of care, and trend in efficiency. The applicant shall~~
829 ~~provide the required data in a format established by the Department or its designee. The applicant shall~~
830 ~~be liable for the cost of data submission and on-site reviews in order for the Department to verify and~~
831 ~~monitor volumes and assure quality.~~

832 ~~—(6) COMPLIANCE WITH THE FOLLOWING ELECTIVE PCI REQUIREMENTS, IF APPLICABLE:~~

833 ~~—(A) THE REQUIREMENTS SET FORTH IN SECTION 3(5).~~

838 (B) THE HOSPITAL SHALL PARTICIPATE IN A BENCHMARKED PCI DATA REGISTRY
839 DESIGNED BY THE DEPARTMENT THAT INCLUDES ALL THE FOLLOWING:
840 (I) PATIENT AND CLINICAL DESCRIPTIONS.
841 (II) MEASURES OF OUTCOMES.
842 (III) MEASURE OF THE ACC APPROPRIATE USE OF THE PROCEDURE INCLUDING STS OR
843 SYNTAX SCORE IN EACH PATIENT. THE DEPARTMENT SHALL REQUIRE THAT THE HOSPITAL
844 SUBMIT DATA ON ALL PCI CASES IN A FORMAT ESTABLISHED BY THE DEPARTMENT. THE
845 HOSPITAL SHALL BE LIABLE FOR COSTS OF DATA SUBMISSION. THE DEPARTMENT SHALL
846 REQUIRE THAT THE HOSPITAL SUBMIT A SUMMARY REPORT ON AN ANNUAL BASIS THAT
847 SHALL BE MADE AVAILABLE TO THE GENERAL PUBLIC.
848 (C) THE HOSPITAL SHALL PARTICIPATE IN AN EXTERNAL IMPARTIAL OVERSIGHT BODY TO
849 BE DESIGNATED BY THE DEPARTMENT. THE HOSPITAL SHALL BE LIABLE FOR THE COSTS OF
850 PARTICIPATING IN THIS OVERSIGHT PROCESS AND MUST CONTINUE TO PARTICIPATE
851 ANNUALLY THEREAFTER. THE OVERSIGHT BODY SHALL PRODUCE AN ANNUAL REPORT OF
852 ALL PCI PROGRAM THAT WILL CONTAIN ALL THE FOLLOWING:
853 (I) COMPLICATION RATES.
854 (II) NUMBER OF PROCEDURES PERFORMED PER OPERATOR.
855 (III) SUCCESS RATES.
856 (IV) APPROPRIATE USE RATES.
857 (V) PATIENT TRANSFER RATES.
858 (VI) THE OVERSIGHT BODY SHALL REVIEW THE FINDINGS WITH EACH OF THE
859 PARTICIPATING HOSPITALS AS A GROUP AND SHALL PROVIDE THOSE FINDINGS TO THE
860 DEPARTMENT TO BE MADE AVAILABLE TO THE GENERAL PUBLIC. ALL ELECTIVE PCI
861 SERVICES PERFORMING LESS THAN 250 PCI CASES PER YEAR IN ANY GIVEN YEAR MUST
862 HAVE ALL CASES REVIEWED BY THIS OVERSIGHT BODY FOR APPROPRIATENESS AND
863 OUTCOMES.
864 (D) THE HOSPITAL SHALL INCLUDE IN THEIR CONSENT FOR PCI NOTIFICATION TO THE
865 PATIENT THAT THE HOSPITAL DOES NOT PROVIDE ON-SITE OPEN HEART SURGICAL SERVICES
866 AND THAT TRANSFER TO A HOSPITAL WITH OPEN HEART SURGICAL SERVICES MAY BE
867 NECESSARY.
868 (E) THE HOSPITAL SHALL ESTABLISH AN INTERNAL REVIEW BODY, INCLUDING AT A
869 MINIMUM THE CHIEF MEDICAL OFFICER, DIRECTOR OF CARDIOVASCULAR SERVICES,
870 DIRECTOR OF CARDIOVASCULAR SERVICES FOR THE HOSPITAL WITH OPEN HEART SURGICAL
871 SERVICES (OR EQUIVALENT PHYSICIAN REPRESENTATIVES), THAT SHALL REVIEW AT LEAST
872 ANNUAL REPORTS DESCRIBING THE ACTIVITIES OF THE CARDIAC CATHETERIZATION SERVICE
873 INCLUDING COMPLICATION RATES, MORBIDITY AND MORTALITY, SUCCESS RATES AND THE
874 NUMBER OF PROCEDURES PERFORMED AND PROCEDURES REQUIRING TRANSFER.
875 (F) THE HOSPITAL SHALL EMPLOY APPROPRIATE DATA MANAGEMENT PERSONNEL TO
876 INSURE TIMELY AND ACCURATE REPORTING TO THE REGISTRY AND REVIEWING BODIES
877 STATED ABOVE.
878 (G) EACH PHYSICIAN CREDENTIALLED BY A HOSPITAL TO PERFORM PCI CASES SHALL
879 PERFORM, AS THE PRIMARY OPERATOR, A MINIMUM OF 100 PCI CASES PER YEAR IN THE
880 SECOND 12 MONTHS AFTER BEING CREDENTIALLED AND ANNUALLY THEREAFTER. THE
881 ANNUAL CASE LOAD FOR A PHYSICIAN MEANS PCI CASES PERFORMED BY THAT PHYSICIAN IN
882 ANY COMBINATION OF HOSPITALS.
883 (H) EACH PHYSICIAN MUST ALSO MAINTAIN THE FOLLOWING IN ORDER TO BE
884 CREDENTIALLED:
885 (I) PARTICIPATION IN AN INSTITUTIONAL QUALITY IMPROVEMENT PROGRAM.
886 (II) BOARD CERTIFIED IN INTERVENTIONAL CARDIOLOGY.
887 (III) PERFORMED AT LEAST 300 PCI CASES TOTAL SINCE FELLOWSHIP.
888 (IV) AT LEAST 30 HOURS OF CONTINUING MEDICAL EDUCATION DIRECTED TOWARD
889 INTERVENTIONAL CARDIOLOGY EVERY 24 MONTHS.

890 (I) THE MEDICAL DIRECTOR OF THE HOSPITAL SHALL PERFORM PCI PROCEDURES AT
891 THE CONTRACTED HOSPITAL WITH OPEN HEART SURGICAL SERVICES AND SHALL ALSO
892 PERFORM PCI PROCEDURES AT THE ELECTIVE PCI SERVICE HOSPITAL DURING EACH YEAR
893 UNTIL THE HOSPITAL REACHES MINIMUM VOLUME.

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

899
900 **Section 9. Methodology for computing cardiac catheterization equivalents—procedures and**
901 **weights**

902
903 Sec. 9. The following procedure equivalents shall be used in calculating PROCEDURE
904 EQUIVALENTS and evaluating utilization of a cardiac catheterization SERVICE AND ITS
905 laboratory/laboratories:
906

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

* 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.

907
908 **Section 1410. Documentation of projections**
909

910 Sec. 1410. An applicant required to project volumes of service under sections 4, 5, 6, and 7 shall
911 specify how the volume projections were developed. This specification of the projections shall include a
912 description of the data source(s) used, AND assessments of the accuracy of these data, and the
913 statistical method used to make the projections. Based on this documentation, tThe Department shall
914 determine if the projections are reasonable. AN APPLICANT MUST MEET DEMONSTRATE THE
915 FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT:

916
917 (1) THE applicant shall specify how the volume projections were developed. Specification of the
918 projections shall include a description of the data source(s) used AND assessment of the accuracy of the
919 data. The Department shall determine if the projections are reasonable.

920
921 (2) AN APPLICANT PROPOSING TO INITIATE A PRIMARY PCI SERVICE SHALL
922 DEMONSTRATE AND CERTIFY THAT THE HOSPITAL TREATED OR TRANSFERRED 36 ST
923 SEGMENT ELEVATION AMI CASES DURING THE MOST RECENT 12-MONTH PERIOD PRECEDING
924 THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT. CASES MAY INCLUDE
925 THROMBOLYTIC ELIGIBLE PATIENTS DOCUMENTED THROUGH PHARMACY RECORDS
926 SHOWING THE NUMBER OF DOSES OF THROMBOLYTIC THERAPY ORDERED AND MEDICAL
927 RECORDS OF EMERGENCY TRANSFERS OF AMI PATIENTS TO AN APPROPRIATE HOSPITAL
928 FOR A PRIMARY PCI PROCEDURE.
929

930 (3) AN APPLICANT PROPOSING TO INITIATE AN ELECTIVE PCI SERVICE SHALL
931 DEMONSTRATE AND CERTIFY THE FOLLOWING:
932 (A) PHYSICIAN COMMITMENTS OF PCI CASES PERFORMED AT AN EXISTING CARDIAC
933 CATHETERIZATION SERVICE IN THE SAME HEALTH SERVICE AREA.
934 (I) COMMITMENTS OF PCI CASES SHALL NOT REDUCE AN EXISTING CARDIAC
935 CATHETERIZATION SERVICE BELOW ITS APPLICABLE VOLUME REQUIREMENT.
936 (II) COMMITMENTS OF PCI CASES DO NOT REPRESENT DUPLICATE CASES WITHIN THIS
937 SUBSECTION.
938 (III) COMMITMENTS IDENTIFY THE FOLLOWING:
939 (A) THE NAME OF EACH PHYSICIAN THAT PERFORMED PCI CASES TO BE COMMITTED TO
940 THE PROPOSED PROJECT.
941 (B) THE NUMBER OF PCI CASES THAT EACH PHYSICIAN PERFORMED DURING THE MOST
942 RECENT 12 MONTHS VERIFIABLE BY THE DEPARTMENT.
943 (C) THE LOCATIONS AT WHICH THE COMMITTED PCI CASES WERE PERFORMED.
944 (D) A WRITTEN COMMITMENT FROM EACH PHYSICIAN THAT HE OR SHE WILL PERFORM AT
945 LEAST THE VOLUME OF PCI CASES COMMITTED TO THE PROPOSED ELECTIVE PCI SERVICE
946 FOR NO LESS THAN THREE YEARS SUBSEQUENT TO THE INITIATION OF THE SERVICES
947 PROPOSED BY THE APPLICANT.
948 (E) THE NUMBER OF PCI CASES PERFORMED AT THE EXISTING CARDIAC
949 CATHETERIZATION SERVICE FROM WHICH PCI CASES WILL BE TRANSFERRED DURING THE
950 MOST RECENT 12- MONTH PERIODS VERIFIABLE BY THE DEPARTMENT FOR WHICH ANNUAL
951 SURVEY DATA IS AVAILABLE.
952 (B) DOCUMENTATION OF EXISTING PATIENT TRANSFERS FROM THE APPLICANT HOSPITAL
953 TO A PCI SERVICE OR OPEN HEART SURGERY HOSPITAL FOR PURPOSES OF RECEIVING A PCI
954 PROCEDURE. IN DEMONSTRATING COMPLIANCE, AN APPLICANT SHALL PROVIDE THE
955 FOLLOWING FOR EACH PATIENT TRANSFER IN THE MOST RECENT 12--MONTH PERIODS
956 VERIFIABLE BY THE DEPARTMENT:
957 (I) UNIQUE PATIENT IDENTIFIER.
958 (II) ICD-9, OR EQUIVALENT, DIAGNOSIS CODE.
959 (III) HOSPITAL WHERE THE PATIENT WAS TRANSFERRED.
960 (IV) PHYSICIAN PATIENT TRANSFERRED TO.
961 (V) DATE OF PATIENT TRANSFER.
962 (C) EXISTING PCI CASES PERFORMED AT THE APPLICANT HOSPITAL IN THE MOST RECENT
963 12 MONTHS VERIFIABLE BY THE DEPARTMENT.

964
965 **Section 1511. Comparative reviews; Effect on prior CON Review Standards; ~~comparative reviews~~**

966
967 Sec. 1511. (4) PROPOSED projects reviewed under these standards shall not be subject to
968 comparative review. These CON Review Standards supercede and replace the CON Review Standards
969 for Cardiac Catheterization Services approved by the CON Commission on March 9, 2004DECEMBER
970 11, 2007 and effective on June 4, 2004FEBRUARY 25, 2008.

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972 ~~(2) Projects reviewed under these standards shall not be subject to comparative review.~~
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<u>HEALTH SERVICE AREAS</u>	<u>COUNTIES</u>		
<u>1 – SOUTHEAST</u>	<u>LIVINGSTON</u>	<u>MONROE</u>	<u>ST. CLAIR</u>
	<u>MACOMB</u>	<u>OAKLAND</u>	<u>WASHTENAW</u>
	<u>WAYNE</u>		
<u>2 – MID-SOUTHERN</u>	<u>CLINTON</u>	<u>HILLSDALE</u>	<u>JACKSON</u>
	<u>EATON</u>	<u>INGHAM</u>	<u>LENAWEE</u>
<u>3 – SOUTHWEST</u>	<u>BARRY</u>	<u>CALHOUN</u>	<u>ST. JOSEPH</u>
	<u>BERRIEN</u>	<u>CASS</u>	<u>VAN BUREN</u>
	<u>BRANCH</u>	<u>KALAMAZOO</u>	
<u>4 – WEST</u>	<u>ALLEGAN</u>	<u>MASON</u>	<u>NEWAYGO</u>
	<u>IONIA</u>	<u>MECOSTA</u>	<u>OCEANA</u>
	<u>KENT</u>	<u>MONTCALM</u>	<u>OSCEOLA</u>
	<u>LAKE</u>	<u>MUSKEGON</u>	<u>OTTAWA</u>
<u>5 - GLS</u>	<u>GENESEE</u>	<u>LAPEER</u>	<u>SHIAWASSEE</u>
<u>6 – EAST</u>	<u>ARENAC</u>	<u>HURON</u>	<u>ROSCOMMON</u>
	<u>BAY</u>	<u>IOSCO</u>	<u>SAGINAW</u>
	<u>CLARE</u>	<u>ISABELLA</u>	<u>SANILAC</u>
	<u>GLADWIN</u>	<u>MIDLAND</u>	<u>TUSCOLA</u>
	<u>GRATIOT</u>	<u>OGEMAW</u>	
<u>7 – NORTHERN LOWER</u>	<u>ALCONA</u>	<u>CRAWFORD</u>	<u>MISSAUKEE</u>
	<u>ALPENA</u>	<u>EMMET</u>	<u>MONTMORENCY</u>
	<u>ANTRIM</u>	<u>GRAND TRAVERSE</u>	<u>OSCODA</u>
	<u>BENZIE</u>	<u>KALKASKA</u>	<u>OTSEGO</u>
	<u>CHARLEVOIX</u>	<u>LEELANAU</u>	<u>PRESQUE ISLE</u>
	<u>CHEBOYGAN</u>	<u>MANISTEE</u>	<u>WEXFORD</u>
<u>8 – UPPER PENINSULA</u>	<u>ALGER</u>	<u>GOGEBIC</u>	<u>MACKINAC</u>
	<u>BARAGA</u>	<u>HOUGHTON</u>	<u>MARQUETTE</u>
	<u>CHIPPEWA</u>	<u>IRON</u>	<u>MENOMINEE</u>
	<u>DELTA</u>	<u>KEWEENAW</u>	<u>ONTONAGON</u>
	<u>DICKINSON</u>	<u>LUCE</u>	<u>SCHOOLCRAFT</u>

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CON REVIEW STANDARDS
FOR CARDIAC CATHETERIZATION SERVICES

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