

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.)
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10 **Section 1. Applicability**

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12 Sec. 1. (1) These standards are requirements for approval of the initiation, replacement, expansion,
13 or acquisition of cardiac catheterization services, and the delivery of these services under Part 222 of the
14 Code. Pursuant to Part 222 of the Code, cardiac catheterization services are a covered clinical service.
15 The Department shall use these standards in applying Section 22225(1) of the Code, being Section
16 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section
17 333.22225(2)(c) of the Michigan Compiled Laws.
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19 **Section 2. Definitions**

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

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

26 (b) "Cardiac catheterization procedure" means any cardiac procedure, including diagnostic,
27 therapeutic, and electrophysiology studies, performed on a patient during a single session in a laboratory.
28 Cardiac catheterization is a medical diagnostic or therapeutic procedure during which a catheter is
29 inserted into a vein or artery in a patient; subsequently the free end of the catheter is manipulated by a
30 physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays
31 and an electronic image intensifier are used as aides in placing the catheter tip in the desired position.
32 When the catheter is in place, the physician is able to perform various diagnostic studies and/or
33 therapeutic procedures in the heart. This term does not include "float catheters" that are performed at the
34 bedside or in settings outside the laboratory or the implantation of cardiac permanent pacemakers and
35 implantable cardioverter defibrillators (ICD) devices that are performed in an interventional radiology
36 laboratory or operating room.

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

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

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

44 (f) "Department" means the Michigan Department of Community Health (MDCH).

45 (g) "Diagnostic cardiac catheterization service" means providing diagnostic cardiac catheterization
46 procedures on an organized, regular basis in a laboratory to diagnose anatomical and/or physiological
47 problems in the heart. Procedures include the intra coronary administration of drugs; left heart
48 catheterization; right heart catheterization; coronary angiography; diagnostic electrophysiology studies;
49 and cardiac biopsies (echo-guided or fluoroscopic). A hospital that provides diagnostic cardiac
50 catheterization services may also perform implantations of cardiac permanent pacemakers and ICD
51 devices.

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

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

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

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

61 (l) "Pediatric cardiac catheterization service" means providing cardiac catheterization services on an
62 organized, regular basis to infants and children ages 18 and below, except for electrophysiology studies
63 that are offered and provided to infants and children ages 14 and below, and others with congenital heart
64 disease as defined by the ICD-9-CM codes (SEE APPENDIX B FOR ICD-10-CM CODES) of 426.7
65 (anomalous atrioventricular excitation), 427.0 (cardiac dysrhythmias), and 745.0 through 747.99 (bulbus
66 cordis anomalies and anomalies of cardiac septal closure, other congenital anomalies of heart, and other
67 congenital anomalies of circulatory system).

68 (m) "Primary percutaneous coronary intervention (PCI)" means a PCI performed on an acute
69 myocardial infarction (AMI) patient with confirmed ST elevation or new left bundle branch block.

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

72 (o) "Therapeutic cardiac catheterization service" means providing therapeutic cardiac
73 catheterizations on an organized, regular basis in a laboratory to treat and resolve anatomical and/or
74 physiological problems in the heart. Procedures include PCI, PTCA, atherectomy, stent, laser, cardiac
75 valvuloplasty, balloon atrial septostomy, catheter ablation, cardiac permanent pacemaker, ICD device
76 implantations, transcatheter valve, other structural heart disease procedures, percutaneous transluminal
77 coronary angioplasty (PTCA) and coronary stent implantation and left sided arrhythmia therapeutic
78 procedures. The term does not include the intra coronary administration of drugs where that is the only
79 therapeutic intervention.

80
81 (2) Terms defined in the Code have the same meanings when used in these standards.
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83 Section 3. Requirements to initiate cardiac catheterization services

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85 Sec. 3. An applicant proposing to initiate cardiac catheterization services shall demonstrate the
86 following, as applicable to the proposed project.
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88 (1) An applicant proposing to initiate an adult diagnostic cardiac catheterization service shall
89 demonstrate the following as applicable to the proposed project:

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

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

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

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

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

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

(c) The applicant has applied to provide adult open heart surgery services at the hospital. The applicant must be approved for an adult open heart surgery service in order to be approved for an adult therapeutic cardiac catheterization service.

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

(3) An applicant proposing to initiate a pediatric cardiac catheterization service shall demonstrate the following:

(a) The applicant has a board certified pediatric cardiologist with training in pediatric catheterization procedures to direct the pediatric catheterization laboratory.

(b) The applicant has standardized equipment as defined in the most current American Academy of Pediatrics (AAP) guidelines for pediatric cardiovascular centers.

(c) The applicant has on-site ICU as outlined in the most current AAP guidelines above.

(d) The applicant has applied to provide pediatric open heart surgery services at the hospital. The applicant must be approved for a pediatric open heart surgery service in order to be approved for pediatric cardiac catheterization services.

(e) The applicant shall project a minimum of 600 procedure equivalents in the category of pediatric cardiac catheterizations based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

(4) An applicant proposing to initiate primary PCI service without on-site open heart surgery services shall demonstrate the following:

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

(b) The applicant has at least two interventional cardiologists to perform the primary PCI procedures and each cardiologist has performed at least 75 PCI sessions annually as the primary operator during the most recent 24-month period preceding the date the application was submitted to the Department.

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

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

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

(f) A written agreement with an open heart surgery hospital that includes all of the following:

(i) Involvement in credentialing criteria and recommendations for physicians approved to perform primary PCI procedures.

- 157 (ii) Provision for ongoing cross-training for professional and technical staff involved in the provision of
158 primary PCI to ensure familiarity with interventional equipment. Competency shall be documented
159 annually.
- 160 (iii) Provision for ongoing cross training for emergency department, catheterization laboratory, and
161 critical care unit staff to ensure experience in handling the high acuity status of primary PCI patient
162 candidates. Competency shall be documented annually.
- 163 (iv) Regularly held joint cardiology/cardiac surgery conferences to include review of all primary PCI
164 cases.
- 165 (v) Development and ongoing review of patient selection criteria for primary PCI patients and
166 implementation of those criteria.
- 167 (vi) A mechanism to provide for appropriate patient transfers between facilities and an agreed plan for
168 prompt care.
- 169 (vii) Written protocols, signed by the applicant and the open heart surgery hospital, for the immediate
170 transfer, within 1 hour from the cardiac catheterization laboratory to evaluation on site in the open heart
171 surgery hospital, of patients requiring surgical evaluation and/or intervention 365 days a year. The
172 protocols shall be reviewed and tested on a quarterly basis.
- 173 (viii) Consultation on facilities, equipment, staffing, ancillary services, and policies and procedures for
174 the provision of interventional procedures.
- 175 (g) A written protocol must be established and maintained for case selection for the performance of
176 primary PCI.
- 177 (h) A system to ensure prompt and efficient identification of potential primary PCI patients and rapid
178 transfer from the emergency department to the cardiac catheterization laboratory must be developed and
179 maintained so that door-to-balloon targets are met.
- 180 (i) At least two physicians credentialed to perform primary PCI must commit to functioning as a
181 coordinated group willing and able to provide this service at the hospital on a 24-hour per day, 365 day
182 per year call schedule, with ability to be on-site and available to operate within 30 minutes of identifying
183 the need for primary PCI. These physicians must be credentialed at the facility and actively collaborate
184 with administrative and clinical staff in establishing and implementing protocols, call schedules, and
185 quality assurance procedures pertaining to primary PCI designed to meet the requirements for this
186 certification and in keeping with the current guidelines for the provision of primary PCI promulgated by the
187 American College of Cardiology and American Heart Association.
- 188 (j) The applicant shall project a minimum of 36 primary PCI cases based on data from the most
189 recent 12-month period preceding the date the application was submitted to the Department.

191 **Section 4. Requirements to replace an existing cardiac catheterization service or laboratory**

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193 Sec. 4. Replacing a cardiac catheterization laboratory means a change in the angiography x-ray
194 equipment or a relocation of the service to a new site. The term does not include a change in any of the
195 other equipment or software used in the laboratory. An applicant proposing to replace a cardiac
196 catheterization laboratory or service shall demonstrate the following as applicable to the proposed project:

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198 (1) An applicant proposing to replace cardiac catheterization laboratory equipment shall demonstrate
199 the following:

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

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

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

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

208
209 (2) An applicant proposing to replace a cardiac catheterization service to a new site shall
210 demonstrate the following:

- 211 (a) The proposed project is part of an application to replace the entire hospital.
212 (b) The applicant has performed the following during the most recent 12-month period preceding the
213 date the application was submitted to the Department as applicable to the proposed project:
214 (i) A minimum of 300 procedure equivalents in the category of adult diagnostic cardiac
215 catheterization procedures.
216 (ii) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac
217 catheterization procedures.
218 (iii) A minimum of 600 procedure equivalents in the category of pediatric cardiac catheterization
219 procedures.
220 (iv) A minimum of 500 procedure equivalents for a hospital in a rural or micropolitan county with one
221 laboratory.
222 (v) A minimum of 750 procedure equivalents for a hospital in a metropolitan county with one
223 laboratory.
224 (vi) A minimum of 1,000 procedure equivalents per cardiac catheterization laboratory for a hospital
225 with two or more laboratories.
226 (c) The existing cardiac catheterization service has been in operation for at least 36 months as of the
227 date the application has been submitted to the Department.
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229 **Section 5. Requirements to expand a cardiac catheterization service**
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231 Sec. 5. An applicant proposing to add a laboratory to an existing cardiac catheterization service shall
232 demonstrate the following:
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- 234 (1) The applicant has performed the following during the most recent 12-month period preceding the
235 date the application was submitted to the Department as applicable to the proposed project:
236 (a) A minimum of 300 procedure equivalents in the category of adult diagnostic cardiac
237 catheterization procedures.
238 (b) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac
239 catheterization procedures.
240 (c) A minimum of 600 procedure equivalents in the category of pediatric cardiac catheterization
241 procedures.
242
243 (2) The applicant has performed a minimum of 1,400 procedure equivalents per existing and
244 approved laboratories during the most recent 12-month period preceding the date the application was
245 submitted to the Department.
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247 **Section 6. Requirements to acquire a cardiac catheterization service**
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249 Sec. 6. Acquiring a cardiac catheterization service and its laboratories means obtaining possession
250 and control by contract, ownership, lease or other comparable arrangement or renewal of a lease for
251 existing angiography x-ray equipment. An applicant proposing to acquire a cardiac catheterization
252 service or renew a lease for equipment shall demonstrate the following as applicable to the proposed
253 project:
254

- 255 (1) An applicant proposing to acquire a cardiac catheterization service shall demonstrate the
256 following:
257 (a) The proposed project is part of an application to acquire the entire hospital.
258 (b) An application for the first acquisition of an existing cardiac catheterization service after February
259 27, 2012 shall not be required to be in compliance with the applicable volume requirements in subsection
260 (c). The cardiac catheterization service shall be operating at the applicable volumes set forth in the
261 project delivery requirements in the second 12 months of operation of the service by the applicant and
262 annually thereafter.

263 (c) The applicant has performed the following during the most recent 12-month period preceding the
264 date the application was submitted to the Department as applicable to the proposed project :

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

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

269 (iii) A minimum of 600 procedure equivalents in the category of pediatric cardiac catheterization
270 procedures.

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

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

275 (vi) A minimum of 1,000 procedure equivalents per cardiac catheterization laboratory for two or more
276 laboratories.

277
278 (2) An applicant proposing to renew a lease for existing angiography x-ray equipment shall
279 demonstrate the renewal of the lease is more cost effective than replacing the equipment.
280

281 **Section 7. Requirements for a hybrid operating room/cardiac catheterization laboratory (OR/CCL)**
282

283 Sec. 7. A hybrid OR/CCL means an operating room located on a sterile corridor and equipped with an
284 angiography system permitting minimally invasive procedures of the heart and blood vessels with full
285 anesthesia capabilities. An applicant proposing to add one or more hybrid OR/CCLs at an existing cardiac
286 catheterization service shall demonstrate each of the following:
287

288 (1) The applicant operates an open heart surgery service which is in full compliance with the current
289 CON Review Standards for Open Heart Surgery Services.
290

291 (2) The applicant operates a therapeutic cardiac catheterization program which is in full compliance
292 with section 4(2) of these standards.
293

294 (3) If the hybrid OR/CCL(s) represents an increase in the number of cardiac catheterization laboratories
295 at the facility, the applicant is in compliance with Section 5 of these standards.
296

297 (4) If the hybrid OR/CCL(s) represents conversion of an existing cardiac catheterization laboratory(s),
298 the applicant is in compliance with the provisions of Section 4, if applicable.
299

300 (5) The applicant meets the applicable requirements of the CON Review Standards for Surgical
301 Services.
302

303 (6) Each case performed in a hybrid OR/CCL shall be included either in the surgical volume or the
304 therapeutic cardiac catheterization volume of the facility. No case shall be counted more than once.
305

306 (7) For each hybrid OR/CCL, a facility shall have 0.5 excluded from its inventory of cardiac
307 catheterization laboratories for the purposes of computing the procedure equivalents per room. A facility
308 will not be limited to the number of hybrid ORCCLs within a single licensed facility.
309

310 **Section 8. Requirement for medicaid participation**
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312 Sec. 8. An applicant shall provide verification of medicaid participation at the time the application is
313 submitted to the Department. An applicant that is initiating a new service or is a new provider not
314 currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the
315 Department within six (6) months from the offering of services if a CON is approved.

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Section 9. Project delivery requirements and terms of approval for all applicants

Sec. 9. An applicant shall agree that, if approved, the cardiac catheterization service and all existing and approved laboratories shall be delivered in compliance with the following terms of approval:

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

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

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

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

(d) Each physician credentialed by a hospital to perform adult therapeutic cardiac catheterization procedures shall perform, as the primary operator, a minimum of 75 adult therapeutic cardiac catheterization procedures per year in the second 12 months after being credentialed to and annually thereafter. The annual case load for a physician means adult therapeutic cardiac catheterization procedures performed by that physician in any combination of hospitals.

(e) Each physician credentialed by a hospital to perform pediatric diagnostic cardiac catheterizations shall perform, as the primary operator, a minimum of 50 pediatric diagnostic cardiac catheterization procedures per year in the second 12 months after being credentialed and annually thereafter. The annual case load for a physician means pediatric diagnostic cardiac catheterization procedures performed by that physician in any combination of hospitals

(f) Each physician credentialed by a hospital to perform pediatric therapeutic cardiac catheterizations shall perform, as a primary operator, a minimum of 25 pediatric therapeutic cardiac catheterizations per year in the second 12 months after being credentialed and annually thereafter. The annual case load for a physician means pediatric therapeutic cardiac catheterization procedures performed by that physician in any combination of hospitals

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

- (i) are trained consistent with the recommendations of the American College of Cardiology;
- (ii) are credentialed by the hospital to perform adult diagnostic cardiac catheterizations; and
- (iii) have each performed a minimum of 100 adult diagnostic cardiac catheterizations in the preceding 12 months.

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

- (i) are trained consistent with the recommendations of the American College of Cardiology;
- (ii) are credentialed by the hospital to perform adult therapeutic cardiac catheterizations; and
- (iii) have each performed a minimum of 75 adult therapeutic cardiac catheterization procedures in the preceding 12 months.

(i) A pediatric cardiac catheterization service shall have an appropriately trained physician on its active hospital staff. The Department may accept other evidence or shall consider it appropriate training if the staff physician:

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

368 (j) A cardiac catheterization service shall be directed by an appropriately trained physician. The
369 Department shall consider appropriate training of the director if the physician is board certified in
370 cardiology, cardiovascular radiology or cardiology, adult or pediatric, as applicable. The director of an
371 adult cardiac catheterization service shall have performed at least 200 catheterizations per year during
372 each of the five preceding years. The Department may accept other evidence that the director is
373 appropriately trained.

374 (k) A cardiac catheterization service shall be operated consistently with the recommendations of the
375 American College of Cardiology.

376

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

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

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

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

384 (d) The operation of and referral of patients to the cardiac catheterization service shall be in
385 conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.1621; MSA 14.15
386 (16221).

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

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

391 (i) 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures.
392 (ii) 300 procedure equivalents in the category of adult therapeutic cardiac catheterization
393 procedures.

394 (iii) 600 procedure equivalents in the category of pediatric cardiac catheterization procedures.
395 (iv) 500 procedure equivalents for a hospital in a rural or micropolitan county with one laboratory.
396 (v) 750 procedure equivalents for a hospital in a metropolitan county with one laboratory.
397 (vi) 1,000 procedure equivalents per cardiac catheterization laboratory for two or more laboratories.
398 (vii) 36 adult primary PCI cases for a primary PCI service.

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

403 (c) The hospital shall participate in a quality improvement data registry administered by the
404 Department or its designee. The hospital shall submit summary reports as required by the Department.
405 The hospital shall provide the required data in a format established by the Department or its designee.
406 The hospital is liable for the cost of data submission and on-site reviews in order for the Department to
407 verify and monitor volumes and assure quality. The hospital must become a member of the data registry
408 upon initiation of the service and continue to participate annually thereafter for the life of that service.
409

410 (5) Compliance with the following primary PCI requirements, if applicable:

411 (a) The requirements set forth in Section 3(4).

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

414 (c) The hospital shall perform a minimum of 36 primary PCI procedures at the hospital in the
415 preceding 12-month period of operation of the service and annually thereafter.

416 (d) The hospital shall maintain a 90-minute door-to-balloon time or less in at least 75% of the primary
417 PCI sessions.

418 (e) The hospital shall participate in a data registry, administered by the Department or its designee.
419 The Department or its designee shall require that the applicant submit data on all consecutive cases of
420 primary PCI as is necessary to comprehensively assess and provide comparative analyses of case

421 selection, processes and outcome of care, and trend in efficiency. The applicant shall provide the
422 required data in a format established by the Department or its designee. The applicant shall be liable for
423 the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes
424 and assure quality.

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426 **Section 10. Methodology for computing cardiac catheterization equivalents**
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428 Sec. 10. The following shall be used in calculating procedure equivalents and evaluating utilization of
429 a cardiac catheterization service and its laboratories:
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Procedure Type	Procedure equivalent	
	Adult	Pediatric
Diagnostic cardiac catheterization/peripheral sessions	1.5	2.7
Therapeutic cardiac catheterization/peripheral sessions	2.7	4.0
Complex percutaneous valvular sessions*	4.0	7.0

* Complex percutaneous valvular sessions includes, but is not limited to, procedures performed percutaneously or with surgical assistance to repair or replace aortic, mitral and pulmonary valves such as transcatheter aortic valvular implantation (Tavi) procedures. These sessions can only be performed at hospitals approved with open heart surgery services.

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432 **Section 11. Documentation of projections**
433

434 Sec. 11. An applicant required to project volumes shall demonstrate the following as applicable to the
435 proposed project:
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437 (1) The applicant shall specify how the volume projections were developed. Specification of the
438 projections shall include a description of the data source(s) used and assessment of the accuracy of the
439 data. The Department shall determine if the projections are reasonable.
440

441 (2) An applicant proposing to initiate a primary PCI service shall demonstrate and certify that the
442 hospital treated or transferred 36 ST segment elevation AMI cases during the most recent 12-month
443 period preceding the date the application was submitted to the Department. Cases may include
444 thrombolytic eligible patients documented through pharmacy records showing the number of doses of
445 thrombolytic therapy ordered and medical records of emergency transfers of AMI patients to an
446 appropriate hospital for a primary PCI procedure.
447

448 **Section 12. Comparative reviews; Effect on prior CON Review Standards**
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450 Sec. 12. Proposed projects reviewed under these standards shall not be subject to comparative
451 review. These CON Review Standards supercede and replace the CON Review Standards for Cardiac
452 Catheterization Services approved by the CON Commission on December 11, 2007 and effective on
453 February 25, 2008.
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Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

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

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ICD-9-CM TO ICD-10-CM CODE TRANSLATION

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
426.7	ANOMALOUS ATRIOVENTRICULAR EXCITATION	I45.6	PRE-EXCITATION SYNDROME
427	CARDIAC DYSRHYTHMIAS	I47.0-I47.9	PAROXYSMAL TACHYCARDIA
		I48.0-I48.92	ATRIAL FIBRILLATION AND FLUTTER
		I49.01-I49.9	OTHER CARDIAC ARRHYTHMIAS
		R00.1	BRADYCARDIA, UNSPECIFIED
745.0 through 747.99	BULBUS CORDIS ANOMALIES AND ANOMALIES OF CARDIAC SEPTAL CLOSURE, OTHER CONGENITAL ANOMALIES OF HEART, AND OTHER CONGENITAL ANOMALIES OF CIRCULATORY SYSTEM	P29.3	PERSISTENT FETAL CIRCULATION
		Q20.0-Q28.9	CONGENITAL MALFORMATIONS OF THE CIRCULATORY SYSTEM

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"ICD-9-CM CODE" MEANS THE DISEASE CODES AND NOMENCLATURE FOUND IN THE INTERNATIONAL CLASSIFICATION OF DISEASES - 9TH REVISION - CLINICAL MODIFICATION, PREPARED BY THE COMMISSION ON PROFESSIONAL AND HOSPITAL ACTIVITIES FOR THE U.S. NATIONAL CENTER FOR HEALTH STATISTICS.

"ICD-10-CM CODE" MEANS THE DISEASE CODES AND NOMENCLATURE FOUND IN THE INTERNATIONAL CLASSIFICATION OF DISEASES - 10TH REVISION - CLINICAL MODIFICATION, NATIONAL CENTER FOR HEALTH STATISTICS.