

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34 ~~across the atrial septum and withdrawn to create an enlarged atrial opening.~~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 (jH) "Electrophysiology study" means a study of the electrical conduction activity of the heart and
75 characterization of atrial and ventricular arrhythmias, obtained by means of a cardiac catheterization
76 procedure. The term also includes the implantation of permanent pacemakers and ICD
77 DEVICES ~~defibrillators~~.

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

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

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

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

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

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

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

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

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

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

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

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

106 | (uL) "Pediatric cardiac catheterization service" means ~~the offering and provision of~~PROVIDING
107 | cardiac catheterization services on an organized, regular basis to infants and children ages 18 and below,
108 | except for electrophysiology studies ~~which-THAT~~ are offered and provided to infants and children ages 14
109 | and below, and others with congenital heart disease as defined by the ICD-9-CM codes of 426.7
110 | (ANOMALOUS ATRIOVENTRICULAR EXCITATION), 427.0 (CARDIAC DYSRHYTHMIAS), and 745.0
111 | through 747.99 (BULBUS CORDIS ANOMALIES AND ANOMALIES OF CARDIAC SEPTAL CLOSURE,
112 | OTHER CONGENITAL ANOMALIES OF HEART, AND OTHER CONGENITAL ANOMALIES OF
113 | CIRCULATORY SYSTEM).

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

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

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

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

128 | (zO) "Therapeutic cardiac catheterization service" means providing therapeutic cardiac
129 | catheterizations on an organized, regular basis in a laboratory to treat and resolve anatomical and/or
130 | physiological problems in the heart. ~~The term~~PROCEDURES includes, ~~but is not limited to:~~ ~~percutaneous~~
131 | ~~coronary intervention (PCI), percutaneous transluminal coronary angioplasty (PTCA), atherectomy, stent,~~
132 | ~~laser, cardiac valvuloplasty, balloon atrial septostomy, or catheter ablation,~~ ~~and~~ cardiac permanent
133 | pacemaker, ~~I~~ ICD device implantations, TRANSCATHETER VALVE, OTHER STRUCTURAL HEART
134 | DISEASE PROCEDURES, PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA)
135 | AND CORONARY STENT IMPLANTATION AND LEFT SIDED ARRHYTHMIA THERAPEUTIC
136 | PROCEDURES. The term does not include the intra coronary administration of drugs where that is the
137 | only therapeutic intervention.

138 |
139 | (2) Terms defined in the Code have the same meanings when used in these standards.
140 |

141 | **Section 3. Requirements for approval -- all applicants**

142 |
143 | ~~—Sec. 3. (1) Cardiac catheterization procedures shall be performed in a cardiac catheterization~~
144 | ~~laboratory located within a hospital, and have within, or immediately available to the room, dedicated~~
145 | ~~emergency equipment to manage cardiovascular emergencies.~~

146 |
147 | ~~—(2) An applicant shall provide verification of Medicaid participation at the time the application is~~
148 | ~~submitted to the Department. An applicant that is initiating a new service or is a new provider not~~
149 | ~~currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the~~
150 | ~~Department within six (6) months from the offering of services if a CON is approved.~~

151 | **Section 4. Requirements for approval -- applicants proposing to initiate an adult diagnostic** 152 | **cardiac catheterization service**S

153 |
154 |
155 | Sec. 43. AN APPLICANT PROPOSING TO INITIATE CARDIAC CATHETERIZATION SERVICES
156 | SHALL DEMONSTRATE THE FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT.
157 |

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

162
163 ~~—(2) An applicant proposing to initiate an adult diagnostic cardiac catheterization service in a new~~
164 ~~single laboratory shall project DEMONSTRATE the following volume of procedure equivalents, as~~
165 ~~applicable, will be performed in the second 12 months of operation after initiation of the service, and~~
166 ~~annually thereafter TO THE PROPOSED PROJECT:~~

167 (a) ~~For a hospital located in~~ FOR AN APPLICANT PROPOSING TO INITIATE A DIAGNOSTIC
168 CARDIAC CATHETERIZATION SERVICE WITH A SINGLE LABORATORY IN A -rural or micropolitan
169 statistical area county, SHALL PROJECT a minimum of 500 procedure equivalents ~~which shall~~
170 ~~include~~ including the 300 procedure equivalents in the category of ~~adult~~ diagnostic cardiac catheterization
171 ~~required under subsection (1)~~ PROCEDURES BASED ON DATA FROM THE MOST RECENT 12-
172 MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE
173 DEPARTMENT.

174 (b) ~~For a hospital located~~ AN APPLICANT PROPOSING TO INITIATE A DIAGNOSTIC CARDIAC
175 CATHETERIZATION SERVICE -WITH A SINGLE LABORATORY in a metropolitan statistical area
176 county, SHALL PROJECT a minimum of 750 procedure equivalents ~~which shall~~ THAT include ~~includes~~ the
177 300 procedure equivalents in the category of ~~adult~~ diagnostic cardiac catheterization ~~required under~~
178 ~~subsection (1)~~ PROCEDURES BASED ON DATA FROM THE MOST RECENT 12-MONTH PERIOD
179 PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT.

180
181 ~~(3C) An applicant proposing to initiate~~ A DIAGNOSTIC CARDIAC CATHETERIZATION SERVICE an
182 ~~adult diagnostic cardiac catheterization service in 2~~ WITH TWO or more laboratories shall project ~~that~~ a
183 minimum of 1,000 procedure equivalents per laboratory THAT INCLUDES 300 PROCEDURE
184 EQUIVALENTS IN THE CATEGORY OF DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES
185 ~~will be performed in~~ DURING BASED ON DATA FROM the ~~second~~ MOST RECENT 12-
186 months of operation after initiation of the service, and annually thereafter. ~~The projected volume shall include the~~
187 ~~procedure equivalents required by subsection (1)~~ PERIOD PRECEDING THE DATE THE APPLICATION
188 WAS SUBMITTED TO THE DEPARTMENT.

189
190 ~~___ (2) An applicant proposing to perform~~ INITIATE AN ADULT therapeutic cardiac catheterization
191 SERVICE shall demonstrate both of the following:

192 ~~___ (a) An~~ THE applicant provides, IS APPROVED TO PROVIDE, or has APPLIED to provide adult
193 diagnostic cardiac catheterization services AT THE HOSPITAL. THE APPLICANT MUST BE
194 APPROVED FOR ADULT DIAGNOSTIC CARDIAC CATHETERIZATION SERVICES IN ORDER TO BE
195 APPROVED FOR ADULT THERAPEUTIC CARDIAC CATHETERIZATION SERVICES.

196 ~~___ (b) AN~~ APPLICANT OPERATING AN ADULT DIAGNOSTIC CARDIAC CATHETERIZATION
197 SERVICE HAS PERFORMED A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY
198 OF ADULT DIAGNOSTIC CARDIAC CATHETERIZATIONS DURING THE MOST RECENT 12-MONTH
199 PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT IF
200 THE SERVICE HAS BEEN IN OPERATION MORE THAN 24 MONTHS.

201 ~~___ (C) THE~~ applicant HAS APPLIED TO provides adult open heart surgery services AT the hospital.
202 The APPLICANT MUST BE APPROVED FOR AN ADULT OPEN HEART SURGERY SERVICE IN
203 ORDER TO BE APPROVED FOR AN ADULT therapeutic cardiac catheterization SERVICE.

204
205 ~~___ (D) THE~~ applicant shall project a minimum of 300 procedure equivalents in the category of adult
206 therapeutic cardiac catheterizations BASED ON DATA FROM THE MOST RECENT 12-MONTH PERIOD
207 PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT.

208
209 ~~___ (3) An applicant proposing to initiate a pediatric cardiac catheterization service SHALL~~
210 DEMONSTRATE THE FOLLOWING:

- 211 (A) THE APPLICANT HAS A board certified pediatric cardiologist with training in pediatric
 212 catheterization procedures to direct the pediatric catheterization laboratory.
 213 (B) THE APPLICANT HAS standardized equipment as DEFINED IN THE MOST CURRENT
 214 AMERICAN ACADEMY OF PEDIATRICS (AAP) Guidelines FOR PEDIATRIC CARDIOVASCULAR
 215 CENTERS.
 216 (C) THE APPLICANT HAS on-site ICU as outlined in THE MOST CURRENT AAP guidelines
 217 ABOVE.
 218 (D) THE APPLICANT HAS APPLIED TO PROVIDE pediatric open heart surgery SERVICES AT THE
 219 HOSPITAL. THE APPLICANT MUST BE APPROVED FOR A PEDIATRIC OPEN HEART SURGERY
 220 SERVICE IN ORDER TO BE APPROVED FOR PEDIATRIC CARDIAC CATHETERIZATION SERVICES.
 221 (E) THE applicant shall project a minimum of 600 procedure equivalents in the category of pediatric
 222 cardiac catheterizations BASED ON DATA FROM THE MOST RECENT 12-MONTH PERIOD
 223 PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT.

224
 225 **Section 5. Requirements for approval -- applicants proposing to initiate an adult diagnostic**
 226 **cardiac catheterization service with provision to perform primary PCI for patients experiencing**
 227 **AMI (ST elevation or new left bundle branch block) without on-site open heart surgery services**
 228

229 ~~Sec. 5. (4)~~ An applicant proposing to initiate primary PCI service without on-site open heart surgery
 230 services shall ~~submit documentation demonstrating demonstrate~~ all of the following:

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

237 (b) The APPLICANT HAS AT LEAST TWO interventional cardiologists ~~(at least two)~~ to perform the
 238 primary PCI PROCEDURES AND are experienced interventionalists who THAT have EACH
 239 CARDIOLOGIST HAS each performed at least 75 interventions PCI SESSIONS annually, as the primary
 240 operator ~~at an open heart surgery facility~~ during the most recent 24-month PERIODs preceding the date
 241 the application was submitted to the Department, ~~and annually thereafter.~~

242 (c) The nursing and technical catheterization laboratory staff: are experienced in handling acutely ill
 243 patients and comfortable with interventional equipment; have acquired experience in dedicated
 244 interventional laboratories at an open heart surgery ~~facility~~ HOSPITAL; and participate in an un-interrupted
 245 24-hour, 365-day call schedule. Competency ~~should~~ SHALL be documented annually.

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

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

251 (f) A written agreement with an open heart surgery ~~facility~~ HOSPITAL that includes ALL OF THE
 252 FOLLOWING:

253 (i) Involvement in credentialing criteria and recommendations for physicians approved to perform
 254 primary PCI PROCEDURES;

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

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

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

263 (v) Development and ongoing review of patient selection criteria for primary PCI patients and
 264 implementation of those criteria;

- 265 (vi) A mechanism to provide for appropriate patient transfers between facilities and an agreed plan for
266 prompt care;
- 267 (vii) Written protocols, signed by the applicant and the open heart surgery ~~facility~~HOSPITAL, ~~must be~~
268 ~~in place, with provisions~~ for the ~~implementation for~~ immediate ~~and efficient~~ transfer, (within 1 hour from
269 THE cardiac catheterization laboratory to evaluation on site in the open heart ~~surgical-surg~~ERY
270 ~~facility~~HOSPITAL), of patients requiring surgical evaluation and/or intervention 365 days a year, ~~the~~
271 The protocols shall be reviewed ~~AND~~ tested on a ~~regular~~ (quarterly) basis; ~~and~~
- 272 (viii) Consultation on facilities, equipment, staffing, ancillary services, and policies and procedures for
273 the provision of interventional procedures.
- 274 (g) A written protocol must be established and maintained for case selection for the performance of
275 primary PCI ~~that is consistent with current practice guidelines set forth by the American College of~~
276 ~~Cardiology and the American Heart Association.~~
- 277 (h) A system to ensure prompt and efficient identification of potential primary PCI patients and rapid
278 transfer from the emergency department to the CARDIAC catheterization laboratory must be developed
279 and maintained so that door-to-balloon targets are met.
- 280 (i) ~~Because primary PCI must be available to emergency patients 24 hours per day, 365 days a~~
281 ~~year, a~~ at least two physicians credentialed to perform primary PCI must commit to functioning as a
282 coordinated group willing and able to provide this service at the hospital on a 24-hour per day, 365 day
283 per year call schedule, with ability to be on-site and available to operate within 30 minutes of identifying
284 the need for primary PCI. These physicians must be credentialed at the facility and actively collaborate
285 with administrative and clinical staff in establishing and implementing protocols, call schedules, and
286 quality assurance procedures pertaining to primary PCI designed to meet the requirements for this
287 certification and in keeping with the current guidelines for the provision of primary PCI promulgated by the
288 American College of Cardiology and American Heart Association.

289
290 (2J) ~~An~~ THE applicant shall project a minimum of ~~48-36~~ primary PCI ~~procedures~~ CASES BASED ON
291 DATA ~~will be performed in the second~~ FROM THE MOST 12-RECENT 12-months of operation after
292 initiation of service, and annually thereafter PERIOD PRECEDING THE DATE THE APPLICATION WAS
293 SUBMITTED TO THE DEPARTMENT. ~~Primary PCI volume shall be projected by documenting, as~~
294 ~~outlined in Section 13, and certifying that the applicant treated or transferred enough ST segment~~
295 ~~elevation AMI cases during the most recent 12 months preceding the date the application was submitted~~
296 ~~to the Department to maintain 48 primary PCI cases annually. Factors that may be considered in~~
297 ~~projecting primary PCI volume are the number of thrombolytic eligible patients per year seen in the~~
298 ~~Emergency Department (as documented through hospital pharmacy records showing the number of~~
299 ~~doses of thrombolytic therapy ordered for AMI in the Emergency Department) and/or documentation of~~
300 ~~emergency transfers to an open heart surgery facility for primary PCI.~~

301
302 **Section 7. Requirements for approval – applicants proposing to initiate an adult therapeutic**
303 **cardiac catheterization service**

- 304
305 ~~—Sec. 7. (1) An applicant proposing to perform therapeutic cardiac catheterization procedures shall~~
306 ~~demonstrate both of the following:~~
- 307 ~~—(a) An applicant provides or has CON approval to provide an adult diagnostic cardiac catheterization~~
308 ~~service.~~
- 309 ~~—(b) An applicant provides or has CON approval to provide an adult open heart surgery service within~~
310 ~~the hospital in which the therapeutic cardiac catheterizations are to be performed.~~
- 311 ~~—(c) Subsections (a) and (b) do not preclude an applicant from simultaneously applying for a~~
312 ~~diagnostic and therapeutic cardiac catheterization service and an open heart surgery service.~~
- 313
314 ~~—(2) An applicant proposing to perform therapeutic cardiac catheterization procedures shall project the~~
315 ~~following volume of procedure equivalents, as applicable, will be performed in the second 12 months of~~
316 ~~operation after initiation of the service, and annually thereafter:~~
- 317 ~~—(a) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac~~
318 ~~catheterizations.~~

319
320 **Section 84. Requirements for approval -- applicants proposing to replace/upgrade AN EXISTING**
321 **cardiac catheterization ~~laboratories~~SERVICE OR laboratory**
322

323 Sec. 84. (1) ~~An applicant, other than a hospital that provides only pediatric cardiac catheterization~~
324 ~~services, proposing to replace/upgrade its only laboratory, shall demonstrate that it meets each of the~~
325 ~~following, as applicable~~ REPLACING A CARDIAC CATHETERIZATION LABORATORY MEANS A
326 CHANGE IN THE ANGIOGRAPHY X-RAY EQUIPMENT OR A RELOCATION OF THE SERVICE TO A
327 NEW SITE. THE TERM DOES NOT INCLUDE A CHANGE IN ANY OF THE OTHER EQUIPMENT OR
328 SOFTWARE USED IN THE LABORATORY. AN APPLICANT PROPOSING TO REPLACE A CARDIAC
329 CATHETERIZATION LABORATORY OR SERVICE SHALL DEMONSTRATE THE FOLLOWING, AS
330 APPLICABLE TO THE PROPOSED PROJECT.:
331

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

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

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

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

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

351 ~~(ii) A minimum of 750 procedure equivalents will be performed in the applicant's cardiac~~
352 ~~catheterization laboratory in the first 12 months of operation after installation of the new equipment, and~~
353 ~~annually thereafter.~~
354

355 (2) ~~If a~~ An applicant is a hospital that provides only pediatric PROPOSING TO REPLACE A cardiac
356 ~~catheterization services proposes to replace/upgrade an existing cardiac catheterization laboratory, an~~
357 ~~applicant shall demonstrate that it meets each of~~ TO A NEW SITE SHALL DEMONSTRATE the following:
358

359 (a) ~~A minimum of 500 procedure equivalents was performed in the applicant's cardiac catheterization~~
360 ~~laboratory in the most recent 12 months of normal operation preceding the date the application was~~
361 ~~submitted to the Department; and~~ THE PROPOSED PROJECT IS PART OF AN APPLICATION TO
362 REPLACE THE ENTIRE HOSPITAL.

363 (b) ~~A minimum of 500 procedure equivalents will be performed in the applicant's cardiac~~
364 ~~catheterization laboratory in the first 12 months of operation after installation of the new equipment, and~~
365 ~~annually thereafter.~~ THE APPLICANT HAS PERFORMED THE FOLLOWING DURING THE MOST
366 RECENT 12-MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE
367 DEPARTMENT, AS APPLICABLE TO THE PROPOSED PROJECT:

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

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

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

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

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

377 (VI) A MINIMUM OF 1,000 PROCEDURE EQUIVALENTS PER CARDIAC CATHETERIZATION
378 LABORATORY FOR- A HOSPITAL WITH TWO OR MORE LABORATORIES.

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

382 ~~—(3) An applicant with 2 or more laboratories proposing to replace/upgrade any of its laboratories shall~~
383 ~~demonstrate that it meets each of the following, as applicable:~~

384 ~~—(a) An average of 1,000 procedure equivalents per room was performed in each existing cardiac~~
385 ~~catheterization laboratory in the hospital during the most recent 12 months of operation preceding the~~
386 ~~date the application was submitted to the Department, and~~

387 ~~—(b) A minimum of 1,000 procedure equivalents will be performed in each cardiac catheterization~~
388 ~~laboratory in the first 12 months of operation after installation of the new equipment, and annually~~
389 ~~thereafter.~~

391 ~~—(4) An applicant proposing to replace equipment shall demonstrate that the existing equipment to be~~
392 ~~replaced is fully depreciated according to generally accepted accounting principles, or can clearly~~
393 ~~demonstrate that the existing equipment poses a threat to the safety of the public, or offers significant~~
394 ~~technological improvements which enhance quality of care, increases efficiency, and/or reduces~~
395 ~~operating costs.~~

397 ~~—(5) If an application involves the replacement/upgrade of equipment used by a mobile cardiac~~
398 ~~catheterization network, an applicant shall demonstrate both of the following:~~

399 ~~—(a) At least 500 procedure equivalents were performed in the most recent 12 months of normal~~
400 ~~operation preceding the date the application was submitted to the Department; and~~

401 ~~—(b) A minimum of 500 procedure equivalents will be performed in the first 12 months of operation~~
402 ~~after installation of the new equipment, and annually thereafter.~~

403 ~~—(c) In evaluating compliance with subsections (a) and (b), the Department shall consider the~~
404 ~~combined utilization for all approved host facilities.~~

406 ~~—(6) In demonstrating compliance with the minimum volume requirements set forth in each applicable~~
407 ~~subsection of this section, an applicant shall demonstrate that the minimum volume requirement~~
408 ~~applicable to the specific type of cardiac catheterization procedures offered by an applicant (adult,~~
409 ~~pediatric, diagnostic or therapeutic) as set forth in Section 4(1), 6(2) or 7(2)(a), as applicable, have also~~
410 ~~been met.~~

411
412 **Section 95. Requirements for approval ~~— applicants proposing to expand a cardiac~~**
413 **catheterization service ~~by adding a laboratory~~**

414
415 ~~Sec. 95. An applicant proposing to add a laboratory to an existing cardiac catheterization service shall~~
416 ~~demonstrate both of the following:~~

417
418 (1) THE APPLICANT HAS PERFORMED THE FOLLOWING DURING THE MOST RECENT 12-
419 MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE
420 DEPARTMENT, AS APPLICABLE TO THE PROPOSED PROJECT~~An average of 1,500 procedure~~
421 ~~equivalents per room per year was performed in each existing cardiac catheterization laboratory in the~~
422 ~~hospital during the most recent 12-month period preceding the date the application was submitted to the~~
423 ~~Department;~~

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

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

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

430
431 (2) ~~THE APPLICANT HAS PERFORMED An An average A MINIMUM OF of 1,0001,400 procedure~~
432 ~~equivalents will be performed in each cardiac catheterization laboratory (both PER existing and~~
433 ~~proposedAPPROVED) LABORATORIES DURING THE MOST RECENT in the second 12-months of~~
434 ~~operation after initiating operation of the additional room, and annually thereafter PERIOD PRECEDING~~
435 ~~THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT.~~

436
437 **Section 106. Requirements for approval -- applicants for TO ACQUIRE a mobile cardiac**
438 **catheterization networkSERVICE**

439
440 Sec. 106. ~~An application involving a mobile cardiac catheterization network shall demonstrate that it~~
441 ~~meets each of the following, as applicable: ACQUIRING A CARDIAC CATHETERIZATION SERVICE~~
442 ~~AND ITS LABORATORIES MEANS OBTAINING POSSESSION AND CONTROL BY CONTRACT,~~
443 ~~OWNERSHIP, LEASE OR OTHER COMPARABLE ARRANGEMENT OR RENEWAL OF A LEASE FOR~~
444 ~~EXISTING ANGIOGRAPHY X-RAY EQUIPMENT. AN APPLICANT PROPOSING TO ACQUIRE A~~
445 ~~CARDIAC CATHETERIZATION SERVICE OR RENEW A LEASE FOR EQUIPMENT SHALL~~
446 ~~DEMONSTRATE THE FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT:~~

447
448 (1) ~~An application will not result in an increase in the number of mobile cardiac catheterization~~
449 ~~networks with valid CON approval as of the effective date of these standards. AN APPLICANT~~
450 ~~PROPOSING TO ACQUIRE A CARDIAC CATHETERIZATION SERVICE SHALL DEMONSTRATE THE~~
451 ~~FOLLOWING:~~

452
453 (2A) ~~An application will not result in an increase in the number of host facilities being served by a~~
454 ~~mobile cardiac catheterization network from the number of host facilities authorized to be served by that~~
455 ~~same network as of the effective date of these standards. THE PROPOSED PROJECT IS PART OF AN~~
456 ~~APPLICATION TO ACQUIRE THE ENTIRE HOSPITAL.~~

457
458 (4)(3B) ~~An application does not involve the initiation of a mobile cardiac catheterization network not~~
459 ~~authorized by a valid CON as of the effective date of these standards. AN APPLICATION FOR THE FIRST~~
460 ~~ACQUISITION OF AN EXISTING CARDIAC CATHETERIZATION SERVICE AFTER <INSERT~~
461 ~~EFFECTIVE DATE OF THESE STANDARDS> SHALL NOT BE REQUIRED TO BE IN COMPLIANCE~~
462 ~~WITH THE APPLICABLE VOLUME REQUIREMENTS IN SUBDIVISION (C). THE CARDIAC~~
463 ~~CATHETERIZATION SERVICE SHALL BE OPERATING AT THE APPLICABLE VOLUMES SET FORTH~~
464 ~~IN THE PROJECT DELIVERY REQUIREMENTS IN THE SECOND 12 MONTHS OF OPERATION OF~~
465 ~~THE SERVICE BY THE APPLICANT AND ANNUALLY THEREAFTER.~~

466
467 (4C) ~~THE APPLICANT HAS PERFORMED THE FOLLOWING DURING THE MOST RECENT 12-~~
468 ~~MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE~~
469 ~~DEPARTMENT, AS APPLICABLE TO THE PROPOSED PROJECT. An application involving the provision~~
470 ~~of mobile cardiac catheterization services shall demonstrate that cardiac catheterization procedures will~~
471 ~~be performed within a hospital. The Department shall consider procedures performed in a mobile cardiac~~
472 ~~catheterization unit as within a hospital if the mobile unit is or will be physically adjoined to the hospital by~~
473 ~~means of a connector such that patients will not be transported outside the hospital in order to receive~~
474 ~~cardiac catheterization services.:~~

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

- 477 (II) A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT
478 THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES.
479 (III) A MINIMUM OF 600 PROCEDURE EQUIVALENTS IN THE CATEGORY OF PEDIATRIC
480 CARDIAC CATHETERIZATION PROCEDURES.
481 (IV) A MINIMUM OF 500 PROCEDURE EQUIVALENTS FOR A HOSPITAL IN A RURAL OR
482 MICROPOLITAN COUNTY WITH ONE LABORATORY.
483 (V) A MINIMUM OF 750 PROCEDURE EQUIVALENTS FOR A HOSPITAL IN A METROPOLITAN
484 COUNTY WITH ONE LABORATORY.
485 (VI) A MINIMUM OF 1,000 PROCEDURE EQUIVALENTS PER CARDIAC CATHETERIZATION
486 LABORATORY FOR TWO OR MORE LABORATORIES.

487 _____
488 (2) AN APPLICANT PROPOSING TO RENEW A LEASE FOR EXISTING ANGIOGRAPHY X-RAY
489 EQUIPMENT SHALL DEMONSTRATE THE RENEWAL OF THE LEASE IS MORE COST EFFECTIVE
490 THAN REPLACING THE EQUIPMENT.

491 _____
492 **Section 7. REQUIREMENTS FOR A HYBRID OPERATING ROOM/CARDIAC CATHETERIZATION**
493 **LABORATORY (OR/CCL)**
494 _____

495 SEC. 7. A HYBRID OR/CCL MEANS AN OPERATING ROOM LOCATED ON A STERILE CORRIDOR
496 AND EQUIPPED WITH AN ANGIOGRAPHY SYSTEM PERMITTING MINIMALLY INVASIVE
497 PROCEDURES OF THE HEART AND BLOOD VESSELS WITH FULL ANESTHESIA CAPABILITIES. AN
498 APPLICANT PROPOSING TO ADD ONE OR MORE HYBRID OR/CCLS AT AN EXISTING CARDIAC
499 CATHETERIZATION SERVICE SHALL DEMONSTRATE EACH OF THE FOLLOWING:

500 _____
501 (1) THE APPLICANT OPERATES AN OPEN HEART SURGERY SERVICE WHICH IS IN FULL
502 COMPLIANCE WITH THE CURRENT CON REVIEW STANDARDS FOR OPEN HEART SURGERY
503 SERVICES.

504 _____
505 (2) THE APPLICANT OPERATES A THERAPEUTIC CARDIAC CATHETERIZATION PROGRAM
506 WHICH IS IN FULL COMPLIANCE WITH SECTION 4(2) OF THESE STANDARDS.

507 _____
508 (3) IF THE HYBRID OR/CCL(S) REPRESENTS AN INCREASE IN THE NUMBER OF CARDIAC
509 CATHETERIZATION LABORATORIES AT THE FACILITY, THE APPLICANT IS IN COMPLIANCE WITH
510 SECTION 5 OF THESE STANDARDS.

511 _____
512 (4) IF THE HYBRID OR/CCL(S) REPRESENTS CONVERSION OF AN EXISTING CARDIAC
513 CATHETERIZATION LABORATORY(S), THE APPLICANT IS IN COMPLIANCE WITH THE PROVISIONS
514 OF SECTION 4, IF APPLICABLE.

515 _____
516 (5) THE APPLICANT MEETS THE APPLICABLE REQUIREMENTS OF THE CON REVIEW
517 STANDARDS FOR CARDIAC CATHETERIZATION SERVICES.

518 _____
519 (6) EACH CASE PERFORMED IN A HYBRID OR/CCL SHALL BE INCLUDED EITHER IN THE
520 SURGICAL VOLUME OR THE THERAPEUTIC CARDIAC CATHETERIZATION VOLUME OF THE
521 FACILITY. NO CASE SHALL BE COUNTED MORE THAN ONCE.

522 _____
523 (7) FOR EACH HYBRID OR/CCL, A FACILITY SHALL HAVE 0.5 EXCLUDED FROM ITS
524 INVENTORY OF CARDIAC CATHETERIZATION LABORATORIES FOR THE PURPOSES OF
525 COMPUTING THE PROCEDURE EQUIVALENTS PER ROOM. A FACILITY WILL NOT BE LIMITED TO
526 THE NUMBER OF HYBRID ORCCLS WITHIN A SINGLE LICENSED FACILITY.

527 _____
528 **Section 8. REQUIREMENT FOR MEDICAID PARTICIPATION**
529 _____

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531
532
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534
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536
537
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539
540
541

Sec. 8. 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 currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved.

Section 11. Methodology for computing cardiac catheterization equivalents — procedures and weights

~~Sec. 11. (1) The following procedure equivalents shall be used in calculating and evaluating 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
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.		

542
543 ~~—(2) For purposes of evaluating whether an applicant meets applicable volume requirements set forth~~
544 ~~in these standards, cardiac catheterization procedures per laboratory must be met exclusive of the intra-~~
545 ~~vascular catheterization procedures when considering expansion or replace/upgrade. The peripheral~~
546 ~~non-cardiac procedures shall count toward the total volume requirements for procedures, but the~~
547 ~~minimum volumes remain the same for initiation of cardiac catheterization services.~~

548 ~~—(a) Intra-vascular catheterization is a medical diagnostic or therapeutic procedure during which a~~
549 ~~catheter is inserted into an artery in a patient. Subsequently, the free end of the catheter is manipulated~~
550 ~~by a physician to travel along the course of a non-coronary artery. X-rays and an electronic image~~
551 ~~intensifier are used as aids in placing the catheter tip into the desired position. When the catheter is in~~
552 ~~place, the physician is able to perform various diagnostic studies and/or therapeutic procedures in the~~
553 ~~artery. Intra-vascular catheterization shall not include "float catheters" or "hemodynamic monitoring~~
554 ~~catheters" which are performed, and/or are used at the bedside for the purposes of monitoring or~~
555 ~~administering hemodynamic medication.~~

556
557 **Section 129. Project delivery requirements —AND terms of approval for all applicants**

558
559 Sec. 129. ~~(1)~~ An applicant shall agree that, if approved, the project-CARDIAC CATHETERIZATION
560 SERVICE AND ALL EXISTING AND APPROVED LABORATORIES shall be delivered in compliance with
561 the following terms of CON-approval:

562
563 (a1) Compliance with these standards.

564
565 ~~—(b) Compliance with applicable operating standards.~~

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

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

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

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

578 (ivD) Each physician credentialed by a hospital to perform adult therapeutic cardiac catheterization
579 procedures shall perform, as the primary operator, a minimum of 75 adult therapeutic cardiac
580 catheterization procedures per year in the second 12 months after being credentialed to perform
581 procedures at the applicant hospital, and annually thereafter. The annual case load for a physician
582 means adult therapeutic cardiac catheterization procedures performed by that physician in any hospital or
583 in any combination of hospitals. ~~The applicant shall be responsible for reporting to the Department, on an~~
584 ~~annual basis, the name and the number of adult therapeutic cardiac catheterization procedures~~
585 ~~performed by each physician credentialed to perform adult therapeutic cardiac catheterization~~
586 ~~procedures.~~

587 (vE) Each physician credentialed by a hospital to perform pediatric diagnostic cardiac catheterizations
588 shall perform, as the primary operator, a minimum of 50 pediatric diagnostic cardiac catheterization
589 procedures per year in the second 12 months after being credentialed to perform procedures at the
590 applicant hospital, and annually thereafter. The annual case load for a physician means pediatric
591 diagnostic cardiac catheterization procedures performed by that physician in any hospital or in any
592 combination of hospitals. ~~The applicant shall be responsible for reporting to the Department, on an~~
593 ~~annual basis, the name and the number of pediatric diagnostic cardiac catheterization procedures~~

594 | ~~performed by each physician credentialed to perform pediatric diagnostic cardiac catheterization~~
595 | ~~procedures.~~

596 | (viF) Each physician credentialed by a hospital to perform pediatric therapeutic cardiac
597 | catheterizations shall perform, as a primary operator, a minimum of 25 pediatric therapeutic cardiac
598 | catheterizations per year in the second 12 months after being credentialed ~~to perform procedures at the~~
599 | ~~applicant hospital,~~ and annually thereafter. The annual case load for a physician means pediatric
600 | therapeutic cardiac catheterization procedures performed by that physician ~~in any hospital or~~ in any
601 | combination of hospitals. ~~The applicant shall be responsible for reporting to the Department, on an~~
602 | ~~annual basis, the name and the number of pediatric therapeutic cardiac catheterization procedures~~
603 | ~~performed by each physician credentialed to perform pediatric therapeutic cardiac catheterization~~
604 | ~~procedures.~~

605 | ~~—(vii) For purposes of evaluating subdivisions (v) or (vi), a diagnostic cardiac catheterization followed~~
606 | ~~by a therapeutic cardiac catheterization (including electrophysiology studies) in the same session shall be~~
607 | ~~considered both 1 diagnostic procedure and 1 therapeutic procedure. Two physicians, one credentialed~~
608 | ~~to perform diagnostic cardiac catheterizations and one credentialed to perform therapeutic cardiac~~
609 | ~~catheterizations, each may be considered to have performed either 1 diagnostic or 1 therapeutic~~
610 | ~~catheterization if both were involved in performing a diagnostic cardiac catheterization procedure followed~~
611 | ~~by a therapeutic procedure in the same session.~~

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

616 | (A) are trained consistent with the recommendations of the American College of Cardiology;
617 | (B) are credentialed by the hospital to perform adult diagnostic cardiac catheterizations; and
618 | (C) have each performed a minimum of 100 adult diagnostic cardiac catheterizations in the preceding
619 | 12 months.

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

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

626 | (A) are trained consistent with the recommendations of the American College of Cardiology;
627 | (B) are credentialed by the hospital to perform adult therapeutic cardiac catheterizations; and
628 | (C) have each performed a minimum of 75 adult therapeutic cardiac catheterization procedures in the
629 | preceding 12 months.

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

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

637 | (A) IS board certified or board eligible in pediatric cardiology by the American Board of Pediatrics;
638 | (B) IS credentialed by the hospital to perform ~~diagnostic or therapeutic, as applicable,~~ pediatric
639 | cardiac catheterizations; and
640 | (C) HAS trained consistently with the recommendations of the American College of Cardiology.

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

643 | (xiJ) A cardiac catheterization service shall be directed by an appropriately trained physician. ~~For~~
644 | ~~purposes of evaluating this subsection, The Department shall consider it prima facie~~ evidence of
645 | appropriate training ~~and experience of the cardiac catheterization service~~ OF THE director if the physician
646 | is board certified in cardiology, cardiovascular radiology or cardiology, adult or pediatric, as applicable.

647 The director of an adult cardiac catheterization service shall have performed at least 200 catheterizations
648 per year during each of the ~~5-FIVE~~ preceding years. ~~However, the applicant may submit and~~ The
649 Department may accept other evidence that the ~~cardiac catheterization service~~ director is appropriately
650 trained.

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

653
654 (3) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:

655 ~~(xiiiA)~~ ~~The SERVICE shall accept referrals for cardiac catheterization services from all appropriately~~
656 ~~licensed health care practitioners.~~

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

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

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

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

662 ~~(AC)~~ THE SERVICE SHALL not deny cardiac catheterization services to any individual based on ability
663 to pay or source of payment; ~~;~~

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

666 ~~(CD)~~ ~~Maintain information by payor and non-paying sources to indicate the volume of care from each~~
667 ~~source provided annually~~ THE OPERATION OF AND REFERRAL OF PATIENTS TO THE CARDIAC
668 CATHETERIZATION SERVICE SHALL BE IN CONFORMANCE WITH 1978 PA 368, SEC. 16221, AS
669 AMENDED BY 1986 PA 319; MCL 333.1621; MSA 14.15 (16221).

670
671 (4) Compliance with ~~selective contracting requirements shall not be construed as a violation of this~~
672 ~~term~~ THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS.:

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

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

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

680 (III) 600 PROCEDURE EQUIVALENTS IN THE CATEGORY OF PEDIATRIC CARDIAC
681 CATHETERIZATION PROCEDURES.

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

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

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

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

689 ~~(iiiB)~~ ~~The applicant~~ HOSPITAL shall participate in a data collection network established and
690 administered by the Department or its designee. ~~The Data~~ may include, but is not limited to, annual
691 budget and cost information, operating schedules, ~~and PATIENT demographics~~ demographics, ~~diagnostic,~~
692 morbidity and mortality information, ~~as well as the volume of care provided to patients from all~~ AND ~~payor~~
693 ~~sources and other data requested by the Department or its designee and approved by the Commission.~~
694 ~~The applicant shall provide the required data on a separate basis for each separate and distinct site or~~
695 ~~unit as required by the Department, in a format established by the Department and in a mutually agreed~~
696 ~~upon media.~~ The Department may ~~elect to~~ verify the data through on-site review of appropriate records.

697 ~~(ivC)~~ ~~The applicant~~ HOSPITAL shall participate in a quality improvement data registry administered by
698 the Department or its designee. ~~The Department or its designee shall require that the~~
699 ~~applicant~~ HOSPITAL SHALL submit ~~a summary report~~ reports as required by the Department. The

700 ~~applicant HOSPITAL~~ shall provide the required data in a format established by the Department or its
 701 designee. The ~~applicant HOSPITAL shall be~~ liable for the cost of data submission and on-site reviews
 702 in order for the Department to verify and monitor volumes and assure quality. ~~An applicant shall~~ **THE**
 703 **HOSPITAL MUST** become a member of the data registry upon initiation of the service and continue to
 704 participate annually thereafter **FOR THE LIFE OF THAT SERVICE**.

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

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

710
 711 ~~—(2) The agreements and assurances required by this section shall be in the form of a certification~~
 712 ~~agreed to by the applicant or its authorized agent.~~

713
 714 **Section 13. Project delivery requirements—additional terms of approval for applicants approved**
 715 **under Section 5**

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

718
 719 ~~__ (a5) COMPLIANCE WITH THE FOLLOWING PRIMARY PCI REQUIREMENTS, IF APPLICABLE:~~

720 ~~__ (A) THE requirements set forth in Section 3(4).~~

721 ~~__ (B) THE HOSPITAL shall immediately report to the Department any changes in the interventional~~
 722 ~~cardiologists who perform the primary PCI procedures.~~

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

724
 725 ~~(2BC) The applicant HOSPITAL shall have performed a minimum of 48-36 primary PCI procedures at~~
 726 ~~the facility HOSPITAL in the preceding 12--months PERIOD OF OPERATION OF THE SERVICE and~~
 727 ~~annually thereafter.~~

728
 729 ~~__ (D) THE HOSPITAL SHALL MAINTAIN A 90-MINUTE DOOR-TO-BALLON TIME OR LESS IN AT~~
 730 ~~LEAST 75% OF THE PRIMARY PCI SESSIONS.~~

731 ~~(3E) The applicant HOSPITAL shall participate in a data registry, administered by the Department or~~
 732 ~~its designee. The Department or its designee shall require that the applicant submit data on all~~
 733 ~~consecutive cases of primary PCI as is necessary to comprehensively assess and provide comparative~~
 734 ~~analyses of case selection, processes and outcome of care, and trend in efficiency. The applicant shall~~
 735 ~~provide the required data in a format established by the Department or its designee. The applicant shall~~
 736 ~~be liable for the cost of data submission and on-site reviews in order for the Department to verify and~~
 737 ~~monitor volumes and assure quality.~~

738
 739 **Section 10. Methodology for computing cardiac catheterization equivalents—procedures and**
 740 **weights**

741
 742 ~~Sec. 10. The following procedure equivalents shall be used in calculating PROCEDURE~~
 743 ~~EQUIVALENTS and evaluating utilization of a cardiac catheterization SERVICE AND ITS laboratories:~~

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		

PROCEDURE TYPE	PROCEDURE EQUIVALENT	
	Adult	Pediatric
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.		

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Section 4411. Documentation of projections

Sec. 4411. An applicant required to project volumes of service under sections 4, 5, 6, and 7 shall specify how the volume projections were developed. This specification of the projections shall include a description of the data source(s) used, assessments of the accuracy of these data, and the statistical method used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable. DEMONSTRATE THE FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT:

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

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

Section 4512. Comparative reviews; Effect on prior CON Review Standards; comparative reviews

Sec. 4512. (4) PROPOSED projects reviewed under these standards shall not be subject to comparative review. These CON Review Standards supercede and replace the CON Review Standards for Cardiac Catheterization Services approved by the CON Commission on March 9, 2004 DECEMBER 11, 2007 and effective on June 4, 2004 FEBRUARY 25, 2008.

(2) Projects reviewed under these standards shall not be subject to comparative review.

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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