

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 and delivery of THE INITIATION,~~
13 ~~REPLACEMENT, EXPANSION, OR ACQUISITION OF CARDIAC CATHETERIZATION services, AND~~
14 ~~THE DELIVERY OF THESE SERVICES for all projects approved and Certificates of Need issued under~~
15 ~~Part 222 of the Code which involve cardiac catheterization services.~~

16
17 ~~—(2) Cardiac catheterization services are covered clinical services for purposes of PURSUANT TO~~
18 ~~Part 222 of the Code. CARDIAC CATHETERIZATION SERVICES ARE A COVERED CLINICAL~~
19 ~~SERVICE.~~

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

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

27
28 ~~—(5) The Department shall use Section 3(2), in applying Section 22215(1)(b) of the Code, being~~
29 ~~Section 333.22215(1)(b) of the Michigan Compiled Laws.~~
30

31 **Section 2. Definitions**

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

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35 across the atrial septum and withdrawn to create an enlarged atrial opening.

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

40 (c) "Cardiac catheterization procedure" means any cardiac procedure, including diagnostic,
41 therapeutic, and electrophysiology studies, as applicable, performed on a patient during a single session
42 in a cardiac catheterization laboratory. Cardiac catheterization is a medical diagnostic or therapeutic
43 procedure during which a catheter is inserted into a vein or artery in a patient; subsequently the free end
44 of the catheter is manipulated by a physician to travel along the course of the blood vessel into the
45 chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aides in placing
46 the catheter tip in the desired position. When the catheter is in place, the physician is able to perform
47 various diagnostic studies and/or therapeutic procedures in the heart. Cardiac catheterization shall not
48 include "float catheters" which are performed at the bedside or in settings outside the cardiac
49 catheterization laboratory.

50 (d) "Cardiac catheterization service" means the provision of one or more of the following types of
51 procedures in compliance with Part 222 of the Code: adult diagnostic cardiac catheterizations; pediatric
52 diagnostic cardiac catheterizations; adult therapeutic cardiac catheterizations; and pediatric therapeutic
53 cardiac catheterizations.

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

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

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

61 | (hG) "Department" means the Michigan Department of Community Health (MDCH).

62 | (iH) "Diagnostic cardiac catheterization service" means providing diagnostic-only cardiac
63 | catheterizations on an organized, regular basis, in a laboratory. The term includes, but is not limited to:
64 | the intra coronary administration of drugs; left heart catheterization; right heart catheterization; coronary
65 | angiography; diagnostic electrophysiology studies; and cardiac biopsies (echo-guided or fluoroscopic).
66 | For purposes of these standards, the term also includes balloon atrial septostomy procedure in a hospital
67 | that provides pediatric diagnostic cardiac catheterization services. This term also includes cardiac
68 | permanent pacemaker/ICD device implantations in a hospital that does not provide therapeutic cardiac
69 | catheterization services.

70 | (jI) "Electrophysiology study" means a study of the electrical conduction activity of the heart and
71 | characterization of atrial and ventricular arrhythmias, obtained by means of a cardiac catheterization
72 | procedure. The term also includes the implantation of permanent pacemakers and defibrillators.

73 | ~~(k) "Expand a cardiac catheterization service" means either:~~
74 | ~~—(i) an increase in the number of cardiac catheterization laboratories at a hospital; or~~
75 | ~~—(ii) expanding the types of cardiac catheterization procedures authorized to be performed including~~
76 | ~~adult or pediatric, diagnostic or therapeutic, at a hospital that currently performs cardiac catheterization~~
77 | ~~procedures.~~

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

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

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

84 | (o) ~~"Initiate a cardiac catheterization service" means to begin performing cardiac catheterization~~
85 | ~~procedures at a hospital that does not perform cardiac catheterization procedures as of the date an~~
86 | ~~application is submitted to the Department.~~

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

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

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

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

99 | (tO) "On-site open heart surgery services" means a facility that does have a CON to perform open
100 | heart surgery services and does perform open heart surgery services in the existing hospital.

101 | (uP) "Pediatric cardiac catheterization service" means the offering and provision of cardiac
102 | catheterization services on an organized, regular basis to infants and children ages 18 and below, except
103 | for electrophysiology studies which are offered and provided to infants and children ages 14 and below,
104 | and others with congenital heart disease as defined by the ICD-9-CM codes of 426.7, 427.0, and 745.0
105 | through 747.99.

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

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

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

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

120 | (zT) "Therapeutic cardiac catheterization service" means providing therapeutic cardiac
121 | catheterizations on an organized, regular basis in a laboratory to treat and resolve anatomical and/or
122 | physiological problems in the heart. The term includes, but is not limited to: percutaneous coronary
123 | intervention (PCI), percutaneous transluminal coronary angioplasty (PTCA), atherectomy, stent, laser,
124 | cardiac valvuloplasty, balloon atrial septostomy, or catheter ablation and cardiac permanent
125 | pacemaker/ICD device implantations. The term does not include the intra coronary administration of
126 | drugs where that is the only therapeutic intervention.

127 |
128 | (2) Terms defined in the Code have the same meanings when used in these standards.
129 |

130 | **Section 3. Requirements for approval -- all applicants TO INITIATE A CARDIAC** 131 | **CATHETERIZATION SERVICE**

132 |
133 | Sec. 3. (4)-To initiate a cardiac catheterization service means to begin performing cardiac catheterization
134 | procedures at a hospital that does not perform cardiac catheterization procedures as of the date an
135 | application is submitted to the -Department. AN APPLICANT PROPOSING TO INITIATE CARDIAC
136 | CATHETERIZATION SERVICES SHALL DEMONSTRATE THE FOLLOWING, AS APPLICABLE TO
137 | THE PROPOSED PROJECT.

138 |
139 | (1) Cardiac catheterization procedures shall be performed in a cardiac catheterization laboratory
140 | located within a hospital, and have within, or immediately available to the room, dedicated emergency
141 | equipment to manage cardiovascular emergencies.

142 |
143 | ~~—(2) An applicant shall provide verification of Medicaid participation at the time the application is~~
144 | ~~submitted to the Department. An applicant that is initiating a new service or is a new provider not~~
145 | ~~currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the~~
146 | ~~Department within six (6) months from the offering of services if a CON is approved.~~

147 | **Section 4. Requirements for approval -- applicants proposing to initiate an adult diagnostic** 148 | **cardiac catheterization service**

149 |
150 | ~~—Sec. 4. (1) An applicant proposing to initiate an adult diagnostic cardiac catheterization service shall~~
151 | ~~project a minimum of 300 procedure equivalents in the category of adult diagnostic cardiac~~
152 | ~~catheterization will be performed in the second 12 months of operation after initiation of the adult~~
153 | ~~diagnostic cardiac catheterization service, and annually thereafter.~~

154 |
155 | (2) An applicant proposing to initiate an adult diagnostic cardiac catheterization service in a new
156 | single laboratory shall project the following volume of procedure equivalents, as applicable, will be
157 | performed in the second 12 months of operation after initiation of the service, and annually thereafter:
158 |

159 (a) For a hospital located in a rural or micropolitan statistical area county, a minimum of 500
160 procedure equivalents which shall include the 300 procedure equivalents in the category of adult
161 diagnostic cardiac catheterization ~~required under subsection (1).~~

162 (b) For a hospital located in a metropolitan statistical area county, a minimum of 750 procedure
163 equivalents which shall include the 300 procedure equivalents in the category of adult diagnostic cardiac
164 catheterization ~~required under subsection (1).~~

165
166 (3) An applicant proposing to initiate an adult diagnostic cardiac catheterization service in 2 or more
167 laboratories shall project ~~that~~ a minimum of 1,000 procedure equivalents per laboratory ~~will be performed~~
168 which shall include 300 procedure equivalents in the category of adult diagnostic cardiac catheterization
169 in the second 12 months of operation after initiation of the service, and annually thereafter. ~~The~~
170 ~~projected volume shall include the procedure equivalents required by subsection (1).~~

171
172 (4) AN APPLICANT PROPOSING TO PERFORM ADULT THERAPEUTIC CARDIAC
173 CATHETERIZATION PROCEDURES SHALL DEMONSTRATE ALL OF THE FOLLOWING:

174 (A) AN APPLICANT PROVIDES OR HAS CON APPROVAL TO PROVIDE AN ADULT DIAGNOSTIC
175 CARDIAC CATHETERIZATION SERVICE.

176 (B) AN APPLICANT PROVIDES OR HAS CON APPROVAL TO PROVIDE AN ADULT OPEN
177 HEART SURGERY SERVICE WITHIN THE HOSPITAL IN WHICH THE THERAPEUTIC CARDIAC
178 CATHETERIZATIONS ARE TO BE PERFORMED.

179 (C) SUBSECTIONS (A) AND (B) DO NOT PRECLUDE AN APPLICANT FROM SIMULTANEOUSLY
180 APPLYING FOR A DIAGNOSTIC AND THERAPEUTIC CARDIAC CATHETERIZATION SERVICE AND
181 AN OPEN HEART SURGERY SERVICE.

182 (D) AN APPLICANT PROPOSING TO PERFORM THERAPEUTIC CARDIAC CATHETERIZATION
183 PROCEDURES SHALL PROJECT THE FOLLOWING VOLUME OF PROCEDURE EQUIVALENTS, AS
184 APPLICABLE, WILL BE PERFORMED IN THE SECOND 12 MONTHS OF OPERATION AFTER
185 INITIATION OF THE SERVICE, AND ANNUALLY THEREAFTER:

186 (I) A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT
187 THERAPEUTIC CARDIAC CATHETERIZATIONS.

188
189 (5) AN APPLICANT PROPOSING TO INITIATE A PEDIATRIC CARDIAC CATHETERIZATION
190 SERVICE AT A HOSPITAL THAT WILL PERFORM CARDIAC CATHETERIZATION PROCEDURES IS
191 REQUIRED TO HAVE EACH OF THE FOLLOWING AS OUTLINED IN THE AMERICAN ACADEMY OF
192 PEDIATRICS (AAP), GUIDELINES FOR PEDIATRIC CARDIOVASCULAR CENTERS (MARCH 2002):

193 (A) A BOARD CERTIFIED PEDIATRIC CARDIOLOGIST WITH TRAINING IN PEDIATRIC
194 CATHETERIZATION PROCEDURES TO DIRECT THE PEDIATRIC CATHETERIZATION
195 LABORATORY;

196 (B) STANDARDIZED EQUIPMENT AS OUTLINED IN AAP GUIDELINES PUBLICATION;

197 (C) ON-SITE ICU AS OUTLINED IN AAP GUIDELINES PUBLICATION; AND

198 (D) ON-SITE PEDIATRIC OPEN HEART SURGERY.

199 (E) AN APPLICANT PROPOSING TO INITIATE A PEDIATRIC CARDIAC CATHETERIZATION
200 SERVICE AT A HOSPITAL THAT CURRENTLY PERFORMS CARDIAC CATHETERIZATION
201 PROCEDURES SHALL PROJECT THAT A MINIMUM OF 600 PROCEDURE EQUIVALENTS IN THE
202 CATEGORY OF PEDIATRIC CARDIAC CATHETERIZATIONS WILL BE PERFORMED IN THE
203 SECOND 12 MONTHS OF OPERATION AFTER INITIATION OF THE PEDIATRIC CARDIAC
204 CATHETERIZATION SERVICE, AND ANNUALLY THEREAFTER.

205
206 **~~Section 5. Requirements for approval – applicants proposing to initiate an adult diagnostic~~**
207 **~~cardiac catheterization service with provision to perform primary PCI for patients experiencing~~**
208 **~~AMI (ST elevation or new left bundle branch block) without on-site open heart surgery services~~**

209
210 ~~Sec. 5. (16)~~ An applicant proposing to initiate primary PCI service without on-site open heart
211 surgery services shall submit documentation demonstrating all of the following:

212 (a) The applicant's adult diagnostic cardiac catheterization service performed a minimum of 400
213 diagnostic procedures (excluding diagnostic electrophysiology studies and right heart catheterizations)
214 during the most recent 12 months preceding the date the application was submitted to the Department.
215 | ~~Mobile cardiac catheterization laboratories are not eligible to apply under Section 5.~~
216 (b) The interventional cardiologists (at least two) to perform the primary PCI are experienced
217 interventionalists who have each performed at least 75 interventions annually as the primary operator at
218 an open heart surgery facility during the most recent 24 months preceding the date the application was
219 submitted to the Department, and annually thereafter.

220 (c) The nursing and technical catheterization laboratory staff: are experienced in handling acutely ill
221 patients and comfortable with interventional equipment; have acquired experience in dedicated
222 interventional laboratories at an open heart surgery facility; and participate in an un-interrupted 24-hour,
223 365-day call schedule. Competency should be documented annually.

224 (d) The catheterization laboratory is well-equipped, with optimal imaging systems, resuscitative
225 equipment, intra-aortic balloon pump (IABP) support, and must be well-stocked with a broad array of
226 interventional equipment.

227 (e) The cardiac care unit nurses are adept in hemodynamic monitoring and IABP management.
228 Competency should be documented annually.

229 (f) A written agreement with an open heart surgery facility that includes:

230 (i) Involvement in credentialing criteria and recommendations for physicians approved to perform
231 primary PCI;

232 (ii) Provision for ongoing cross-training for professional and technical staff involved in the provision of
233 primary PCI to ensure familiarity with interventional equipment; and competency should be documented
234 annually;

235 (iii) Provision for ongoing cross training for Emergency Department, Catheterization Laboratory and
236 Critical Care Unit staff to ensure experience in handling the high acuity status of primary PCI patient
237 candidates and competency should be documented annually;

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

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

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

244 (vii) Written protocols, signed by the applicant and the open heart surgery facility, must be in place,
245 with provisions for the implementation for immediate and efficient transfer (within 1 hour from cardiac
246 catheterization laboratory to evaluation on site in the open heart surgical facility) of patients requiring
247 surgical evaluation and/or intervention 365 days a year, the protocols shall be reviewed/tested on a
248 regular (quarterly) basis; and

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

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

254 (h) A system to ensure prompt and efficient identification of potential primary PCI patients and rapid
255 transfer from the Emergency Department to the Catheterization Laboratory must be developed and
256 maintained so that door-to-balloon targets are met.

257 (i) Because primary PCI must be available to emergency patients 24 hours per day, 365 days a
258 year, at least two physicians credentialed to perform primary PCI must commit to functioning as a
259 coordinated group willing and able to provide this service at the hospital on a 24-hour per day, 365 day
260 per year call schedule, with ability to be on-site and available to operate within 30 minutes of identifying
261 the need for primary PCI. These physicians must be credentialed at the facility and actively collaborate
262 with administrative and clinical staff in establishing and implementing protocols, call schedules, and
263 quality assurance procedures pertaining to primary PCI designed to meet the requirements for this
264 certification and in keeping with the current guidelines for the provision of primary PCI promulgated by the
265 American College of Cardiology and American Heart Association.
266

267 | (2J) An applicant shall project a minimum of 48 primary PCI procedures will be performed in the
268 second 12 months of operation after initiation of service, and annually thereafter. Primary PCI volume
269 shall be projected by documenting, as outlined in Section 13, and certifying that the applicant treated or
270 transferred enough ST segment elevation AMI cases during the most recent 12 months preceding the
271 date the application was submitted to the Department to maintain 48 primary PCI cases annually.
272 Factors that may be considered in projecting primary PCI volume are the number of thrombolytic eligible
273 patients per year seen in the Emergency Department (as documented through hospital pharmacy records
274 showing the number of doses of thrombolytic therapy ordered for AMI in the Emergency Department)
275 and/or documentation of emergency transfers to an open heart surgery facility for primary PCI.

276 |
277 **Section 6. Requirements for approval – applicants proposing to initiate a pediatric cardiac**
278 **catheterization service**

280 | ~~Sec. 6. (1) An applicant proposing to initiate a pediatric cardiac catheterization service at a hospital~~
281 ~~that will perform cardiac catheterization procedures is required to have each of the following as outlined in~~
282 ~~the American Academy of Pediatrics (AAP), Guidelines for Pediatric Cardiovascular Centers (March~~
283 ~~2002):~~

- 284 | ~~— (a) a board certified pediatric cardiologist with training in pediatric catheterization procedures to direct~~
285 ~~the pediatric catheterization laboratory;~~
- 286 | ~~— (b) standardized equipment as outlined in AAP guidelines publication;~~
- 287 | ~~— (c) on-site ICU as outlined in AAP guidelines publication; and~~
- 288 | ~~— (d) on-site pediatric open heart surgery.~~

289 |
290 | ~~— (2) An applicant proposing to initiate a pediatric cardiac catheterization service at a hospital that~~
291 ~~currently performs cardiac catheterization procedures shall project that a minimum of 600 procedure~~
292 ~~equivalents in the category of pediatric cardiac catheterizations will be performed in the second 12~~
293 ~~months of operation after initiation of the pediatric cardiac catheterization service, and annually thereafter.~~

294 |
295 **Section 7. Requirements for approval – applicants proposing to initiate an adult therapeutic**
296 **cardiac catheterization service**

297 |
298 | ~~Sec. 7. (1) An applicant proposing to perform therapeutic cardiac catheterization procedures shall~~
299 ~~demonstrate both of the following:~~

- 300 | ~~— (a) An applicant provides or has CON approval to provide an adult diagnostic cardiac catheterization~~
301 ~~service.~~
- 302 | ~~— (b) An applicant provides or has CON approval to provide an adult open heart surgery service within~~
303 ~~the hospital in which the therapeutic cardiac catheterizations are to be performed.~~
- 304 | ~~— (c) Subsections (a) and (b) do not preclude an applicant from simultaneously applying for a~~
305 ~~diagnostic and therapeutic cardiac catheterization service and an open heart surgery service.~~

306 |
307 | ~~— (2) An applicant proposing to perform therapeutic cardiac catheterization procedures shall project the~~
308 ~~following volume of procedure equivalents, as applicable, will be performed in the second 12 months of~~
309 ~~operation after initiation of the service, and annually thereafter:~~

- 310 | ~~— (a) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac~~
311 ~~catheterizations.~~

312 |
313 **Section 84. Requirements for approval – applicants proposing to replace AN EXISTING/upgrade**
314 **cardiac catheterization laboratories**

315 |
316 | ~~Sec. 84. – (1) REPLACE/UPGRADE MEANS ANY EQUIPMENT CHANGE THAT INVOLVES A~~
317 ~~CAPITAL EXPENDITURE OF \$500,000 OR MORE IN ANY CONSECUTIVE 24-MONTH PERIOD~~
318 ~~WHICH RESULTS IN THE APPLICANT OPERATING THE SAME NUMBER OF CARDIAC~~
319 ~~CATHETERIZATION LABORATORIES BEFORE AND AFTER PROJECT COMPLETION.~~ An applicant,

320 other than a hospital that provides only pediatric cardiac catheterization services, proposing to
321 replace/upgrade its only laboratory, shall demonstrate that it meets each of the following, as applicable:
322

323 ~~—(a) For a hospital located in a rural county:~~

324 ~~—(i) A minimum of 500 procedure equivalents were performed in the applicant's cardiac catheterization~~
325 ~~laboratory during the most recent 12 months of normal operation preceding the date the application was~~
326 ~~submitted to the Department; and~~

327 ~~—(ii) A minimum of 500 procedure equivalents will be performed in the applicant's cardiac~~
328 ~~catheterization laboratory in the first 12 months of operation after installation of the new equipment, and~~
329 ~~annually thereafter.~~

330 ~~—(b) For a hospital located in a non-rural county:~~

331 ~~—(i) A minimum of 750 procedure equivalents was performed in the applicant's cardiac catheterization~~
332 ~~laboratory during the most recent 12 months of normal operation preceding the date the application was~~
333 ~~submitted to the Department; and~~

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

337

338 ~~—(2) If an applicant is a hospital that provides only pediatric cardiac catheterization services proposes~~
339 ~~to replace/upgrade an existing cardiac catheterization laboratory, an applicant shall demonstrate that it~~
340 ~~meets each of the following:~~

341 ~~(a) A minimum of 500 procedure equivalents was performed in the applicant's cardiac catheterization~~
342 ~~laboratory in the most recent 12 months of normal operation preceding the date the application was~~
343 ~~submitted to the Department; and~~

344 ~~—(b) A minimum of 500 procedure equivalents will be performed in the applicant's cardiac~~
345 ~~catheterization laboratory in the first 12 months of operation after installation of the new equipment, and~~
346 ~~annually thereafter.~~

347

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

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

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

356

357 (41) An applicant proposing to replace equipment shall demonstrate that the existing equipment to be
358 replaced is fully depreciated according to generally accepted accounting principles, or EITHER OF THE
359 FOLLOWING:

360 ~~—(A) can clearly demonstrate that t~~ The existing equipment poses a threat to the safety of the
361 publicPATIENTS.

362 ~~—(B) , of~~ THE REPLACEMENT EQUIPMENT offers significant technological improvements which
363 THAT enhance quality of care, increases efficiency, and/or reduces operating costs AND PATIENT
364 CHARGES.

365

366 ~~(52) THE APPLICANT AGREES THAT THE EQUIPMENT TO BE REPLACED WILL BE REMOVED~~
367 ~~FROM SERVICE ON OR BEFORE BEGINNING OPERATION OF THE REPLACEMENT EQUIPMENT. If~~
368 ~~an application involves the replacement/upgrade of equipment used by a mobile cardiac catheterization~~
369 ~~network, an applicant shall demonstrate both of the following:~~

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

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

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

376
377 (63) AN APPLICANT PROPOSING TO REPLACE A CARDIAC CATHETERIZATION SERVICE TO A
378 NEW SITE SHALL DEMONSTRATE THE FOLLOWING:

379 (A) THE PROPOSED SITE IS WITHIN A XX-MILE RADIUS OF THE EXISTING SITE FOR A
380 METROPOLITAN STATISTICAL AREA COUNTY OR A XX-MILE RADIUS FOR A RURAL OR
381 MICROPOLITAN STATISTICAL AREA COUNTY.

382 (B) THE EXISTING CARDIAC CATHETERIZATION SERVICE PERFORMED XXX CARDIAC
383 CATHETERIZATION PROCEDURES PER ROOM IN THE MOST RECENT 12-MONTH PERIOD
384 VERIFIABLE BY THE DEPARTMENT.

385 (C) THE EXISTING CARDIAC CATHETERIZATION SERVICE HAS BEEN IN OPERATION FOR AT
386 LEAST 36 MONTHS AS OF THE DATE OF THE APPLICATION SUBMITTED TO THE DEPARTMENT.~~In~~
387 ~~demonstrating compliance with the minimum volume requirements set forth in each applicable subsection~~
388 ~~of this section, an applicant shall demonstrate that the minimum volume requirement applicable to the~~
389 ~~specific type of cardiac catheterization procedures offered by an applicant (adult, pediatric, diagnostic or~~
390 ~~therapeutic) as set forth in Section 4(1), 6(2) or 7(2)(a), as applicable, have also been met.~~

391
392 **Section 95. Requirements for approval ~~— applicants proposing to expand a cardiac~~**
393 **~~catheterization service by adding a laboratory~~**

394
395
396 Sec. ~~9-5.~~ EXPANDING A CARDIAC CATHETERIZATION SERVICE MEANS EITHER AN
397 INCREASE IN THE NUMBER OF CARDIAC CATHETERIZATION LABORATORIES AT A HOSPITAL
398 OR EXPANDING THE TYPES OF CARDIAC CATHETERIZATION PROCEDURES AUTHORIZED TO
399 BE PERFORMED INCLUDING ADULT OR PEDIATRIC, DIAGNOSTIC OR THERAPEUTIC AT A
400 HOSPITAL THAT CURRENTLY PERFORMS CARDIAC CATHETERIZATION PROCEDURES. An
401 applicant proposing to add a laboratory to an existing cardiac catheterization service shall demonstrate
402 ~~both of~~ the following:

403
404
405 (1) An average of 1,500 procedure equivalents per room per year was performed in each existing
406 cardiac catheterization laboratory in the hospital during the most recent 12-month period preceding the
407 date the application was submitted to the Department.

408
409 ~~(2) An average of 1,000 procedure equivalents will be performed in each cardiac catheterization~~
410 ~~laboratory (both existing and proposed) in the second 12 months of operation after initiating operation of~~
411 ~~the additional room, and annually thereafter.~~

412
413 **Section 106. Requirements for approval ~~— applicants for a mobile cardiac catheterization network~~**
414 **REQUIREMENTS TO ACQUIRE A CARDIAC CATHETERIZATION SERVICE**

415
416
417 SEC.6. ACQUIRING A CARDIAC CATHETERIZATION SERVICE AND ITS EQUIPMENT MEANS
418 OBTAINING POSSESSION AND CONTROL BY CONTRACT, OWNERSHIP, LEASE OR OTHER
419 COMPARABLE ARRANGEMENT AND RENEWAL OF LEASE FOR AN EXISTING CARDIAC
420 CATHETERIZATION SERVICE. AN APPLICANT PROPOSING TO ACQUIRE A HOSPITAL THAT HAS
421 BEEN APPROVED TO PERFORM CARDIAC CATHETERIZATION SERVICES MAY ALSO ACQUIRE
422 THE EXISTING CARDIAC CATHETERIZATION SERVICE IF IT CAN DEMONSTRATE THAT THE
423 PROPOSED PROJECT MEETS ALL OF THE FOLLOWING:

424
425 (1) AN APPLICATION FOR THE FIRST ACQUISITION OF AN EXISTING CARDIAC
426 CATHETERIZATION SERVICE AFTER ~~<INSERT EFFECTIVE DATE OF THESE STANDARDS>~~ SHALL
427 NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE APPLICABLE VOLUME REQUIREMENTS

428 ON THE DATE OF ACQUISITION. THE CARDIAC CATHETERIZATION SERVICE SHALL BE
429 OPERATING AT XXX PROCEDURE EQUIVALENTS IN THE SECOND 12 MONTHS AFTER THE DATE
430 THE SERVICE IS ACQUIRED, AND ANNUALLY THEREAFTER.

431
432 (2) EXCEPT AS PROVIDED FOR IN SUBSECTION (1), AN APPLICATION FOR THE
433 ACQUISITION OF AN EXISTING CARDIAC CATHETERIZATION SERVICE AFTER <INSERT
434 EFFECTIVE DATE OF THESE STANDARDS> SHALL BE OPERATING AT XXX PROCEDURE
435 EQUIVALENTS IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE DEPARTMENT
436 PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT.

437
438 (3) THE APPLICANT AGREES TO OPERATE THE CARDIAC CATHETERIZATION SERVICE IN
439 ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN
440 SECTION 8 OF THESE STANDARDS.

441
442 ~~—Sec. 10. An application involving a mobile cardiac catheterization network shall demonstrate that it~~
443 ~~meets each of the following, as applicable:~~

444
445 ~~—(1) An application will not result in an increase in the number of mobile cardiac catheterization~~
446 ~~networks with valid CON approval as of the effective date of these standards.~~

447
448 ~~—(2) An application will not result in an increase in the number of host facilities being served by a~~
449 ~~mobile cardiac catheterization network from the number of host facilities authorized to be served by that~~
450 ~~same network as of the effective date of these standards.~~

451
452 ~~—(3) An application does not involve the initiation of a mobile cardiac catheterization network not~~
453 ~~authorized by a valid CON as of the effective date of these standards.~~

454
455 ~~—(4) An application involving the provision of mobile cardiac catheterization services shall demonstrate~~
456 ~~that cardiac catheterization procedures will be performed within a hospital. The Department shall~~
457 ~~consider procedures performed in a mobile cardiac catheterization unit as within a hospital if the mobile~~
458 ~~unit is or will be physically adjoined to the hospital by means of a connector such that patients will not be~~
459 ~~transported outside the hospital in order to receive cardiac catheterization services.~~

460 SECTION 7. REQUIREMENT FOR MEDICAID PARTICIPATION

461
462
463 SEC 7. AN APPLICANT SHALL PROVIDE VERIFICATION OF MEDICAID PARTICIPATION AT
464 THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT. AN APPLICANT THAT IS
465 INITIATING A NEW SERVICE OR IS A NEW PROVIDER NOT CURRENTLY ENROLLED IN MEDICAID
466 SHALL CERTIFY THAT PROOF OF MEDICAID PARTICIPATION WILL BE PROVIDED TO THE
467 DEPARTMENT WITHIN SIX (6) MONTHS FROM THE OFFERING OF SERVICES IF A CON IS
468 APPROVED.

469 SECTION 8. PROJECT DELIVERY REQUIREMENTS AND TERMS OF APPROVAL FOR ALL

470 APPLICANTS

471
472
473 SEC. 8. (1) AN APPLICANT SHALL AGREE THAT, IF APPROVED, THE CARDIAC
474 CATHETERIZATION SERVICES SHALL BE DELIVERED IN COMPLIANCE WITH THE FOLLOWING
475 TERMS OF APPROVAL.

476
477 (1) COMPLIANCE WITH THESE STANDARDS.

478
479 (2) COMPLIANCE WITH THE FOLLOWING QUALITY ASSURANCE REQUIREMENTS:

480 (A) THE APPROVED SERVICES SHALL BE STAFFED WITH SUFFICIENT MEDICAL, NURSING,
481 TECHNICAL AND OTHER PERSONNEL TO PERMIT REGULAR SCHEDULED HOURS OF
482 OPERATION AND CONTINUOUS 24-HOUR ON-CALL AVAILABILITY.
483 (B) THE MEDICAL STAFF AND GOVERNING BODY SHALL RECEIVE AND REVIEW AT LEAST
484 ANNUAL REPORTS DESCRIBING THE ACTIVITIES OF THE CARDIAC CATHETERIZATION SERVICE
485 INCLUDING: COMPLICATION RATES (INCLUDING EMERGENCY SURGICAL PROCEDURES);
486 MORBIDITY AND MORTALITY DATA; SUCCESS RATES AND THE NUMBER OF PROCEDURES
487 PERFORMED.
488 (C) EACH PHYSICIAN CREDENTIALLED BY A HOSPITAL TO PERFORM ADULT THERAPEUTIC
489 CARDIAC CATHETERIZATION PROCEDURES SHALL PERFORM, AS THE PRIMARY OPERATOR, A
490 MINIMUM OF 75 ADULT THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES PER YEAR IN
491 THE SECOND 12 MONTHS AFTER BEING CREDENTIALLED TO PERFORM PROCEDURES AT THE
492 APPLICANT HOSPITAL, AND ANNUALLY THEREAFTER. THE ANNUAL CASE LOAD FOR A
493 PHYSICIAN MEANS ADULT THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES
494 PERFORMED BY THAT PHYSICIAN IN ANY HOSPITAL OR IN ANY COMBINATION OF HOSPITALS.
495 THE APPLICANT SHALL BE RESPONSIBLE FOR REPORTING TO THE DEPARTMENT, ON AN
496 ANNUAL BASIS, THE NAME AND THE NUMBER OF ADULT THERAPEUTIC CARDIAC
497 CATHETERIZATION PROCEDURES PERFORMED BY EACH PHYSICIAN CREDENTIALLED TO
498 PERFORM ADULT THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES.
499 (D) EACH PHYSICIAN CREDENTIALLED BY A HOSPITAL TO PERFORM PEDIATRIC
500 DIAGNOSTIC CARDIAC CATHETERIZATIONS SHALL PERFORM, AS THE PRIMARY OPERATOR, A
501 MINIMUM OF 50 PEDIATRIC DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES PER YEAR
502 IN THE SECOND 12 MONTHS AFTER BEING CREDENTIALLED TO PERFORM PROCEDURES AT
503 THE APPLICANT HOSPITAL, AND ANNUALLY THEREAFTER. THE ANNUAL CASE LOAD FOR A
504 PHYSICIAN MEANS PEDIATRIC DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES
505 PERFORMED BY THAT PHYSICIAN IN ANY HOSPITAL OR IN ANY COMBINATION OF HOSPITALS.
506 THE APPLICANT SHALL BE RESPONSIBLE FOR REPORTING TO THE DEPARTMENT, ON AN
507 ANNUAL BASIS, THE NAME AND THE NUMBER OF PEDIATRIC DIAGNOSTIC CARDIAC
508 CATHETERIZATION PROCEDURES PERFORMED BY EACH PHYSICIAN CREDENTIALLED TO
509 PERFORM PEDIATRIC DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES.
510 (E) EACH PHYSICIAN CREDENTIALLED BY A HOSPITAL TO PERFORM PEDIATRIC
511 THERAPEUTIC CARDIAC CATHETERIZATIONS SHALL PERFORM, AS A PRIMARY OPERATOR, A
512 MINIMUM OF 25 PEDIATRIC THERAPEUTIC CARDIAC CATHETERIZATIONS PER YEAR IN THE
513 SECOND 12 MONTHS AFTER BEING CREDENTIALLED TO PERFORM PROCEDURES AT THE
514 APPLICANT HOSPITAL, AND ANNUALLY THEREAFTER. THE ANNUAL CASE LOAD FOR A
515 PHYSICIAN MEANS PEDIATRIC THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES
516 PERFORMED BY THAT PHYSICIAN IN ANY HOSPITAL OR IN ANY COMBINATION OF HOSPITALS.
517 THE APPLICANT SHALL BE RESPONSIBLE FOR REPORTING TO THE DEPARTMENT, ON AN
518 ANNUAL BASIS, THE NAME AND THE NUMBER OF PEDIATRIC THERAPEUTIC CARDIAC
519 CATHETERIZATION PROCEDURES PERFORMED BY EACH PHYSICIAN CREDENTIALLED TO
520 PERFORM PEDIATRIC THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES.
521 (F) FOR PURPOSES OF EVALUATING SUBDIVISIONS (V) OR (VI), A DIAGNOSTIC CARDIAC
522 CATHETERIZATION FOLLOWED BY A THERAPEUTIC CARDIAC CATHETERIZATION (INCLUDING
523 ELECTROPHYSIOLOGY STUDIES) IN THE SAME SESSION SHALL BE CONSIDERED BOTH 1
524 DIAGNOSTIC PROCEDURE AND 1 THERAPEUTIC PROCEDURE. TWO PHYSICIANS, ONE
525 CREDENTIALLED TO PERFORM DIAGNOSTIC CARDIAC CATHETERIZATIONS AND ONE
526 CREDENTIALLED TO PERFORM THERAPEUTIC CARDIAC CATHETERIZATIONS, EACH MAY BE
527 CONSIDERED TO HAVE PERFORMED EITHER 1 DIAGNOSTIC OR 1 THERAPEUTIC
528 CATHETERIZATION IF BOTH WERE INVOLVED IN PERFORMING A DIAGNOSTIC CARDIAC
529 CATHETERIZATION PROCEDURE FOLLOWED BY A THERAPEUTIC PROCEDURE IN THE SAME
530 SESSION.
531 (G) AN APPLICANT PROPOSING TO OFFER AN ADULT DIAGNOSTIC CARDIAC
532 CATHETERIZATION SERVICE SHALL HAVE A MINIMUM OF TWO (2) APPROPRIATELY TRAINED
533 PHYSICIANS ON ITS ACTIVE HOSPITAL STAFF. FOR PURPOSES OF EVALUATING THIS

534 SUBSECTION, THE DEPARTMENT SHALL CONSIDER IT PRIMA FACIE EVIDENCE OF
535 APPROPRIATE TRAINING IF THE STAFF PHYSICIANS:
536 (I) ARE TRAINED CONSISTENT WITH THE RECOMMENDATIONS OF THE AMERICAN
537 COLLEGE OF CARDIOLOGY;
538 (II) ARE CREDENTIALLED BY THE HOSPITAL TO PERFORM ADULT DIAGNOSTIC CARDIAC
539 CATHETERIZATIONS; AND
540 (III) HAVE EACH PERFORMED A MINIMUM OF 100 ADULT DIAGNOSTIC CARDIAC
541 CATHETERIZATIONS IN THE PRECEDING 12 MONTHS.
542 HOWEVER, THE APPLICANT MAY SUBMIT AND THE DEPARTMENT MAY ACCEPT OTHER
543 EVIDENCE THAT THE STAFF PHYSICIANS PERFORMING ADULT DIAGNOSTIC CARDIAC
544 CATHETERIZATIONS ARE APPROPRIATELY TRAINED.
545 (H) AN APPLICANT PROPOSING TO OFFER AN ADULT THERAPEUTIC CARDIAC
546 CATHETERIZATION SERVICE SHALL HAVE A MINIMUM OF TWO (2) APPROPRIATELY TRAINED
547 PHYSICIANS ON ITS ACTIVE HOSPITAL STAFF. FOR PURPOSES OF EVALUATING THIS
548 SUBSECTION, THE DEPARTMENT SHALL CONSIDER IT PRIMA FACIE EVIDENCE OF
549 APPROPRIATE TRAINING IF THE STAFF PHYSICIANS:
550 (I) ARE TRAINED CONSISTENT WITH THE RECOMMENDATIONS OF THE AMERICAN
551 COLLEGE OF CARDIOLOGY;
552 (II) ARE CREDENTIALLED BY THE HOSPITAL TO PERFORM ADULT THERAPEUTIC CARDIAC
553 CATHETERIZATIONS; AND
554 (III) HAVE EACH PERFORMED A MINIMUM OF 75 ADULT THERAPEUTIC CARDIAC
555 CATHETERIZATION PROCEDURES IN THE PRECEDING 12 MONTHS.
556 HOWEVER, THE APPLICANT MAY SUBMIT AND THE DEPARTMENT MAY ACCEPT OTHER
557 EVIDENCE THAT THE STAFF PHYSICIANS PERFORMING ADULT THERAPEUTIC CARDIAC
558 CATHETERIZATIONS ARE APPROPRIATELY TRAINED.
559 (I) AN APPLICANT PROPOSING TO OFFER A PEDIATRIC CARDIAC CATHETERIZATION
560 SERVICE SHALL DEMONSTRATE AN APPROPRIATELY TRAINED PHYSICIAN(S) SHALL BE ON
561 THE ACTIVE HOSPITAL STAFF TO PERFORM DIAGNOSTIC OR THERAPEUTIC, AS APPLICABLE,
562 PEDIATRIC CARDIAC CATHETERIZATIONS. FOR PURPOSES OF EVALUATING THIS
563 SUBSECTION, THE DEPARTMENT SHALL CONSIDER IT PRIMA FACIE EVIDENCE OF
564 APPROPRIATE TRAINING IF THE STAFF PHYSICIAN(S) IS:
565 (I) BOARD CERTIFIED OR BOARD ELIGIBLE IN PEDIATRIC CARDIOLOGY BY THE AMERICAN
566 BOARD OF PEDIATRICS;
567 (II) CREDENTIALLED BY THE HOSPITAL TO PERFORM DIAGNOSTIC OR THERAPEUTIC, AS
568 APPLICABLE, PEDIATRIC CARDIAC CATHETERIZATIONS; AND
569 (III) TRAINED CONSISTENTLY WITH THE RECOMMENDATIONS OF THE AMERICAN COLLEGE
570 OF CARDIOLOGY.
571 HOWEVER, THE APPLICANT MAY SUBMIT AND THE DEPARTMENT MAY ACCEPT OTHER
572 EVIDENCE THAT THE STAFF PHYSICIAN(S) PERFORMING PEDIATRIC CARDIAC
573 CATHETERIZATIONS IS APPROPRIATELY TRAINED.
574 (J) A CARDIAC CATHETERIZATION SERVICE SHALL BE DIRECTED BY AN APPROPRIATELY
575 TRAINED PHYSICIAN. FOR PURPOSES OF EVALUATING THIS SUBSECTION, THE DEPARTMENT
576 SHALL CONSIDER IT PRIMA FACIE EVIDENCE OF APPROPRIATE TRAINING AND EXPERIENCE
577 OF THE CARDIAC CATHETERIZATION SERVICE DIRECTOR IF THE PHYSICIAN IS BOARD
578 CERTIFIED IN CARDIOLOGY, CARDIOVASCULAR RADIOLOGY OR CARDIOLOGY, ADULT OR
579 PEDIATRIC, AS APPLICABLE. THE DIRECTOR OF AN ADULT CARDIAC CATHETERIZATION
580 SERVICE SHALL HAVE PERFORMED AT LEAST 200 CATHETERIZATIONS PER YEAR DURING
581 EACH OF THE 5 PRECEDING YEARS. HOWEVER, THE APPLICANT MAY SUBMIT AND THE
582 DEPARTMENT MAY ACCEPT OTHER EVIDENCE THAT THE CARDIAC CATHETERIZATION
583 SERVICE DIRECTOR IS APPROPRIATELY TRAINED.
584 (K) AN APPROVED CARDIAC CATHETERIZATION SERVICE SHALL BE OPERATED
585 CONSISTENTLY WITH THE RECOMMENDATIONS OF THE AMERICAN COLLEGE OF
586 CARDIOLOGY.
587

588 (3) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:
589 (A) THE CARDIAC CATHETERIZATION SERVICES SHALL ACCEPT REFERRALS FOR CARDIAC
590 CATHETERIZATION SERVICES FROM ALL APPROPRIATELY LICENSED PRACTITIONERS.
591 (B) THE CARDIAC CATHETERIZATION SERVICE SHALL PARTICIPATE IN MEDICAID AT LEAST
592 12 CONSECUTIVE MONTHS WITHIN THE FIRST TWO YEARS OF OPERATION AND CONTINUE TO
593 PARTICIPATE ANNUALLY THEREAFTER.
594 (C) THE CARDIAC CATHETERIZATION SERVICE SHALL NOT DENY CARDIAC
595 CATHETERIZATION SERVICES TO ANY INDIVIDUAL BASED ON ABILITY TO PAY OR SOURCE OF
596 PAYMENT.
597 (D) THE OPERATION OF AND REFERRAL OF PATIENTS TO THE CARDIAC CATHETERIZATION
598 SERVICE SHALL BE IN COMFROMANCE WITH 1978 PA 368, SEC. 16221, AS AMENDED BY 1986 PA
599 319; MCL 333.1621; MSA 14.15 (16221).
600
601 (4) COMPLIANCE WITH THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:
602 (A) THE APPROVED SERVICES SHALL BE OPERATING AT THE APPLICABLE REQUIRED
603 VOLUMES WITHIN THE TIME PERIOD SPECIFIED IN THESE STANDARDS, AND ANNUALLY
604 THEREAFTER.
605 (B) THE APPLICANT SHALL PARTICIPATE IN A DATA COLLECTION NETWORK ESTABLISHED
606 AND ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE. THE DATA MAY INCLUDE, BUT IS
607 NOT LIMITED TO, ANNUAL BUDGET AND COST INFORMATION, OPERATING SCHEDULES, AND
608 DEMOGRAPHIC, DIAGNOSTIC, MORBIDITY AND MORTALITY INFORMATION, AS WELL AS THE
609 VOLUME OF CARE PROVIDED TO PATIENTS FROM ALL PAYOR SOURCES AND OTHER DATA
610 REQUESTED BY THE DEPARTMENT OR ITS DESIGNEE AND APPROVED BY THE COMMISSION.
611 THE APPLICANT SHALL PROVIDE THE REQUIRED DATA ON A SEPARATE BASIS FOR EACH
612 SEPARATE AND DISTINCT SITE OR UNIT AS REQUIRED BY THE DEPARTMENT, IN A FORMAT
613 ESTABLISHED BY THE DEPARTMENT AND IN A MUTUALLY AGREED UPON MEDIA. THE
614 DEPARTMENT MAY ELECT TO VERIFY THE DATA THROUGH ON-SITE REVIEW OF APPROPRIATE
615 RECORDS.
616 (C) THE APPLICANT SHALL PARTICIPATE IN A QUALITY IMPROVEMENT DATA REGISTRY
617 ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE. THE DEPARTMENT OR ITS DESIGNEE
618 SHALL REQUIRE THAT THE APPLICANT SUBMIT A SUMMARY REPORT AS REQUIRED BY THE
619 DEPARTMENT. THE APPLICANT SHALL PROVIDE THE REQUIRED DATA IN A FORMAT
620 ESTABLISHED BY THE DEPARTMENT OR ITS DESIGNEE. THE APPLICANT SHALL BE LIABLE FOR
621 THE COST OF DATA SUBMISSION AND ON-SITE REVIEWS IN ORDER FOR THE DEPARTMENT TO
622 VERIFY AND MONITOR VOLUMES AND ASSURE QUALITY. AN APPLICANT SHALL BECOME A
623 MEMBER OF THE DATA REGISTRY UPON INITIATION OF THE SERVICE AND CONTINUE TO
624 PARTICIPATE ANNUALLY THEREAFTER.
625 (D) THE CARDIAC CATHETERIZATION SERVICE SHALL PROVIDE THE DEPARTMENT WITH
626 TIMELY NOTICE OF THE PROPOSED PROJECT IMPLEMENTATION CONSISTENT WITH
627 APPPPLICABLE STATUTE AND PROMULGATED RULES.
628 (E) EQUIPMENT THAT IS REPLACED SHALL BE REMOVED FROM THE CARDIAC
629 CATHETERIZATION SERVICE.
630
631 (5) COMPLIANCE WITH THE FOLLOWING PRIMARY PCI REQUIREMENTS, IF APPLICABLE:
632 (A) SHALL IMMEDIATELY REPORT TO THE DEPARTMENT ANY CHANGES IN THE
633 INTERVENTIONAL CARDIOLOGISTS WHO PERFORM THE PRIMARY PCI PROCEDURES.
634 (B) COMPLIANCE WITH REQUIREMENTS OF THE STANDARDS SET FORTH IN SECTION 5(1).
635 (C) THE APPLICANT SHALL HAVE PERFORMED A MINIMUM OF 48 PRIMARY PCI
636 PROCEDURES AT THE FACILITY IN THE PRECEDING 12 MONTHS AND ANNUALLY THEREAFTER.
637 (D) THE APPLICANT SHALL PARTICIPATE IN A DATA REGISTRY, ADMINISTERED BY THE
638 DEPARTMENT OR ITS DESIGNEE. THE DEPARTMENT OR ITS DESIGNEE SHALL REQUIRE THAT
639 THE APPLICANT SUBMIT DATA ON ALL CONSECUTIVE CASES OF PRIMARY PCI AS IS
640 NECESSARY TO COMPREHENSIVELY ASSESS AND PROVIDE COMPARATIVE ANALYSES OF
641 CASE SELECTION, PROCESSES AND OUTCOME OF CARE, AND TREND IN EFFICIENCY. THE

642 APPLICANT SHALL PROVIDE THE REQUIRED DATA IN A FORMAT ESTABLISHED BY THE
 643 DEPARTMENT OR ITS DESIGNEE. THE APPLICANT SHALL BE LIABLE FOR THE COST OF DATA
 644 SUBMISSION AND ON-SITE REVIEWS IN ORDER FOR THE DEPARTMENT TO VERIFY AND
 645 MONITOR VOLUMES AND ASSURE QUALITY.

646
 647 (6) THE AGREEMENTS AND ASSURANCES REQUIRED BY THIS SECTION SHALL BE IN THE
 648 FORM OF A CERTIFICATION AGREED TO BY THE APPLICANT OR ITS AUTHORIZED AGENT.

649
 650 **Section 419. Methodology for computing cardiac catheterization equivalents – procedures and**
 651 **weights**

652
 653 Sec. 419. (1) The following procedure equivalents shall be used in calculating and evaluating
 654 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 ¹	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

¹ Excludes selective common femoral angiography when performed as part of a diagnostic or therapeutic cardiac catheterization for a possible closure device.

657
 658 (2) For purposes of evaluating whether an applicant meets applicable volume requirements set forth
 659 in these standards, cardiac catheterization procedures per laboratory must be met exclusive of the intra-
 660 vascular catheterization procedures when considering expansion or replace/upgrade. The peripheral
 661 non-cardiac procedures shall count toward the total volume requirements for procedures, but the
 662 minimum volumes remain the same for initiation of cardiac catheterization services.

663 (a) Intra-vascular catheterization is a medical diagnostic or therapeutic procedure during which a
 664 catheter is inserted into an artery in a patient. Subsequently, the free end of the catheter is manipulated
 665 by a physician to travel along the course of a non-coronary artery. X-rays and an electronic image
 666 intensifier are used as aids in placing the catheter tip into the desired position. When the catheter is
 667 in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures in the
 668 artery. Intra-vascular catheterization shall not include "float catheters" or "hemodynamic monitoring

669 catheters" which are performed, and/or are used at the bedside for the purposes of monitoring or
670 administering hemodynamic medication.

671

672 **Section 12. Project delivery requirements – terms of approval for all applicants**

673

674 ~~—Sec. 12. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance~~
675 ~~with the following terms of CON approval:~~

676 ~~—(a) Compliance with these standards.~~

677 ~~—(b) Compliance with applicable operating standards.~~

678 ~~—(c) Compliance with the following quality assurance standards:~~

679 ~~—(i) The approved services shall be operating at the applicable required volumes within the time~~
680 ~~periods specified in these standards, and annually thereafter.~~

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

683 ~~—(iii) The medical staff and governing body shall receive and review at least annual reports describing~~
684 ~~the activities of the cardiac catheterization service including: complication rates (including emergency~~
685 ~~surgical procedures); morbidity and mortality data; success rates and the number of procedures~~
686 ~~performed.~~

687 ~~—(iv) Each physician credentialed by a hospital to perform adult therapeutic cardiac catheterization~~
688 ~~procedures shall perform, as the primary operator, a minimum of 75 adult therapeutic cardiac~~
689 ~~catheterization procedures per year in the second 12 months after being credentialed to perform~~
690 ~~procedures at the applicant hospital, and annually thereafter. The annual case load for a physician~~
691 ~~means adult therapeutic cardiac catheterization procedures performed by that physician in any hospital or~~
692 ~~in any combination of hospitals. The applicant shall be responsible for reporting to the Department, on an~~
693 ~~annual basis, the name and the number of adult therapeutic cardiac catheterization procedures~~
694 ~~performed by each physician credentialed to perform adult therapeutic cardiac catheterization~~
695 ~~procedures.~~

696 ~~—(v) Each physician credentialed by a hospital to perform pediatric diagnostic cardiac catheterizations~~
697 ~~shall perform, as the primary operator, a minimum of 50 pediatric diagnostic cardiac catheterization~~
698 ~~procedures per year in the second 12 months after being credentialed to perform procedures at the~~
699 ~~applicant hospital, and annually thereafter. The annual case load for a physician means pediatric~~
700 ~~diagnostic cardiac catheterization procedures performed by that physician in any hospital or in any~~
701 ~~combination of hospitals. The applicant shall be responsible for reporting to the Department, on an~~
702 ~~annual basis, the name and the number of pediatric diagnostic cardiac catheterization procedures~~
703 ~~performed by each physician credentialed to perform pediatric diagnostic cardiac catheterization~~
704 ~~procedures.~~

705 ~~—(vi) Each physician credentialed by a hospital to perform pediatric therapeutic cardiac~~
706 ~~catheterizations shall perform, as a primary operator, a minimum of 25 pediatric therapeutic cardiac~~
707 ~~catheterizations per year in the second 12 months after being credentialed to perform procedures at the~~
708 ~~applicant hospital, and annually thereafter. The annual case load for a physician means pediatric~~
709 ~~therapeutic cardiac catheterization procedures performed by that physician in any hospital or in any~~
710 ~~combination of hospitals. The applicant shall be responsible for reporting to the Department, on an~~
711 ~~annual basis, the name and the number of pediatric therapeutic cardiac catheterization procedures~~
712 ~~performed by each physician credentialed to perform pediatric therapeutic cardiac catheterization~~
713 ~~procedures.~~

714 ~~—(vii) For purposes of evaluating subdivisions (v) or (vi), a diagnostic cardiac catheterization followed~~
715 ~~by a therapeutic cardiac catheterization (including electrophysiology studies) in the same session shall be~~
716 ~~considered both 1 diagnostic procedure and 1 therapeutic procedure. Two physicians, one credentialed~~
717 ~~to perform diagnostic cardiac catheterizations and one credentialed to perform therapeutic cardiac~~
718 ~~catheterizations, each may be considered to have performed either 1 diagnostic or 1 therapeutic~~
719 ~~catheterization if both were involved in performing a diagnostic cardiac catheterization procedure followed~~
720 ~~by a therapeutic procedure in the same session.~~

721 ~~—(viii) An applicant proposing to offer an adult diagnostic cardiac catheterization service shall have a~~
722 ~~minimum of two (2) appropriately trained physicians on its active hospital staff. For purposes of~~
723 ~~evaluating this subsection, the Department shall consider it prima facie evidence of appropriate training if~~
724 ~~the staff physicians:~~
725 ~~—(A) are trained consistent with the recommendations of the American College of Cardiology;~~
726 ~~—(B) are credentialed by the hospital to perform adult diagnostic cardiac catheterizations; and~~
727 ~~—(C) have each performed a minimum of 100 adult diagnostic cardiac catheterizations in the preceding~~
728 ~~12 months.~~
729 ~~—However, the applicant may submit and the Department may accept other evidence that the staff~~
730 ~~physicians performing adult diagnostic cardiac catheterizations are appropriately trained.~~
731 ~~—(ix) An applicant proposing to offer an adult therapeutic cardiac catheterization service shall have a~~
732 ~~minimum of two (2) appropriately trained physicians on its active hospital staff. For purposes of~~
733 ~~evaluating this subsection, the Department shall consider it prima facie evidence of appropriate training if~~
734 ~~the staff physicians:~~
735 ~~—(A) are trained consistent with the recommendations of the American College of Cardiology;~~
736 ~~—(B) are credentialed by the hospital to perform adult therapeutic cardiac catheterizations; and~~
737 ~~—(C) have each performed a minimum of 75 adult therapeutic cardiac catheterization procedures in the~~
738 ~~preceding 12 months.~~
739 ~~—However, the applicant may submit and the Department may accept other evidence that the staff~~
740 ~~physicians performing adult therapeutic cardiac catheterizations are appropriately trained.~~
741 ~~—(x) An applicant proposing to offer a pediatric cardiac catheterization service shall demonstrate an~~
742 ~~appropriately trained physician(s) shall be on the active hospital staff to perform diagnostic or therapeutic,~~
743 ~~as applicable, pediatric cardiac catheterizations. For purposes of evaluating this subsection, the~~
744 ~~Department shall consider it prima facie evidence of appropriate training if the staff physician(s) is:~~
745 ~~—(A) board certified or board eligible in pediatric cardiology by the American Board of Pediatrics;~~
746 ~~—(B) credentialed by the hospital to perform diagnostic or therapeutic, as applicable, pediatric cardiac~~
747 ~~catheterizations; and~~
748 ~~—(C) trained consistently with the recommendations of the American College of Cardiology.~~
749 ~~—However, the applicant may submit and the Department may accept other evidence that the staff~~
750 ~~physician(s) performing pediatric cardiac catheterizations is appropriately trained.~~
751 ~~—(xi) A cardiac catheterization service shall be directed by an appropriately trained physician. For~~
752 ~~purposes of evaluating this subsection, the Department shall consider it prima facie evidence of~~
753 ~~appropriate training and experience of the cardiac catheterization service director if the physician is board~~
754 ~~certified in cardiology, cardiovascular radiology or cardiology, adult or pediatric, as applicable. The~~
755 ~~director of an adult cardiac catheterization service shall have performed at least 200 catheterizations per~~
756 ~~year during each of the 5 preceding years. However, the applicant may submit and the Department may~~
757 ~~accept other evidence that the cardiac catheterization service director is appropriately trained.~~
758 ~~—(xii) An approved cardiac catheterization service shall be operated consistently with the~~
759 ~~recommendations of the American College of Cardiology.~~
760 ~~—(xiii) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years~~
761 ~~of operation and continue to participate annually thereafter.~~
762 ~~—(d) Compliance with the following terms of approval:~~
763 ~~—(i) Equipment that is replaced shall be removed from the cardiac catheterization service.~~
764 ~~—(ii) The applicant, to assure appropriate utilization by all segments of the Michigan population, shall:~~
765 ~~—(A) Not deny cardiac catheterization services to any individual based on ability to pay or source of~~
766 ~~payment;~~
767 ~~—(B) Provide cardiac catheterization services to all individuals based on the clinical indications of need~~
768 ~~for the service; and~~
769 ~~—(C) Maintain information by payor and non-paying sources to indicate the volume of care from each~~
770 ~~source provided annually.~~
771 ~~—Compliance with selective contracting requirements shall not be construed as a violation of this term.~~
772 ~~—(iii) The applicant shall participate in a data collection network established and administered by the~~
773 ~~Department or its designee. The data may include, but is not limited to, annual budget and cost~~
774 ~~information, operating schedules, and demographic, diagnostic, morbidity and mortality information, as~~

well as the volume of care provided to patients from all payor sources and other data requested by the Department or its designee and approved by the Commission. The applicant shall provide the required data on a separate basis for each separate and distinct site or unit as required by the Department, in a format established by the Department and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

—(iv) The applicant shall participate in a quality improvement data registry administered by the Department or its designee. The Department or its designee shall require that the applicant submit a summary report as required by the Department. The applicant shall provide the required data in a format established by the Department or its designee. The applicant shall be liable for the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes and assure quality. An applicant shall become a member of the data registry upon initiation of the service and continue to participate annually thereafter.

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

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

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

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

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

(a) Shall immediately report to the Department any changes in the interventional cardiologists who perform the primary PCI procedures.

—(b) Compliance with requirements of the standards set forth in Section 5(1).

—(2) The applicant shall have performed a minimum of 48 primary PCI procedures at the facility in the preceding 12 months and annually thereafter.

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

Section 1410. Documentation of projections

Sec. 1410. 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.

Section 1511. COMPARATIVE REVIEWS; Effect on prior CON Review Standards; comparative reviews

Sec. 1511. (4) PROPOSED PROJECTS REVIEWED UNDER THESE STANDARDS SHALL NOT BE SUBJECT TO COMPARATIVE REVIEW. These CON Review Standards supercede and replace the

829 | CON ~~Review~~ Standards for Cardiac Catheterization Services approved by the CON Commission on
830 | ~~March 9, 2004~~DECEMBER 11, 2007 and effective on ~~June 4, 2004~~FEBRUARY 25, 2008.
831 |
832 | ~~(2) Projects reviewed under these standards shall not be subject to comparative review.~~
833 |
834 |

CON REVIEW STANDARDS
FOR CARDIAC CATHETERIZATION SERVICES

Rural Michigan counties are as follows:

842	Alcona	Hillsdale	Ogemaw
843	Alger	Huron	Ontonagon
844	Antrim	Iosco	Osceola
845	Arenac	Iron	Oscoda
846	Baraga	Lake	Otsego
847	Charlevoix	Luce	Presque Isle
848	Cheboygan	Mackinac	Roscommon
849	Clare	Manistee	Sanilac
850	Crawford	Mason	Schoolcraft
851	Emmet	Montcalm	Tuscola
852	Gladwin	Montmorency	
853	Gogebic	Oceana	

Micropolitan statistical area Michigan counties are as follows:

857	Allegan	Gratiot	Mecosta
858	Alpena	Houghton	Menominee
859	Benzie	Isabella	Midland
860	Branch	Kalkaska	Missaukee
861	Chippewa	Keweenaw	St. Joseph
862	Delta	Leelanau	Shiawassee
863	Dickinson	Lenawee	Wexford
864	Grand Traverse	Marquette	

Metropolitan statistical area Michigan counties are as follows:

868	Barry	Ionia	Newaygo
869	Bay	Jackson	Oakland
870	Berrien	Kalamazoo	Ottawa
871	Calhoun	Kent	Saginaw
872	Cass	Lapeer	St. Clair
873	Clinton	Livingston	Van Buren
874	Eaton	Macomb	Washtenaw
875	Genesee	Monroe	Wayne
876	Ingham	Muskegon	

Source:

879 65 F.R., p. 82238 (December 27, 2000)
 880 Statistical Policy Office
 881 Office of Information and Regulatory Affairs
 882 United States Office of Management and Budget

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