

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. These standards are requirements for approval of the initiation, replacement, expansion, or  
13 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.

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

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

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

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

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

51 (h) "Elective Percutaneous Coronary Intervention (PCI) Service" means providing percutaneous  
52 transluminal coronary angioplasty (PTCA) and coronary stent implantation on an organized, regular basis  
53 in a laboratory at a hospital without on-site open heart surgical services. The term does not include  
54 transcatheter valve, other structural heart disease procedures, or left sided arrhythmia therapeutic

55 procedures. A hospital that provides elective PCI services may also perform implantations of cardiac  
56 permanent pacemakers, ICD devices, and right sided catheter ablation procedures. Structural heart  
57 disease procedures can only be performed within a hospital that has on-site open heart surgical services.

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

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

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

65 (l) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and 1396r-  
66 8 to 1396v.

67 (m) "Pediatric cardiac catheterization service" means providing cardiac catheterization services on an  
68 organized, regular basis to infants and children ages 18 and below, except for electrophysiology studies  
69 that are offered and provided to infants and children ages 14 and below, and others with congenital heart  
70 disease as defined by the ICD-9-CM codes of 426.7 (anomalous atrioventricular excitation), 427.0  
71 (cardiac dysrhythmias), and 745.0 through 747.99 (bulbus cordis anomalies and anomalies of cardiac  
72 septal closure, other congenital anomalies of heart, and other congenital anomalies of circulatory  
73 system).

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

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

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

86  
87 (2) Terms defined in the Code have the same meanings when used in these standards.  
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### 89 **Section 3. Requirements to initiate cardiac catheterization services**

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91 Sec. 3. An applicant proposing to initiate cardiac catheterization services shall demonstrate the  
92 following, as applicable to the proposed project.

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94 (1) An applicant proposing to initiate an adult diagnostic cardiac catheterization service shall  
95 demonstrate the following, as applicable to the proposed project:

96 (a) An applicant in a rural or micropolitan statistical area county shall project a minimum of 500  
97 procedure equivalents that includes 300 procedure equivalents in the category of diagnostic cardiac  
98 catheterization procedures during the most recent 12-month period preceding the date the application  
99 was submitted to the Department for a single laboratory.

100 (b) An applicant in a metropolitan statistical area county shall project a minimum of 750 procedure  
101 equivalents that includes 300 procedure equivalents in the category of diagnostic cardiac catheterization  
102 procedures during the most recent 12-month period preceding the date the application was submitted to  
103 the Department for a single laboratory.

104 (c) An applicant proposing to initiate with two or more laboratories shall project a minimum of 1,000  
105 procedure equivalents per laboratory that includes 300 procedure equivalents in the category of  
106 diagnostic cardiac catheterization procedures during the most recent 12-month period preceding the date  
107 the application was submitted to the 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) The applicant 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 adult diagnostic cardiac catheterization service has been in operation more than 24 months.

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

(d) The applicant shall project a minimum of 300 procedure equivalents in the category of adult therapeutic cardiac catheterizations during 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 demonstrates the following:

(i) A board certified pediatric cardiologist with training in pediatric catheterization procedures to direct the pediatric catheterization laboratory.

(ii) Standardized equipment as defined in the most current American Academy of Pediatric (AAP) Guidelines for Pediatric Cardiovascular centers.

(iii) On-site ICU as defined in the most current AAP guidelines above.

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

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

(4) An applicant proposing to initiate a primary PCI service without on-site open heart surgical 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 that have performed at least 75 PCI sessions each annually as the primary operator during the most recent 24 months 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 surgical hospital; and participate in an un-interrupted 24-hour, 365-day call schedule. Competency should 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 should be documented annually.

(f) A written agreement with an open heart surgical hospital that includes:

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

- 161 (ii) Provision for ongoing cross-training for professional and technical staff involved in the provision of  
162 primary PCI to ensure familiarity with interventional equipment. Competency should be documented  
163 annually.
- 164 (iii) Provision for ongoing cross training for emergency department, catheterization laboratory and  
165 critical care unit staff to ensure experience in handling the high acuity status of primary PCI patient  
166 candidates. Competency should be documented annually;
- 167 (iv) Regularly held joint cardiology/cardiac surgery conferences to include review of primary PCI  
168 cases.
- 169 (v) Development and ongoing review of patient selection criteria for primary PCI patients and  
170 implementation of those criteria.
- 171 (vi) A mechanism to provide for appropriate patient transfers between facilities and an agreed plan for  
172 prompt care.
- 173 (vii) Written protocols, signed by the applicant and the open heart surgical hospital, for the immediate  
174 transfer within 1 hour from the cardiac catheterization laboratory to evaluation on site in the open heart  
175 surgical hospital of patients requiring surgical evaluation and/or intervention 365 days a year. The  
176 protocols shall be reviewed/tested on a quarterly basis; and
- 177 (viii) Consultation on facilities, equipment, staffing, ancillary services, and policies and procedures for  
178 the provision of interventional procedures.
- 179 (g) A written protocol must be established and maintained for case selection for the performance of  
180 primary PCI.
- 181 (h) A system to ensure prompt and efficient identification of potential primary PCI patients and rapid  
182 transfer from the emergency department to the cardiac catheterization Laboratory must be developed and  
183 maintained so that door-to-balloon targets are met.
- 184 (i) At least two physicians credentialed to perform primary PCI must commit to functioning as a  
185 coordinated group willing and able to provide this service at the hospital on a 24-hour per day, 365 days  
186 per year call schedule, with ability to be on-site and available to operate within 30 minutes of identifying  
187 the need for primary PCI. These physicians must be credentialed at the hospital and actively collaborate  
188 with administrative and clinical staff in establishing and implementing protocols, call schedules, and  
189 quality assurance procedures pertaining to primary PCI designed to meet the requirements for this  
190 certification and in keeping with the current guidelines for the provision of primary PCI promulgated by the  
191 American College of Cardiology and American Heart Association.
- 192 (J) The applicant shall project a minimum of 36 primary PCI cases during the most recent 12-month  
193 period preceding the date the application was submitted to the Department.
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- 195 (5) An applicant proposing to initiate an elective PCI service without on-site open heart surgical  
196 services shall demonstrate the following:
- 197 (a) The applicant provides, is approved to provide, or has applied to provide adult diagnostic cardiac  
198 catheterization services at the hospital. The applicant must be approved for adult diagnostic cardiac  
199 catheterization services in order to be approved for elective PCI services.
- 200 (b) The applicant has at least two interventional cardiologists to perform PCI procedures at the  
201 hospital that meet the following:
- 202 (i) Board certified in interventional cardiology.
- 203 (ii) Individual outcomes are comparable to national outcomes.
- 204 (iii) Performed at least 300 PCI sessions since fellowship.
- 205 (iv) Performed at least 100 PCI sessions in each of the most recent two years preceding the date the  
206 application was submitted to the Department.
- 207 (c) A written agreement with an open heart surgical hospital that includes:
- 208 (i) Signatures by senior executives from the applicant hospital and the hospital with open heart  
209 surgical services.
- 210 (ii) Involvement in the credentialing criteria and recommendations for physicians approved to perform  
211 PCI.
- 212 (iii) Provision for ongoing cross-training for professional and technical staff involved in the provision of  
213 PCI to ensure familiarity with interventional equipment. Competency to be documented annually.

- 214 (iv) Provision for ongoing cross training for emergency department, catheterization laboratory and  
215 critical care unit staff to ensure experience in handling the high acuity status of PCI patient candidates.  
216 Competency to be documented annually.
- 217 (v) Regularly held joint cardiology/cardiac surgery conferences (at least quarterly) to include review  
218 of all PCI cases and outcomes;
- 219 (vi) Development and ongoing review of patient selection criteria for PCI patients and implementation  
220 of those criteria.
- 221 (vii) A mechanism to provide for appropriate patient transfers between hospitals and an agreed plan  
222 for prompt care; written protocols, signed by the applicant and the open heart surgical hospital, must be in  
223 place with provisions for immediate and efficient transfer within one hour of patients requiring surgical  
224 evaluation and/or intervention 24 hours per day, 365 days a year. The protocols shall be reviewed/tested  
225 on a regular, semi-annual basis.
- 226 (viii) Ability to transfer images electronically for the concurrent review of cases with the open heart  
227 surgical hospital if needed.
- 228 (ix) Consultation on facilities, equipment, staffing, ancillary services, and policies and procedures for  
229 the provision of interventional procedures.
- 230 (d) The applicant agrees to the following:
- 231 (i) A written protocol must be established and maintained for case selection for the performance of  
232 PCI that is consistent with current practice guidelines set forth by the American College of Cardiology and  
233 the American Heart Association, including a risk stratification tool (STS or SYNTAX) used and recorded to  
234 insure appropriate triage to coronary artery bypass graft surgery. Exclusions for elective PCI should  
235 include decompensated heart failure without acute ischemia, recent stroke, advanced malignancy, known  
236 clotting disorders, EF less than 25%, left main disease unprotected by prior surgery, lesions that  
237 jeopardize >50% of myocardium, diffuse disease and excessive tortuosity, degenerated vein grafts,  
238 substantial thrombus, aggressive measures to open chronic total occlusions, and inability to protect major  
239 side branches.
- 240 (ii) Establish and maintain written policy and procedures for training, staffing, and program review.
- 241 (iii) The nursing and technical catheterization staff are experienced in handling acutely ill patients and  
242 comfortable with interventional equipment; have acquired experience in dedicated interventional  
243 laboratories at open heart surgical services or at primary PCI services; and participate in an un-  
244 interrupted 24-hour, 365-day call schedule. Competency to be documented annually.
- 245 (iv) The catheterization laboratory is equipped with imaging systems, resuscitative equipment, intra-  
246 aortic balloon pump (IABP) support, and stocked with appropriate interventional equipment.
- 247 (v) The cardiac care unit nurses are adept in hemodynamic monitoring and IABP management.  
248 Competency to be documented annually.
- 249 (vi) Establish and maintain a system to ensure prompt and efficient identification of potential primary  
250 PCI patients and rapid transfer to the catheterization laboratory so that door-to-balloon targets are met.
- 251 (vii) At least two physicians credentialed to perform primary PCI must commit to functioning as a  
252 coordinated group willing and able to provide this service at the hospital on a 24-hour per day, 365 day  
253 per year call schedule, with ability to be on-site and available to operate within 30 minutes of identifying  
254 the need for primary PCI. These physicians must be credentialed at the facility and actively collaborate  
255 with administrative and clinical staff in establishing and implementing protocols, call schedules, and  
256 quality assurance procedures pertaining to primary PCI designed to meet the requirements for this  
257 certification and in keeping with the current guidelines for the provision of primary PCI promulgated by the  
258 American College of Cardiology and American Heart Association.
- 259 (e) The applicant shall project the following, as applicable to the proposed project:
- 260 (i) 350 PCI (PTCA and coronary stent) cases during the most recent 12-month period preceding the  
261 date the application was submitted to the Department if the hospital is within one hour drive time of an  
262 existing PCI or open heart surgical hospital.
- 263 (ii) 250 PCI (PTCA and coronary stent) cases during the most recent 12-month period preceding the  
264 date the application was submitted to the Department if the hospital is more than one hour drive time of  
265 an existing PCI or open heart surgical hospital.  
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267 **Section 4. Requirements to replace an existing cardiac catheterization laboratory**  
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269 Sec. 4. Replacing a cardiac catheterization laboratory means a change in the angiography X-ray  
270 equipment or a relocation of the service to a new site. The term does not include a change in any of the  
271 other equipment or software used in the laboratory. An applicant proposing to replace a cardiac  
272 catheterization service or laboratory shall demonstrate the following, as applicable to the proposed  
273 project.  
274

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

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

279 (i) The existing angiography X-ray equipment to be replaced poses a threat to the safety of the  
280 patients.

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

283 (b) The existing angiography X-ray equipment to be replaced will be removed from service on or  
284 before beginning operations of the replacement equipment.  
285

286 (2) An applicant proposing to replace a cardiac catheterization service to a new site shall  
287 demonstrate the following:

288 (a) The proposed project is part of an application to replace the entire hospital.

289 (b) The existing cardiac catheterization service is in compliance with the applicable volume  
290 requirements:

291 (i) 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures.

292 (ii) 300 procedure equivalents in the category of adult therapeutic cardiac catheterization procedures.

293 (iii) 600 procedure equivalents in the category of pediatric cardiac catheterization procedures.

294 (iv) 500 procedure equivalents for a hospital in a rural or micropolitan county with one laboratory.

295 (v) 750 procedure equivalents for a hospital in a metropolitan county with one laboratory.

296 (vi) 1,000 procedure equivalents per cardiac catheterization laboratory for two or more laboratories.

297 (c) The existing cardiac catheterization service has been in operation for at least 36 months as of the  
298 date the application has been submitted to the Department.  
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300 **Section 5. Requirements to expand a cardiac catheterization service**  
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302 Sec. 5. An applicant proposing to add a laboratory to an existing cardiac catheterization service shall  
303 demonstrate the following:  
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305 (1) The existing cardiac catheterization service is in compliance with the applicable volume  
306 requirements:

307 (a) 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures.

308 (b) 300 procedure equivalents in the category of adult therapeutic cardiac catheterization procedures.

309 (c) 600 procedure equivalents in the category of pediatric cardiac catheterization procedures.  
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311 (2) The applicant has performed an average of 1,400 procedure equivalents per existing and  
312 approved laboratories during the most recent 12-month period preceding the date the application was  
313 submitted to the Department.  
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315 **Section 6. Requirements to acquire a cardiac catheterization service**  
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317 Sec 6. Acquiring a cardiac catheterization services and its laboratories means obtaining possession  
318 and control by contract, ownership, lease or other comparable arrangement or renewal of a lease for  
319 existing angiography X-ray equipment. An applicant proposing to acquire a cardiac catheterization

320 service or renew a lease for equipment shall demonstrate the following, as applicable to the proposed  
321 project:  
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323 (1) An applicant proposing to acquire a cardiac catheterization service shall demonstrate the  
324 following:

325 (a) The proposed project is part of an application to acquire the entire hospital.

326 (b) An application for the first acquisition of an existing cardiac catheterization services after <INSERT  
327 EFFECTIVE DATE OF THESE STANDARDS> shall not be required to be in compliance with the  
328 applicable volume requirements in subdivision (c). The cardiac catheterization service shall be operating  
329 at the applicable volumes set forth in the project delivery requirements in the second 12 months of  
330 operation of the service by the applicant and annually thereafter:

331 (c) Except as provided for in subdivision (b), an application for the acquisition of an existing cardiac  
332 catheterization service after <INSERT EFFECTIVE DATE OF THESE STANDARDS> shall demonstrate  
333 the following, as applicable to the proposed project:

334 (i) 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures.

335 (ii) 300 procedure equivalents in the category of adult therapeutic cardiac catheterization procedures.

336 (iii) 600 procedure equivalents in the category of pediatric cardiac catheterization procedures.

337 (iv) 500 procedure equivalents for a hospital in a rural or micropolitan county with one laboratory.

338 (v) 750 procedure equivalents for a hospital in a metropolitan county with one laboratory.

339 (vi) 1,000 procedure equivalents per cardiac catheterization laboratory for two or more laboratories.  
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341 (2) An applicant proposing to renew a lease for existing angiography X-ray equipment shall  
342 demonstrate the renewal of the lease is more cost effective than replacing the equipment.  
343

#### 344 **Section 7. Requirement for Medicaid Participation**

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346 Sec. 7. An applicant shall provide verification of Medicaid participation at the time the application is  
347 submitted to the Department. An applicant that is initiating a new service or is a new provider not  
348 currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the  
349 Department within six (6) months from the offering of services if a con is approved.  
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#### 351 **Section 8. Project delivery requirements and terms of approval for all applicants**

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353 Sec. 8. An applicant shall agree that, if approved, the cardiac catheterization service and all existing  
354 and approved laboratories shall be delivered in compliance with the following terms of approval.  
355

356 (1) Compliance with these standards.  
357

358 (2) Compliance with the following quality assurance requirements:

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

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

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

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

372 (e) Each physician credentialed by a hospital to perform pediatric diagnostic cardiac catheterizations  
373 shall perform, as the primary operator, a minimum of 50 pediatric diagnostic cardiac catheterization

374 procedures per year in the second 12 months after being credentialed and annually thereafter. The  
375 annual case load for a physician means pediatric diagnostic cardiac catheterization procedures  
376 performed by that physician in any combination of hospitals.

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

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

385 (i) Are trained consistent with the recommendations of the American College of Cardiology.

386 (ii) Are credentialed by the hospital to perform adult diagnostic cardiac catheterizations.

387 (iii) Have each performed a minimum of 100 adult diagnostic cardiac catheterizations in the preceding  
388 12 months.

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

392 (i) Are trained consistent with the recommendations of the American College of Cardiology;

393 (ii) Are credentialed by the hospital to perform adult therapeutic cardiac catheterizations; and

394 (iii) Have each performed a minimum of 75 adult therapeutic cardiac catheterization procedures in the  
395 preceding 12 months.

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

399 (i) Is a board certified or board eligible in pediatric cardiology by the American Board of Pediatrics.

400 (ii) Is credentialed by the hospital to perform pediatric cardiac catheterizations.

401 (iii) Has trained consistently with the recommendations of the American College of Cardiology.

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

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

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

412 (a) The cardiac catheterization service shall accept referrals for cardiac catheterizations from all  
413 appropriately licensed practitioners.

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

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

418 (d) The operation of and referral of patients to the cardiac catheterization service shall be in  
419 conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.1621; MSA 14.15  
420 (16221).

421  
422 (4) Compliance with the following monitoring and reporting requirements:

423 (a) The cardiac catheterization services shall be operating at the applicable volumes in the second 12  
424 months of operation of the service, or an additional laboratory, and annually thereafter:

425 (i) 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures.

426 (ii) 300 procedure equivalents in the category of adult therapeutic cardiac catheterization procedures.

427 (iii) 600 procedure equivalents in the category of pediatric cardiac catheterization procedures.



428 (iv) 500 procedure equivalents for a hospital in a rural or micropolitan county with one laboratory.  
429 (v) 750 procedure equivalents for a hospital in a metropolitan county with one laboratory.  
430 (vi) 1,000 procedure equivalents per cardiac catheterization laboratory for two or more laboratories.  
431 (vii) 36 adult primary PCI cases for a primary PCI service.  
432 (viii) 350 adult PCI cases for an elective PCI service within one-hour drive time of an existing hospital  
433 with an open heart surgical service.  
434 (ix) 250 adult PCI cases for an elective PCI service more than one-hour drive time of an existing  
435 hospital with an open heart surgical service.  
436 (b) The hospital shall participate in a data collection network established and administered by the  
437 Department or its designee. Data may include, but is not limited to, annual budget and cost information,  
438 operating schedules, patient demographics, morbidity and mortality information, and payer sources. The  
439 hospital shall provide the required data in a format established by the Department. The Department may  
440 verify the data through on-site review of appropriate records.  
441 (c) The hospital shall participate in a quality improvement data registry administered by the  
442 Department or its designee. The hospital shall submit summary reports as required by the Department.  
443 The hospital is liable for the cost of data submission and on-site reviews in order for the Department to  
444 verify and monitor volumes and assure quality. The hospital must become a member of the data registry  
445 upon initiation of the service and continue to participate annually thereafter for the life of that service.  
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447 (5) Compliance with the following PCI requirements, if applicable:  
448 (a) The hospital shall maintain all quality requirements set forth in subsection 3(4) and 3(5) as  
449 applicable to the cardiac catheterization service.  
450 (b) The hospital shall participate in a benchmarked PCI data registry designed by the Department that  
451 includes all the following:  
452 (i) Patient and clinical descriptions.  
453 (ii) Measures of outcomes.  
454 (iii) Measure of the ACC appropriate use of the procedure including STS or SYNTAX score in each  
455 patient. The Department shall require that the hospital submit data on all PCI cases in a format  
456 established by the Department. The hospital shall be liable for costs of data submission. The  
457 Department shall require that the hospital submit a summary report on an annual basis that shall be made  
458 available to the general public.  
459 (c) The hospital shall participate in an external impartial oversight body to be designated by the  
460 Department. The hospital shall be liable for the costs of participating in this oversight process and must  
461 continue to participate annually thereafter. The oversight body shall produce an annual report of all PCI  
462 program that will contain all the following:  
463 (i) Complication rates.  
464 (ii) Number of procedures performed per operator.  
465 (iii) Success rates.  
466 (iv) Appropriate use rates.  
467 (v) Patient transfer rates.  
468 (vi) The oversight body shall review the findings with each of the participating hospitals as a group  
469 and shall provide those findings to the Department to be made available to the general public. All elective  
470 PCI services performing less than 250 PCI cases per year in any given year must have all cases  
471 reviewed by this oversight body for appropriateness and outcomes.  
472 (d) The hospital shall include in their consent for PCI notification to the patient that the hospital does  
473 not provide on-site open heart surgical services and that transfer to a hospital with open heart surgical  
474 services may be necessary.  
475 (e) The hospital shall establish an internal review body, including at a minimum the chief medical  
476 officer, director of cardiovascular services, director of cardiovascular services for the hospital with open  
477 heart surgical services (or equivalent physician representatives), that shall review at least annual reports  
478 describing the activities of the cardiac catheterization service including complication rates, morbidity and  
479 mortality, success rates and the number of procedures performed and procedures requiring transfer.  
480 (f) The hospital shall employ appropriate data management personnel to insure timely and accurate  
481 reporting to the registry and reviewing bodies stated above.

482 (g) Each physician credentialed by a hospital to perform PCI cases shall perform, as the primary  
483 operator, a minimum of 100 PCI cases per year in the second 12 months after being credentialed and  
484 annually thereafter. The annual case load for a physician means PCI cases performed by that physician  
485 in any combination of hospitals.

486 (h) Each physician must also maintain the following in order to be credentialed:

487 (i) Participation in an institutional quality improvement program.

488 (ii) Board certified in interventional cardiology.

489 (iii) Performed at least 300 PCI cases total since fellowship.

490 (iv) At least 30 hours of continuing medical education directed toward interventional cardiology every  
491 24 months.

492 (i) The medical director of the hospital shall perform PCI procedures at the contracted hospital with  
493 open heart surgical services and shall also perform PCI procedures at the elective PCI service hospital  
494 during each year until the hospital reaches minimum volume.

495 (j) The hospital shall always have in place a written agreement meeting all of the requirements of the  
496 written agreement between the hospital and the hospital with the open heart surgical service as long as  
497 the elective PCI service does not have on-site open heart surgical services, but may change the  
498 contracted open heart surgical hospital.

499  
500 (6) The agreements and assurances required by this section shall be in the form of a certification  
501 agreed to by the applicant or its authorized agent.

502  
503 **Section 9. Methodology for computing cardiac catheterization equivalents**

504  
505 Sec. 9. The following shall be used in calculating procedure equivalents and evaluating utilization of a  
506 cardiac catheterization service and laboratory:  
507

PROCEDURE TYPE	PROCEDURE EQUIVALENT	
	Adult	Pediatric
Diagnostic Cardiac Catheterization/Peripheral Sessions	1.5	2.7
Therapeutic Cardiac Catheterization/Peripheral Sessions	2.7	4.0
Percutaneous Valvular Sessions*	4.0	7.0
*Percutaneous valvular sessions means providing...		

508  
509 **Section 10. Documentation of projections**

510  
511 Sec. 10. An applicant required to project volumes shall specify how the volume projections were  
512 developed. Specification of the projections shall include a description of the data source(s) used and  
513 assessment of the accuracy of the data. The Department shall determine if the projections are  
514 reasonable. An applicant must also meet the following requirements as applicable to the proposed  
515 project:

516  
517 (1) An applicant proposing to initiate a primary PCI service shall demonstrate and certify that the  
518 hospital treated or transferred 36 ST segment elevation AMI cases during the most recent 12 months  
519 preceding the date the application was submitted to the Department. Cases may include thrombolytic  
520 eligible patients documented through pharmacy records showing the number of doses of thrombolytic  
521 therapy ordered and medical records of emergency transfers of AMI patients to an appropriate hospital  
522 for a primary PCI procedure.

523  
524 (2) An applicant proposing to initiate an elective PCI service shall demonstrate and certify the  
525 following:

526 (a) Physician commitments of PCI cases performed at an existing cardiac catheterization service in  
527 the same health service area.

- 528 (i) Commitments of PCI cases shall not reduce an existing cardiac catheterization service below its  
529 applicable volume requirement.
- 530 (ii) Commitments of PCI cases do not represent duplicate cases with this subsection.
- 531 (iii) Commitments identify the following:
- 532 (A) The name of each physician that performed PCI cases to be committed to the proposed project.
- 533 (B) The number of PCI cases of each physician performed during the most recent 12 months  
534 verifiable by the Department.
- 535 (C) The locations at which the committed PCI cases were performed.
- 536 (D) A written commitment from each physician that he or she will perform at least the volume of PCI  
537 cases committed to the proposed cardiac catheterization service for no less than three years subsequent  
538 to the initiation of services proposed by the applicant.
- 539 (E) The number of PCI cases performed at the existing cardiac catheterization service from which  
540 PCI cases will be transferred during the most recent 12 months verifiable by the Department for which  
541 annual survey data is available.
- 542 (b) Documentation of existing patient transfers from the applicant hospital to an PCI service or open  
543 heart surgical hospital for purposes of receiving a PCI procedure. In demonstrating compliance, an  
544 applicant shall provide the following for each patient transfer in the most recent 12 months verifiable by  
545 the Department:
- 546 (i) Unique patient identifier.
- 547 (ii) ICD-9, or equivalent, diagnosis code.
- 548 (iii) Hospital where the patient was transferred.
- 549 (iv) Physician patient transferred to.
- 550 (v) Date of patient transfer.
- 551 (c) Existing PCI cases performed at the applicant hospital in the most recent 12 months verifiable by  
552 the Department.

553

#### 554 **Section 11. Comparative Reviews; Effect on prior CON Review Standards**

555

556 Sec. 11. Proposed projects reviewed under these standards shall not be subject to comparative  
557 review. These standards supersede and replace the CON Review Standards for Cardiac Catheterization  
558 Services approved by the CON Commission on December 11, 2007 and effective on February 25, 2008.

559 **Appendix A**

560

561 **HEALTH SERVICE AREAS**

**COUNTIES**

562

563	1 – Southeast	Livingston	Monroe	St. Clair
564		Macomb	Oakland	Washtenaw
565		Wayne		

566

567	2 – Mid-Southern	Clinton	Hillsdale	Jackson
568		Eaton	Ingham	Lenawee

569

570	3 – Southwest	Barry	Calhoun	St. Joseph
571		Berrien	Cass	Van Buren
572		Branch	Kalamazoo	

573

574	4 – West	Allegan	Mason	Newaygo
575		Ionia	Mecosta	Oceana
576		Kent	Montcalm	Osceola
577		Lake	Muskegon	Ottawa

578

579	5 - GLS	Genesee	Lapeer	Shiawassee
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580

581	6 – East	Arenac	Huron	Roscommon
582		Bay	Iosco	Saginaw
583		Clare	Isabella	Sanilac
584		Gladwin	Midland	Tuscola
585		Gratiot	Ogemaw	

586

587	7 – Northern Lower	Alcona	Crawford	Missaukee
588		Alpena	Emmet	Montmorency
589		Antrim	Grand Traverse	Oscoda
590		Benzie	Kalkaska	Otsego
591		Charlevoix	Leelanau	Presque Isle
592		Cheboygan	Manistee	Wexford

593

594	8 – Upper Peninsula	Alger	Gogebic	Mackinac
595		Baraga	Houghton	Marquette
596		Chippewa	Iron	Menominee
597		Delta	Keweenaw	Ontonagon
598		Dickinson	Luce	Schoolcraft

599

600

601 **APPENDIX B**

602

603

604 Rural Michigan counties are as follows:

605

606	Alcona	Hillsdale	Ogemaw
607	Alger	Huron	Ontonagon
608	Antrim	Iosco	Osceola
609	Arenac	Iron	Oscoda
610	Baraga	Lake	Otsego
611	Charlevoix	Luce	Presque Isle
612	Cheboygan	Mackinac	Roscommon
613	Clare	Manistee	Sanilac
614	Crawford	Mason	Schoolcraft
615	Emmet	Montcalm	Tuscola
616	Gladwin	Montmorency	
617	Gogebic	Oceana	

618

619 Micropolitan statistical area Michigan counties are as follows:

620

621	Allegan	Gratiot	Mecosta
622	Alpena	Houghton	Menominee
623	Benzie	Isabella	Midland
624	Branch	Kalkaska	Missaukee
625	Chippewa	Keweenaw	St. Joseph
626	Delta	Leelanau	Shiawassee
627	Dickinson	Lenawee	Wexford
628	Grand Traverse	Marquette	

629

630 Metropolitan statistical area Michigan counties are as follows:

631

632	Barry	Ionia	Newaygo
633	Bay	Jackson	Oakland
634	Berrien	Kalamazoo	Ottawa
635	Calhoun	Kent	Saginaw
636	Cass	Lapeer	St. Clair
637	Clinton	Livingston	Van Buren
638	Eaton	Macomb	Washtenaw
639	Genesee	Monroe	Wayne
640	Ingham	Muskegon	

641

642 Source:

643 65 F.R., p. 82238 (December 27, 2000)

644 Statistical Policy Office

645 Office of Information and Regulatory Affairs

646 United States Office of Management and Budget