

1 MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

2  
3 CERTIFICATE OF NEED (CON) REVIEW STANDARDS  
4 FOR CARDIAC CATHETERIZATION SERVICES  
5

6 (By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of  
7 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being  
8 sections 333.22215, 24.207 and 24.208 of the Michigan Compiled Laws.)  
9

10 **Section 1. Applicability**

11  
12 Sec. 1. (1) These standards are requirements for approval of the initiation, replacement, 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.  
18

19 **Section 2. Definitions**

20  
21 Sec. 2. (1) For purposes of these standards:

22 (a) "Adult cardiac catheterization service" means providing cardiac catheterization services on an  
23 organized, regular basis to patients age 18 and above, and for electrophysiology procedures to patients  
24 age 15 and older.

25 (b) "APPLICANT" MEANS ONE OF THE FOLLOWING TYPES OF FACILITIES:

26 (i) AMBULATORY SURGICAL CENTER (ASC) WHICH IS DEFINED AS ANY DISTINCT ENTITY  
27 CERTIFIED BY MEDICARE AS AN ASC UNDER THE PROVISIONS OF TITLE 42, PART 416 THAT  
28 OPERATES EXCLUSIVELY FOR THE PURPOSE OF PROVIDING SURGICAL SERVICES TO  
29 PATIENTS NOT REQUIRING HOSPITALIZATION.

30 (ii) FREESTANDING SURGICAL OUTPATIENT FACILITY (FSOF) WHICH IS DEFINED AS A  
31 HEALTH FACILITY LICENSED UNDER PART 208 OF THE CODE. IT DOES NOT INCLUDE A  
32 SURGICAL OUTPATIENT FACILITY OWNED AND OPERATED AS A PART OF A LICENSED  
33 HOSPITAL SITE. A FREESTANDING SURGICAL OUTPATIENT FACILITY IS A HEALTH FACILITY  
34 FOR PURPOSES OF PART 222 OF THE CODE.

35 (iii) "Hospital" means WHICH IS DEFINED AS a health facility licensed under Part 215 of the Code.

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 and digital  
38 subtraction units to assist in performing diagnostic or therapeutic cardiac catheterizations or  
39 electrophysiology studies.

40 (c) "Cardiac catheterization procedure" means any cardiac procedure, including diagnostic,  
41 therapeutic, and electrophysiology studies, performed on a patient during a single session in a laboratory.  
42 Cardiac catheterization is a medical diagnostic or therapeutic procedure during which a catheter is  
43 inserted into a vein or artery in a patient; subsequently the free end of the catheter is manipulated by a  
44 physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays  
45 and an electronic image intensifier are used as aides in placing the catheter tip in the desired position.  
46 When the catheter is in place, the physician is able to perform various diagnostic studies and/or  
47 therapeutic procedures in the heart. This term does not include "float catheters" that are performed at the  
48 bedside or in settings outside the laboratory or the implantation of cardiac permanent pacemakers and  
49 implantable cardioverter defibrillators (ICD) devices that are performed in an interventional radiology  
50 laboratory or operating room in a licensed hospital and has diagnostic cardiac catheterization con  
51 approval.

52 (d) "Cardiac catheterization service" means the provision of one or more of the following types of  
53 procedures: adult diagnostic cardiac catheterizations; adult therapeutic cardiac catheterizations; and  
54 pediatric/congenital cardiac catheterizations.

55 (e) "Cardiac catheterization session" means a continuous time period during which a patient may  
56 undergo one or more diagnostic or therapeutic cardiac or peripheral procedures in a cardiac  
57 catheterization laboratory. The term session applies to both adult and pediatric/congenital  
58 catheterizations.

59 (f) "CARDIAC IMPLANTABLE ELECTRONIC DEVICE (CIED) PROCEDURE" MEANS  
60 IMPLANTATION OF TRANSVENOUS SINGLE AND DUAL CHAMBER PACEMAKER, TRANSVENOUS  
61 SINGLE AND DUAL CHAMBER IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICDS), AND ALL  
62 GENERATOR CHANGES.

63 (g) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to  
64 Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

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

67 (hi) "Complex therapeutic session" means a continuous time period during which a patient undergoes  
68 one or more of the following procedures:

- 69 (i) PCI for chronic total occlusion
- 70 (ii) TAVR, mitral/pulmonary/tricuspid valve repair or replacement, paravalvular leak closure
- 71 (iii) ablation for atrial fibrillation (AF) or ventricular tachycardia (VT), pacemaker or ICD lead  
72 extraction

73 (ij) "Department" means the Michigan Department of Health and Human Services (MDHHS).

74 (jk) "Diagnostic cardiac catheterization procedure" includes right heart catheterization, left heart  
75 catheterization, coronary angiography, coronary artery bypass graft angiography, intracoronary  
76 administration of drugs, fractional flow reserve (FFR), intra-coronary imaging such as intravascular  
77 ultrasound (IVUS), optical coherence tomography (OCT), or near-infrared spectroscopy (NIRS) when  
78 performed without a therapeutic procedure, cardiac biopsy, intra-cardiac echocardiography, and  
79 electrophysiology study.

80 (kl) "Diagnostic cardiac catheterization service" means providing diagnostic cardiac catheterization  
81 procedures on an organized, regular basis in a laboratory to diagnose anatomical and/or physiological  
82 problems in the heart. A hospital that provides diagnostic cardiac catheterization services may also  
83 perform permanent pacemaker and ICD implantation (therapeutic procedures).

84 (lm) "Diagnostic cardiac catheterization session" means a continuous time period during which a  
85 patient may undergo one or more diagnostic cardiac catheterization procedures.

86 (mn) "Diagnostic peripheral procedure" includes angiography or hemodynamic measurements in the  
87 arterial or venous circulation (excluding the heart).

88 (no) "Diagnostic peripheral session" means a continuous time period during which a patient may  
89 undergo one or more diagnostic peripheral procedures in a cardiac catheterization laboratory.

90 (op) "Elective percutaneous coronary intervention (PCI)" means a PCI procedure performed on a non-  
91 emergent basis.

92 (pq) "Elective PCI services without on-site open heart surgery (OHS)" means performing PCI on an  
93 organized, regular basis in a hospital having a diagnostic cardiac catheterization service and a primary  
94 PCI service but not having OHS on-site and adhering to patient selection as outlined in the  
95 SCAI/ACC/AHA Expert Consensus Document: 2014 Update on PCI Without On-Site Surgical Backup  
96 and published in Circulation 2014, 129:2610-2626 and its update or further guideline changes. A hospital  
97 that provides elective PCI without on-site OHS may also perform right-sided cardiac ablation procedures  
98 including right atrial flutter, AV reentry, AV node reentry, right atrial tachycardia, and AV node ablation.

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

102 (rs) "EXCESS PROCEDURE EQUIVALENTS" MEANS THE NUMBER OF PROCEDURE  
103 EQUIVALENTS PERFORMED BY AN EXISTING CARDIAC CATHETERIZATION SERVICE IN EXCESS  
104 OF 1200 PER CARDIAC CATHETERIZATION LABORATORY AND 300 PCI SESSIONS (810  
105 PROCEDURE EQUIVALENTS) PER SERVICE. THE NUMBER OF CARDIAC CATHETERIZATION  
106 LABORATORIES USED TO COMPUTE EXCESS PROCEDURE EQUIVALENTS SHALL INCLUDE  
107 BOTH EXISTING AND APPROVED BUT NOT YET OPERATIONAL CARDIAC CATHETERIZATION  
108 LABORATORIES. IN THE CASE OF A CARDIAC CATHETERIZATION SERVICE THAT OPERATES

109 OR HAS A VALID CON TO OPERATE MORE THAN ONE LABORATORY AT THE SAME SITE, THE  
110 TERM MEANS NUMBER OF PROCEDURE EQUIVALENTS IN EXCESS OF 1200 MULTIPLIED BY THE  
111 NUMBER OF CARDIAC CATHETERIZATION LABORATORIES AT THE SAME SITE. FOR EXAMPLE,  
112 IF A CARDIAC CATHETERIZATION SERVICE OPERATES, OR HAS A VALID CON TO OPERATE, 2  
113 CARDIAC CATHETERIZATION LABORATORIES AT THE SAME SITE, THE EXCESS PROCEDURE  
114 EQUIVALENTS IS THE NUMBER THAT IS IN EXCESS OF 2400 PROCEDURE EQUIVALENTS AND IN  
115 EXCESS OF 300 PCI SESSIONS (810 PROCEDURE EQUIVALENTS).

116 "Hospital" means a health facility licensed under Part 215 of the Code.

117 (st) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C. 1396 to  
118 1396g and 1396i to 1396u.

119 (tu) "Pediatric/congenital cardiac catheterization service" means providing cardiac and  
120 electrophysiology catheterization services on an organized, regular basis to infants and children ages 18  
121 and below and patients born with congenital heart disease.

122 (uv) "Percutaneous coronary intervention" (PCI) means a therapeutic cardiac catheterization  
123 procedure to resolve anatomic and/or physiologic problems in the coronary arteries of the heart. A PCI  
124 session may include several procedures including balloon angioplasty, atherectomy, laser, stent  
125 implantation and thrombectomy. The term does not include the intracoronary administration of drugs,  
126 FFR or IVUS where these are the only procedures performed.

127 (vw) "Peripheral catheterization session" means a continuous time period during which a patient may  
128 undergo one or more diagnostic or therapeutic procedures in the arterial or venous circulation (excluding  
129 the heart) when performed in a cardiac catheterization laboratory.

130 (wx) "Primary percutaneous coronary intervention (PCI)" means a PCI performed on an emergent  
131 basis on a patient with ST-Segment elevation, new left bundle branch block, ECG evidence of true  
132 posterior MI, or cardiogenic shock.

133 (xy) "Primary PCI service without on-site OHS" means performing primary PCI on an emergent basis  
134 in a hospital having a diagnostic cardiac catheterization service. A hospital that provides primary PCI  
135 without on-site OHS may also perform right-sided cardiac ablation procedures including right atrial flutter,  
136 AV reentry, AV node reentry, right atrial tachycardia, and AV node ablation.

137 (yz) "Procedure equivalent" means a unit of measure that reflects the relative average length of time  
138 one patient spends in one session in a cardiac catheterization laboratory based on the type of procedures  
139 being performed. If a diagnostic and therapeutic procedure is performed in the same session, the higher  
140 procedure equivalent weighting will be used to evaluate utilization.

141 (zaa) "Structural heart procedure" means a therapeutic cardiac catheterization procedure to resolve  
142 anatomic and/or physiologic problems of the heart valves or chambers. Procedures include: balloon  
143 valvuloplasty, balloon atrial septostomy, transcatheter valve repair, transcatheter valve implantation,  
144 paravalvular leak closure, left atrial appendage occlusion, PFO/ASD/VSD/PDA closure, alcohol ablation  
145 of cardiac tissue, embolization of coronary fistulae and abnormal vascular connections in the heart.

146 (aabb) "Therapeutic cardiac catheterization service" means providing therapeutic cardiac  
147 catheterizations on an organized, regular basis in a laboratory to treat and resolve anatomical and/or  
148 physiological problems in the heart.

149 (bbcc) "Therapeutic cardiac catheterization session" may include: PCI (elective, emergent),  
150 pericardiocentesis, permanent pacemaker implantation, ICD implantation (endovascular or  
151 subcutaneous), pacemaker or ICD generator change, pacemaker or ICD lead revision, cardiac ablation,  
152 and/or structural heart procedure. This also includes implantation of a circulatory support device such as  
153 IABP, Impella, ECMO or TandemHeart where this is the only therapeutic procedure. when PCI is  
154 performed in more than one coronary artery during the same setting, this is counted as one session.

155 (eedd) "Therapeutic peripheral procedure" means a therapeutic catheterization procedure to resolve  
156 anatomic and/or physiologic problems in the arterial or venous circulation (excluding the heart).  
157 Procedures may include percutaneous transluminal angioplasty (PTA), atherectomy, drug eluting balloon,  
158 laser, stent implantation, IVC filter implantation or retrieval, catheter-directed ultrasound/thrombolysis, and  
159 thrombectomy.

160 (ddee) "Therapeutic peripheral session" means a continuous time period during which a patient may  
161 undergo one or more therapeutic peripheral procedures in a cardiac catheterization laboratory.

(eff) "Therapeutic pediatric/congenital cardiac catheterization session" may include: structural heart procedure (as listed above), pulmonary artery angioplasty/stent implantation, pulmonary valve perforation, angioplasty/stent implantation for aortic coarctation, cardiac ablation, pacemaker/ICD implantation, and PCI.

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

### Section 3. Requirements to initiate cardiac catheterization services

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

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

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

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

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

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

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

(b) An applicant hospital 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 hospital has applied to provide adult OHS services at the hospital. The applicant hospital must be approved for an adult OHS service in order to be approved for an adult therapeutic cardiac catheterization service.

(d) The applicant hospital 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 hospital proposing to initiate a pediatric/congenital cardiac catheterization service shall demonstrate the following:

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

(b) The applicant hospital has standardized biplane equipment as defined in the most current American Academy of Pediatrics (AAP) and American College of Cardiology Foundation (ACCF)/Society for Cardiovascular Angiography and Interventions (SCAI) guidelines for pediatric cardiovascular centers.

215 (c) The applicant hospital has on-site pediatric and neonatal ICU as outlined in the most current AAP  
216 and ACCF/SCAI guidelines above.

217 (d) The applicant hospital has applied to provide pediatric OHS services at the hospital. The  
218 applicant hospital must be approved for a pediatric OHS service in order to be approved for  
219 pediatric/congenital cardiac catheterization services.

220 (e) The applicant hospital has on-site pediatric extracorporeal membrane oxygenation (ECMO)  
221 capability as outlined in the most current ACCF/SCAI guidelines.

222 (f) A pediatric/congenital cardiac catheterization service shall have a quality assurance plan as  
223 outlined in the most current ACCF/SCAI guidelines.

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

227  
228 **Section 4. Requirements to initiate primary or elective PCI Services without on-site OHS services**  
229

230 **Sec. 4. An applicant hospital proposing to initiate primary or elective PCI services without on-site OHS**  
231 **services shall demonstrate the following, AS APPLICABLE:**  
232

233 **(1) AN APPLICANT HOSPITAL PROPOSING TO INITIATE PRIMARY OR ELECTIVE PCI**  
234 **WITHOUT ON-SITE OHS SERVICES SHALL DEMONSTRATE THE FOLLOWING:**

235 **(a) The applicant hospital operates an adult diagnostic cardiac catheterization service THAT IS IN**  
236 **FULL COMPLIANCE WITH SECTION 10(4)(a) OF THESE STANDARDS that has performed a minimum**  
237 **of 500 procedure equivalents that includes 400 procedure equivalents in the category of cardiac**  
238 **catheterization procedures during the most recent 12 months preceding the date the application was**  
239 **submitted to the Department.**

240  
241 **(2b) The applicant hospital has at least two interventional cardiologists to perform the PCI procedures**  
242 **and each cardiologist has performed at least 50 PCI sessions annually as the primary operator during the**  
243 **most recent 24-month period preceding the date the application was submitted to the Department.**

244  
245 **(3c) The nursing and technical catheterization laboratory staff are experienced in handling acutely ill**  
246 **patients and comfortable with interventional equipment; have acquired experience in dedicated**  
247 **interventional laboratories at an OHS hospital; and participate in an un-interrupted 24-hour, 365-day call**  
248 **schedule. Competency shall be documented annually.**

249  
250 **(4d) The laboratory or laboratories are equipped with optimal imaging systems, resuscitative**  
251 **equipment, and intra-aortic balloon pump (IABP) support, and stocked with a broad array of interventional**  
252 **equipment.**

253  
254 **(5e) The cardiac care unit nurses are adept in hemodynamic monitoring and IABP management.**  
255 **Competency shall be documented annually.**

256  
257 **(6f) A written agreement with an OHS hospital that includes all of the following:**

258 **(ai) Involvement in credentialing criteria and recommendations for physicians approved to perform**  
259 **PCI procedures.**

260 **(bii) Provision for ongoing cross-training for professional and technical staff involved in the provision of**  
261 **PCI to ensure familiarity with interventional equipment. Competency shall be documented annually.**

262 **(ciii) Provision for ongoing cross training for emergency department, catheterization laboratory, and**  
263 **critical care unit staff to ensure experience in handling the high acuity status of PCI patient candidates.**  
264 **Competency shall be documented annually.**

265 **(div) Regularly held joint cardiology/cardiac surgery conferences to include review of all PCI cases.**

266 **(ev) Development and ongoing review of patient selection criteria for PCI patients and implementation**  
267 **of those criteria.**

268 **(fvi) A mechanism to provide for appropriate patient transfers between facilities and an agreed plan for**  
269 **prompt care.**

270 (gvii) Written protocols, signed by the applicant hospital and the OHS hospital, for the immediate  
271 transfer within 60 minutes travel time from the cardiac catheterization laboratory to evaluation on site in  
272 the OHS hospital, of patients requiring surgical evaluation and/or intervention 365 days a year. If the  
273 applicant hospital meets the requirements of subsection (13)(c), then the OHS hospital can be more than  
274 60 minutes travel time from the proposed site. The protocols shall be reviewed and tested on a quarterly  
275 basis.

276 (hvi) Consultation on facilities, equipment, staffing, ancillary services, and policies and procedures for  
277 the provision of interventional procedures.

278  
279 (7g) A written protocol must be established and maintained for case selection for the performance of  
280 PCI.

281  
282 (8h) A system to ensure prompt and efficient identification of potential primary PCI patients and rapid  
283 transfer from the emergency department to the cardiac catheterization laboratory must be developed and  
284 maintained so that door-to-balloon targets are met.

285  
286 (9i) At least two physicians credentialed to perform PCI must commit to functioning as a coordinated  
287 group willing and able to provide this service at the hospital on a 24-hour per day, 365 day per year call  
288 schedule, with ability to be on-site and available to operate within 30 minutes of identifying the need for  
289 primary PCI. These physicians must be credentialed at the facility and actively collaborate with  
290 administrative and clinical staff in establishing and implementing protocols, call schedules, and quality  
291 assurance procedures pertaining to PCI designed to meet the requirements for this certification and in  
292 keeping with the current guidelines for the provision of PCI without on-site OHS services promulgated by  
293 the American College of Cardiology and American Heart Association.

294  
295 (10j) The applicant hospital shall participate in a data registry administered by the Department or its  
296 designee as a means to measure quality and risk adjusted outcomes within PCI services without on-site  
297 OHS services, and the applicant hospital shall identify a physician point of contact for the data registry.

298  
299 (11k) Cath lab facility requirements and collaborative cardiologists-heart surgeon relationship  
300 requirements shall conform to all SCAI/ACC Guidelines for PCI Services Without On-Site OHS including  
301 the SCAI/ACC/AHA Expert Consensus Document. The applicant hospital shall be liable for the cost of  
302 demonstrating compliance with these criteria in their application.

303  
304 (12l) The applicant hospital shall project the following based on data from the most recent 12-month  
305 period preceding the date the application was submitted to the Department, as applicable.

306 (a) If the applicant hospital is applying for a primary PCI service without open heart surgery, the  
307 applicant hospital shall project a minimum of 36 primary PCI procedures per year.

308 (b) If the applicant hospital is applying for an elective PCI service without on-site OHS, the applicant  
309 hospital shall project a minimum of 200 PCI procedures per year.

310  
311 (13m) If the applicant hospital is applying for an elective PCI service without on-site OHS, the applicant  
312 hospital also shall demonstrate the following:

313 (a) The applicant hospital operated a primary PCI service for at least one year prior to the date of  
314 application.

315 (b) The applicant hospital submitted data to a data registry administered by the Department or its  
316 designee and been found to have acceptable performance as compared to the registry benchmarks for  
317 the most recent 12 months prior to the date of application.

318 (c) If the applicant hospital was not approved as a primary PCI service prior to September 14, 2015,  
319 then, in addition, the applicant hospital shall demonstrate that there is no PCI or OHS service within 60  
320 radius miles or 60 minutes travel time from the proposed site.

321  
322 (14n) If the applicant hospital is currently providing OHS services and therapeutic cardiac  
323 catheterization services and is proposing to discontinue OHS services and therapeutic cardiac  
324 catheterization services, then the applicant hospital shall apply to initiate primary or elective PCI services  
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For CON Commission Proposed Action on March 18, 2021

without on-site OHS using this section. The applicant hospital shall demonstrate all of the requirements in this section except for subsection (13) and is subject to all requirements in Section 10.

(2) AN APPLICANT FSOE PROPOSING TO INITIATE DIAGNOSTIC CARDIAC CATHETERIZATION AND ELECTIVE PCI SHALL DEMONSTRATE THE FOLLOWING:

(a) THE APPLICANT HAS IDENTIFIED AT LEAST ONE INTERVENTIONAL CARDIOLOGIST TO PERFORM THE DIAGNOSTIC CARDIAC CATHETERIZATIONS AND PCI PROCEDURES WHO HAS PERFORMED AT LEAST 50 PCI SESSIONS ANNUALLY AS THE PRIMARY OPERATOR DURING THE MOST RECENT 24-MONTH PERIOD PRECEDING THE DATE THIS APPLICATION WAS SUBMITTED TO THE DEPARTMENT. THE INTERVENTIONAL CARDIOLOGIST SHALL HAVE COMPLETED AN INTERVENTIONAL CARDIOLOGY FELLOWSHIP TRAINING PROGRAM, BE BOARD CERTIFIED IN INTERVENTIONAL CARDIOLOGY, HAVE PERFORMED A TOTAL OF AT LEAST 250 PCI SESSIONS AS THE PRIMARY OPERATOR, AND HAVE A MINIMUM OF 2 YEARS EXPERIENCE AT AN ATTENDING LEVEL.

(b) THE APPLICANT HAS IDENTIFIED NURSING AND TECHNICAL CATHETERIZATION LABORATORY STAFF THAT ARE EXPERIENCED IN HANDLING ACUTELY ILL PATIENTS AND COMFORTABLE WITH INTERVENTIONAL EQUIPMENT AND HAVE ACQUIRED EXPERIENCE IN DEDICATED INTERVENTIONAL LABORATORIES AT AN OHS HOSPITAL. COMPETENCY SHALL BE DOCUMENTED ANNUALLY.

(c) THE APPLICANT HAS IDENTIFIED CARDIAC CARE UNIT NURSES WHO ARE ADEPT IN HEMODYNAMIC MONITORING AND IABP MANAGEMENT. COMPETENCY SHALL BE DOCUMENTED ANNUALLY.

(d) THE LABORATORY OR LABORATORIES WILL BE EQUIPPED WITH OPTIMAL IMAGING SYSTEMS, RESUSCITATIVE EQUIPMENT, AND INTRA-AORTIC BALLOON PUMP (IABP) SUPPORT, AND STOCKED WITH A BROAD ARRAY OF INTERVENTIONAL EQUIPMENT. THE LABORATORIES WILL BE EQUIPPED WITH SYSTEMS FOR ASSESSING HEMODYNAMIC SIGNIFICANCE OF CORONARY LESIONS (I.E., FFR, IFR, OR OTHER) AND INTRACORONARY IMAGING TECHNOLOGY (I.E., IVUS OR OCT) FOR ENSURING PCI OPTIMIZATION.

(e) A WRITTEN AGREEMENT WITH AN OHS HOSPITAL THAT IS WITHIN 30 MINUTES TRAVEL TIME THAT INCLUDES ALL OF THE FOLLOWING:

(i) INVOLVEMENT IN CREDENTIALING CRITERIA AND RECOMMENDATIONS FOR PHYSICIANS APPROVED TO PERFORM PCI PROCEDURES.

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

(iii) REGULARLY HELD JOINT CARDIOLOGY/CATHETERIZATION LABORATORY CONFERENCES TO INCLUDE REVIEW OF PCI CASES.

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

(v) A MECHANISM TO PROVIDE FOR APPROPRIATE PATIENT TRANSFERS BETWEEN FACILITIES AND AN AGREED PLAN FOR PROMPT CARE.

(vi) WRITTEN PROTOCOLS, SIGNED BY THE APPLICANT AND THE OHS HOSPITAL, FOR THE IMMEDIATE TRANSFER FROM THE CARDIAC CATHETERIZATION LABORATORY TO EVALUATION ON SITE IN THE OHS HOSPITAL, OF PATIENTS REQUIRING SURGICAL EVALUATION AND/OR INTERVENTION 365 DAYS A YEAR. THE PROTOCOLS SHALL BE REVIEWED AND TESTED ON A QUARTERLY BASIS.

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

(f) A WRITTEN PROTOCOL SHALL BE ESTABLISHED AND MAINTAINED FOR CASE SELECTION FOR THE PERFORMANCE OF PCI CONSISTENT WITH THE CASE SELECTION CRITERIA DOCUMENTED IN THE SCAI POSITION STATEMENT ON THE PERFORMANCE OF PERCUTANEOUS CORONARY INTERVENTION IN AMBULATORY SURGICAL CENTERS (BOX ET AL. CATHETER CARDIOVASC INTERV. 2020;1-9).

(g) THE APPLICANT SHALL PARTICIPATE IN A DATA REGISTRY ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE AS A MEANS TO MEASURE QUALITY AND RISK ADJUSTED

380 OUTCOMES WITHIN PCI SERVICES WITHOUT ON-SITE OHS SERVICES, AND THE APPLICANT  
381 SHALL IDENTIFY A PHYSICIAN POINT OF CONTACT FOR THE DATA REGISTRY.  
382 (h) CATH LAB FACILITY REQUIREMENTS SHALL CONFORM TO THE POSITION STATEMENT  
383 ON THE PERFORMANCE OF PERCUTANEOUS CORONARY INTERVENTION IN AMBULATORY  
384 SURGICAL CENTERS (BOX ET AL. CATHETER CARDIOVASC INTERV. 2020;1-9). THE APPLICANT  
385 SHALL BE LIABLE FOR THE COST OF DEMONSTRATING COMPLIANCE WITH THE PRINCIPLES  
386 DOCUMENTED IN THIS POSITION STATEMENT IN THEIR APPLICATION.  
387 (i) THE APPLICANT SHALL PROJECT THE FOLLOWING BASED ON VERIFIABLE DATA FROM  
388 THE MOST RECENT 12-MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS  
389 SUBMITTED TO THE DEPARTMENT, AS APPLICABLE:  
390 (i) IF THE APPLICANT IS PROPOSING A SINGLE LAB, AT LEAST 750 PROCEDURE  
391 EQUIVALENTS TOTAL, INCLUDING AT LEAST 540 PROCEDURES EQUIVALENTS FROM ELECTIVE  
392 PCIs (200 PCI SESSIONS).  
393 (ii) IF THE APPLICANT IS PROPOSING MULTIPLE LABS, AT LEAST 1,000 PROCEDURE  
394 EQUIVALENTS PER LAB, INCLUDING AT LEAST 540 PROCEDURE EQUIVALENTS TOTAL FROM  
395 ELECTIVE PCIs (200 PCI SESSIONS).  
396 (j) THE APPLICANT SHALL HAVE OR OBTAIN WITHIN 12 MONTHS OF BEGINNING  
397 OPERATIONS AMBULATORY SURGERY CENTER (ASC) CERTIFICATION OR HOSPITAL  
398 OUTPATIENT DEPARTMENT (HOPD) STATUS FROM THE CENTERS FOR MEDICARE AND  
399 MEDICAID SERVICES (CMS). AN APPLICANT THAT DOES NOT CURRENTLY HOLD THE  
400 CERTIFICATION SHALL ATTEST THAT THE CERTIFICATION WILL BE OBTAINED WITHIN 12  
401 MONTHS OF BEGINNING OPERATIONS.  
402  
403 (3) AN APPLICANT FSOE PROPOSING TO PERFORM CIED PROCEDURES SHALL  
404 DEMONSTRATE ALL OF THE FOLLOWING:  
405 (a) THE FSOE IS APPROVED TO PERFORM DIAGNOSTIC CARDIAC CATHETERIZATION AND  
406 ELECTIVE PCI OR IS APPLYING TO PROVIDE BOTH OF THOSE SERVICES AS A PART OF THIS  
407 APPLICATION.  
408 (b) THE APPLICANT IS LOCATED LESS THAN 30 MINUTES TRAVEL TIME FROM A HOSPITAL  
409 WITH OHS SERVICE.  
410 (c) THE APPLICANT HAS OR WILL HAVE CARDIAC CATHETERIZATION LAB CAPABILITIES  
411 INCLUDING PERICARDIOCENTESIS EQUIPMENT ON SITE.  
412 (d) THE APPLICANT HAS IDENTIFIED AT LEAST ONE PHYSICIAN WHO MEETS ALL OF THE  
413 FOLLOWING:  
414 (i) IS CARDIOLOGY BOARD CERTIFIED FOR PERMANENT PACEMAKER IMPLANTS;  
415 (ii) IS EP BOARD CERTIFIED FOR ICD IMPLANTS;  
416 (iii) HAS ACTIVE PRIVILEGES FOR IMPLANTING DEVICES, MODERATE SEDATION, AND  
417 ADMITTING AT THE TERTIARY CARE HOSPITAL IDENTIFIED IN (3)(b);  
418 (iv) HAS AT LEAST 2 YEARS OF POST-FELLOWSHIP EXPERIENCE AS AN IMPLANTER; AND  
419 (v) HAS IMPLANTED AT LEAST 75 DEVICES AS THE PRIMARY OPERATOR IN THE PREVIOUS  
420 2 YEARS POST FELLOWSHIP TRAINING.  
421 (e) THE APPLICANT SHALL PROJECT AT LEAST 100 CIED PROCEDURES.  
422 (f) THE APPLICANT SHALL HAVE OR OBTAIN WITHIN 12 MONTHS OF BEGINNING  
423 OPERATIONS AMBULATORY SURGERY CENTER (ASC) CERTIFICATION OR HOSPITAL  
424 OUTPATIENT DEPARTMENT (HOPD) STATUS FROM THE CENTERS FOR MEDICARE AND  
425 MEDICAID SERVICES (CMS). AN APPLICANT THAT DOES NOT CURRENTLY HOLD THE  
426 CERTIFICATION SHALL ATTEST THAT THE CERTIFICATION WILL BE OBTAINED WITHIN 12  
427 MONTHS OF BEGINNING OPERATIONS.  
428

## 429 **Section 5. Requirements to replace an existing cardiac catheterization service or laboratory**

430  
431 Sec. 5. Replacing a cardiac catheterization laboratory means a change in the angiography x-ray  
432 equipment or a relocation of the service to a new site. The term does not include a change in any of the  
433 other equipment or software used in the laboratory. An applicant hospital proposing to replace a cardiac  
434 catheterization laboratory or service shall demonstrate the following as applicable to the proposed project:  
435

436 (1) An applicant hospital proposing to replace cardiac catheterization laboratory equipment shall  
437 demonstrate the following:

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

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

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

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

446

447 (2) An applicant hospital proposing to replace a cardiac catheterization service to a new site shall  
448 demonstrate the following:

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

450 (b) The applicant hospital has performed the following during the most recent 12-month period  
451 preceding the date the application was submitted to the Department as applicable to the proposed  
452 project:

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

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

457 (iii) A minimum of 600 procedure equivalents in the category of pediatric/congenital cardiac  
458 catheterization procedures.

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

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

463 (vi) A minimum of 1,000 procedure equivalents per cardiac catheterization laboratory for a hospital  
464 with two or more laboratories.

465 (c) The existing cardiac catheterization service has been in operation for at least 36 months as of the  
466 date the application has been submitted to the Department.

467

468 (3) An applicant hospital proposing to replace a cardiac catheterization service to a new site  
469 simultaneously with an open heart surgery service shall demonstrate the following:

470 (a) The existing cardiac catheterization service to be replaced has been in operation for at least 36  
471 months as of the date an application is submitted to the Department.

472 (b) The proposed new site is a hospital that is owned by, is under common control of, or has a  
473 common parent as the applicant hospital.

474 (c) The proposed new site is the same site where the existing OHS service is to be located which is  
475 within the same planning area as the OHS service and within 5 miles of the existing OHS and cardiac  
476 catheterization service if located in a metropolitan statistical area county or within 10 miles of the existing  
477 OHS and cardiac catheterization service if located in a rural or micropolitan statistical area county.

478 (d) The existing cardiac catheterization service to be relocated performed at least the applicable  
479 minimum number of cardiac catheterization cases set forth in Section 10 as of the date an application is  
480 deemed submitted by the Department.

481

## 482 **Section 6. Requirements to expand a cardiac catheterization service**

483

484 **Sec. 6. An applicant hospital proposing to add a laboratory to an existing cardiac catheterization**  
485 **service shall demonstrate the following:**

486

487 (1) The applicant hospital has performed the following during the most recent 12-month period  
488 preceding the date the application was submitted to the Department as applicable to the proposed  
489 project:

- 490 (a) A minimum of 300 procedure equivalents in the category of adult diagnostic cardiac  
491 catheterization procedures.  
492 (b) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac  
493 catheterization procedures.  
494 (c) A minimum of 600 procedure equivalents in the category of pediatric/congenital cardiac  
495 catheterization procedures.

496 **(d) A MINIMUM OF 540 PROCEDURE EQUIVALENTS IN THE CATEGORY OF PCI**  
497 **PROCEDURES.**

- 498 (2) The applicant ~~hospital~~ has performed a minimum of 1,400 procedure equivalents per existing and  
499 approved laboratories during the most recent 12-month period preceding the date the application was  
500 submitted to the Department.

501  
502 **Section 7. Requirements to acquire a cardiac catheterization service**  
503

504 Sec. 7. Acquiring a cardiac catheterization service and its laboratories means obtaining possession  
505 and control by contract, ownership, lease or other comparable arrangement or renewal of a lease for  
506 existing angiography x-ray equipment. An applicant ~~hospital~~ proposing to acquire a cardiac  
507 catheterization service or renew a lease for equipment shall demonstrate the following as applicable to  
508 the proposed project:

- 509  
510 (1) An applicant ~~hospital~~ proposing to acquire a cardiac catheterization service shall demonstrate the  
511 following:

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

513 (b) An application for the first acquisition of an existing cardiac catheterization service after February  
514 27, 2012 shall not be required to be in compliance with the applicable volume requirements in Section 10.  
515 The cardiac catheterization service shall be operating at the applicable volumes set forth in the project  
516 delivery requirements in the second 12 months of operation of the service by the applicant ~~hospital~~ and  
517 annually thereafter.

518 (c) For any application proposing to acquire an existing cardiac catheterization service, except the  
519 first application approved pursuant to subsection (b), an applicant ~~hospital~~ shall be required to document  
520 that the cardiac catheterization service to be acquired is operating in compliance with the volume  
521 requirements set forth in section 10 of these standards applicable to an existing cardiac catheterization  
522 service on the date the application is submitted to the Department.

- 523  
524 (2) An applicant ~~hospital~~ proposing to renew a lease for existing angiography x-ray equipment shall  
525 demonstrate the renewal of the lease is more cost effective than replacing the equipment.

526  
527 **Section 8. Requirements for a hybrid operating room/cardiac catheterization laboratory (OR/CCL)**  
528

529 Sec. 8. A hybrid OR/CCL means an operating room located on a sterile corridor and equipped with an  
530 angiography system permitting minimally invasive procedures of the heart and blood vessels with full  
531 anesthesia capabilities. An applicant hospital proposing to add one or more hybrid OR/CCLs at an existing  
532 cardiac catheterization service shall demonstrate each of the following:

533  
534 (1) The applicant hospital operates an OHS service which is in full compliance with the current CON  
535 Review Standards for OHS Services.

536  
537 (2) The applicant operates a therapeutic cardiac catheterization program which is in full compliance  
538 with Sections 3(2) and 10(4) of these standards.

539  
540 (3) If the hybrid OR/CCL(s) represents an increase in the number of cardiac catheterization laboratories  
541 at the facility, the applicant hospital is in compliance with Section 6 of these standards.  
542

543 (4) If the hybrid OR/CCL(s) represents conversion of an existing cardiac catheterization laboratory(s),  
544 the applicant hospital is in compliance with the provisions of Section 5, if applicable.

545  
546 (5) The applicant hospital meets the applicable requirements of the CON Review Standards for  
547 Surgical Services.

548  
549 (6) Each case performed in a hybrid OR/CCL shall be included either in the surgical volume or the  
550 therapeutic cardiac catheterization volume of the facility. No case shall be counted more than once.

551  
552 (7) For each hybrid OR/CCL, a facility shall have 0.5 excluded from its inventory of cardiac  
553 catheterization laboratories for the purposes of computing the procedure equivalents per room. A facility  
554 will not be limited to the number of hybrid ORCCLs within a single licensed facility.

### 555 556 **Section 9. Requirement for Medicaid participation**

557  
558 **Sec. 9.** An applicant ~~hospital~~ shall provide verification of Medicaid participation at the time the  
559 application is submitted to the Department. An applicant ~~hospital~~ that is initiating a new service or is a  
560 new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be  
561 provided to the Department within six (6) months from the offering of services if a CON is approved.

### 562 563 564 **Section 10. Project delivery requirements and terms of approval for all applicants**

565  
566 **Sec. 10.** An applicant ~~hospital~~ shall agree that, if approved, the cardiac catheterization service and all  
567 existing and approved laboratories shall be delivered in compliance with the following terms of approval:

568  
569 (1) Compliance with these standards.

570  
571 (2) Compliance with the following quality assurance standards:

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

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

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

580 (d) Each physician credentialed by a ~~hospital~~ **FACILITY** to perform diagnostic left-heart  
581 catheterization and/or coronary angiography must perform, as the primary operator, an average of at  
582 least 50 diagnostic cardiac catheterization sessions involving a left-heart catheterization or coronary  
583 angiography per year averaged over the most recent 2 years starting in the second 12 months after being  
584 credentialed. This two-year average will be evaluated on a rolling basis annually thereafter. The annual  
585 case load for a physician means a cardiac catheterization session in which that physician performed, as  
586 the primary operator, at least one left-heart catheterization or coronary angiography, in any combination  
587 ~~of hospitals~~ **FACILITIES**. Physicians falling below this volume requirement must be placed on a focused  
588 professional practice evaluation (FPPE) plan, which must include an independent review of all diagnostic  
589 cardiac catheterization sessions by an appropriate designee, to ensure quality outcomes are maintained.  
590 In the event a physician does not perform cardiac catheterization procedures on a temporary or  
591 permanent basis for a period of 3 months or more, the physician diagnostic procedure volume will be  
592 annualized on the 24-month period preceding the absence. When a diagnostic cardiac catheterization  
593 session and ad hoc therapeutic cardiac catheterization session are performed together, diagnostic and  
594 therapeutic sessions are counted separately for the purposes of this subsection. If a physician is doing  
595 right heart only procedures, then they are not required to meet this volume requirement. Physicians who

596 are credentialed by a hospital to perform adult therapeutic cardiac catheterization procedures are not  
597 required to meet the volume requirement for diagnostic cardiac catheterization sessions.

598 (e) Each physician credentialed by a hospital FACILITY to perform adult therapeutic cardiac  
599 catheterization procedures shall perform, as the primary operator, an average of at least 50 adult  
600 therapeutic cardiac catheterization sessions per year averaged over the most recent two years starting in  
601 the second 12 months after being credentialed. This two-year average will be evaluated on a rolling basis  
602 annually thereafter. The annual case load for a physician means adult therapeutic cardiac catheterization  
603 sessions performed by that physician in any combination of hospitals FACILITIES. Physicians falling  
604 below this volume requirement must be placed on a focused professional practice evaluation (FPPE)  
605 plan, which must include an independent review of all therapeutic cardiac catheterization sessions by an  
606 appropriate designee, to ensure quality outcomes are maintained. In the event a physician does not  
607 perform cardiac catheterization procedures on a temporary or permanent basis for a period of 3 months  
608 or more, the physician therapeutic procedure volume will be annualized on the 24-month period  
609 preceding the absence. When a diagnostic cardiac catheterization session and ad hoc therapeutic  
610 cardiac catheterization session are performed together, diagnostic and therapeutic sessions are counted  
611 separately for the purposes of this subsection (this includes interventional cardiologists and  
612 electrophysiologists). For interventional cardiologists, the therapeutic session volume excludes  
613 pacemaker and ICD implantation. For electrophysiologists, pacemaker and ICD implants performed in an  
614 operating room may also be counted toward the physician therapeutic volume.

615 (f) Each physician credentialed by a hospital to perform pediatric/congenital cardiac catheterizations  
616 shall perform, as the primary operator, an average of at least 50 pediatric/congenital cardiac  
617 catheterization sessions per year averaged over the most recent 2 years starting in the second 12 months  
618 after being credentialed. This two-year average will be evaluated on a rolling basis annually thereafter.  
619 The annual case load for a physician means pediatric/congenital cardiac catheterization sessions  
620 performed by that physician in any combination of hospitals. Physicians falling below this volume  
621 requirement must be placed on a focused professional practice evaluation (FPPE) plan, which must  
622 include an independent review of all cardiac catheterization sessions by an appropriate designee, to  
623 ensure quality outcomes are maintained. In the event a physician does not perform cardiac  
624 catheterization procedures on a temporary or permanent basis for a period of 3 months or more, the  
625 physician therapeutic procedure volume will be annualized on the 24-month period preceding the  
626 absence.

627 (g) EACH PHYSICIAN CREDENTIALLED BY AN FSOF TO PERFORM PCI SHALL MEET THE  
628 FOLLOWING CRITERIA:

629 (i) HAS PERFORMED AT LEAST 50 PCI SESSIONS ANNUALLY AS THE PRIMARY OPERATOR  
630 DURING THE MOST RECENT PRECEDING 24 MONTHS;

631 (ii) HAS COMPLETED AN INTERVENTIONAL CARDIOLOGY FELLOWSHIP TRAINING  
632 PROGRAM;

633 (iii) IS BOARD CERTIFIED IN INTERVENTIONAL CARDIOLOGY;

634 (iv) HAS PERFORMED A TOTAL OF AT LEAST 250 PCI SESSIONS AS THE PRIMARY  
635 OPERATOR; AND

636 (v) HAS A MINIMUM OF 2 YEARS EXPERIENCE AT AN ATTENDING LEVEL.

637 (h) EACH PHYSICIAN CREDENTIALLED BY A FSOF TO PERFORM CIED PROCEDURES SHALL  
638 MEET THE FOLLOWING CRITERIA:

639 (i) PERFORMED AT LEAST 75 DEVICE IMPLANTS AS THE PRIMARY OPERATOR IN THE  
640 PREVIOUS 24 MONTHS;

641 (ii) HAS AT LEAST 2 YEARS OF POST-FELLOWSHIP EXPERIENCE AS AN IMPLANTER;

642 (iii) IS CARDIOLOGY BOARD CERTIFIED FOR PERMANENT PACEMAKER IMPLANTS;

643 (iv) IS EP BOARD CERTIFIED FOR ICD IMPLANTS; AND

644 (v) HAS ACTIVE PRIVILEGES FOR IMPLANTING DEVICES, MODERATE SEDATION, AND  
645 ADMITTING AT THE HOSPITAL IDENTIFIED IN SECTION 4(3)(b).

646 (l) An adult diagnostic cardiac catheterization service shall have a minimum of two physicians on its  
647 active hospital staff meeting the following criteria:

648 (i) are trained consistent with the recommendations of the American College of Cardiology;

649 (ii) are credentialed by the hospital-FACILITY to perform adult diagnostic cardiac catheterizations;  
650 and

651 (iii) have performed a minimum of 100 adult diagnostic cardiac catheterization sessions in the  
652 preceding 12 months. The annual case load for a physician means a cardiac catheterization session in  
653 which that physician performed, as the primary operator, at least one diagnostic cardiac catheterization,  
654 in any combination of hospitalsFACILITIES.

655 (hj) An adult therapeutic cardiac catheterization service shall have a minimum of two physicians on its  
656 active hospital staff meeting the following criteria:

657 (i) are trained consistent with the recommendations of the American College of Cardiology;

658 (ii) are credentialed by the hospital to perform adult therapeutic cardiac catheterizations; and

659 (iii) have performed a minimum of 50 adult therapeutic cardiac catheterization sessions in the  
660 preceding 12 months. The annual case load for a physician means a cardiac catheterization session in  
661 which that physician performed, as the primary operator, at least one therapeutic cardiac catheterization,  
662 in any combination of hospitals.

663 (hk) A pediatric/congenital cardiac catheterization service shall have at least one physician on its  
664 active hospital staff meeting the following criteria:

665 (i) is board certified or board eligible in pediatric cardiology by the American Board of Pediatrics;

666 (ii) is credentialed by the hospital to perform pediatric/congenital cardiac catheterizations; and

667 (iii) has trained consistently with the recommendations of the American College of Cardiology.

668 (hl) A pediatric/congenital cardiac catheterization service shall maintain a quality assurance plan as  
669 outlined in the most current ACCF/SCAI Guidelines.

670 (km) A DIAGNOSTIC CARDIAC CATHETERIZATION AND ELECTIVE PCI PROGRAM LOCATED AT  
671 AN FSOFF SHALL OBTAIN AMBULATORY SURGERY CENTER (ASC) CERTIFICATION OR HOSPITAL  
672 OUTPATIENT DEPARTMENT (HOPD) STATUS FROM THE CENTERS FOR MEDICARE AND  
673 MEDICAID SERVICES (CMS) WITHIN 12 MONTHS OF BEGINNING OPERATIONS AND SHALL HAVE  
674 AT LEAST ONE INTERVENTIONAL CARDIOLOGIST ON ITS ACTIVE STAFF MEETING THE  
675 FOLLOWING CRITERIA:

676 (i) HAS PERFORMED AT LEAST 50 PCI SESSIONS ANNUALLY AS THE PRIMARY OPERATOR  
677 DURING THE MOST RECENT 24-MONTH PERIOD;

678 (ii) HAS COMPLETED AN INTERVENTIONAL CARDIOLOGY FELLOWSHIP TRAINING  
679 PROGRAM;

680 (iii) IS BOARD CERTIFIED IN INTERVENTIONAL CARDIOLOGY;

681 (iv) HAS PERFORMED A TOTAL OF AT LEAST 250 PCI SESSIONS AS THE PRIMARY  
682 OPERATOR; AND

683 (v) HAS A MINIMUM OF 2 YEARS EXPERIENCE AT AN ATTENDING LEVEL.

684 (n) AN FSOFF PERFORMING CIED PROCEDURES SHALL HAVE AT LEAST ONE  
685 ELECTROPHYSIOLOGIST ON ITS ACTIVE STAFF MEETING THE FOLLOWING CRITERIA:

686 (i) IS CARDIOLOGY BOARD CERTIFIED FOR PPM IMPLANTS;

687 (ii) IS EP BOARD CERTIFIED FOR ICD IMPLANTS;

688 (iii) HAS ACTIVE PRIVILEGES FOR IMPLANTING DEVICES, MODERATE SEDATION, AND  
689 ADMITTING AT THE HOSPITAL IDENTIFIED IN SECTION 4(3)(B);

690 (iv) HAS AT LEAST 2 YEARS OF POST-FELLOWSHIP EXPERIENCE AS AN IMPLANTER; AND

691 (v) HAS IMPLANTED AT LEAST 75 DEVICES AS THE PRIMARY OPERATOR IN THE PREVIOUS  
692 2 YEARS POST FELLOWSHIP TRAINING.

693 (o) A cardiac catheterization service shall be directed by an appropriately trained physician. The  
694 Department shall consider appropriate training of the director if the physician is board certified in  
695 cardiology, cardiovascular radiology or cardiology, adult or pediatric, as applicable. The director of an  
696 adult cardiac catheterization service shall have performed at least 100 catheterizations per year during  
697 each of the five preceding years. The Department may accept other evidence that the director is  
698 appropriately trained.

699 (hp) A cardiac catheterization service shall be operated consistently with the recommendations of the  
700 American College of Cardiology.

701 (mq) The applicant hospital-FACILITY providing therapeutic cardiac catheterization services, primary  
702 PCI services without on-site OHS service, or elective PCI services without on-site OHS service shall

703 participate with a data registry administered by the Department or its designee that monitors quality and  
704 risk adjusted outcomes.

705  
706 (3) Compliance with the following access to care requirements:

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

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

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

713 (d) The operation of and referral of patients to the cardiac catheterization service shall be in  
714 conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.1621; MSA 14.15  
715 (16221).

716  
717 (4) Compliance with the following monitoring and reporting requirements:

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

720 (i) 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures  
721 **FOR A HOSPITAL IN A METROPOLITAN COUNTY.**

722 (ii) **150 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT DIAGNOSTIC CARDIAC**  
723 **CATHETERIZATION PROCEDURES FOR A HOSPITAL IN A RURAL OR MICROPOLITAN COUNTY.**

724 (iii) 300 procedure equivalents in the category of adult therapeutic cardiac catheterization  
725 procedures.

726 (iiii) **600 procedure equivalents in the category of pediatric/congenital cardiac catheterization**  
727 **procedures.**

728 (iv) **500-250** procedure equivalents for a hospital in a rural or micropolitan county with one laboratory.

729 (v) 750 procedure equivalents for a hospital in a metropolitan county **OR AN FSOF** with one  
730 laboratory.

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

732 (vii) 36 adult primary PCI cases for a primary PCI service without on-site OHS service.

733 (viii) 200 adult PCI procedures for an elective PCI service without on-site OHS service **LOCATED IN A**  
734 **HOSPITAL OR FSOF.**

735 (x) **100 CIED PROCEDURES FOR AN FSOF PROVIDING CIED SERVICES.**

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

740 (c) The applicant hospital providing therapeutic cardiac catheterization services, primary PCI  
741 services without on-site OHS service, or elective PCI services without on-site OHS service shall  
742 participate in a data registry administered by the Department or its designee as a means to measure  
743 quality and risk adjusted outcomes within cardiac catheterization services. The Department or its  
744 designee shall require that the applicant hospital submit summary reports as specified by the Department.  
745 The applicant hospital shall provide the required data in a format established by the Department or its  
746 designee. The applicant hospital shall be liable for the cost of data submission and on-site reviews in  
747 order for the Department to verify and monitor volumes and assure quality. The applicant hospital shall  
748 become a member of the data registry specified by the Department upon initiation of the service and  
749 continue to participate annually thereafter for the life of that service.

750 (d) **The applicant hospital shall provide the department with timely notice of the proposed project**  
751 **implementation consistent with applicable statute and promulgated rules.**

752  
753 (5) Compliance with the following primary and elective PCI requirements for ~~hospitals~~ **FACILITIES**  
754 providing therapeutic cardiac catheterization services, primary PCI services without on-site OHS service,  
755 or elective PCI services without on-site OHS service, if applicable:

756 (a) The requirements set forth in Section 4.

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

759 (c) The hospital shall maintain a 90-minute door-to-balloon time or less in at least 75% of the primary  
760 PCI sessions (excluding patients with cardiogenic shock).

761 (d) The applicant ~~hospital~~ FACILITY shall participate in a data registry administered by the  
762 Department or its designee as a means to measure quality and risk adjusted outcomes within PCI  
763 services by service level. The Department or its designee shall require that the applicant ~~hospital~~  
764 FACILITY submit all consecutive PCI cases performed within the ~~hospital~~ FACILITY and meet data  
765 submission timeliness requirements and threshold requirements for PCI data submission, accuracy and  
766 completeness established by a data registry administered by the Department or its designee. The  
767 applicant ~~hospital~~ FACILITY shall provide the required data in a format established by the Department or  
768 its designee. The applicant ~~hospital~~ FACILITY shall be liable for the cost of data submission and on-site  
769 reviews in order for the Department to verify and monitor volumes and assure quality. The applicant  
770 ~~hospital~~ FACILITY shall become a member of the data registry specified by the Department upon  
771 initiation of the service and continue to participate annually thereafter for the life of that service. At a  
772 minimum, the applicant ~~hospital~~ FACILITY shall report the following AS APPLICABLE:

- 773 (i) the number of patients treated with and without STEMI,
- 774 (ii) the proportion of PCI patients with emergency CABG or required emergent transfer,
- 775 (iii) risk and reliability adjusted patient mortality for all PCI patients and a subset of patients with  
776 STEMI,
- 777 (iv) PCI appropriate use in elective non-acute MI cases, and
- 778 (v) rates of ad-hoc multi-vessel PCI procedures in the same session.

779 (e) The applicant ~~hospital~~ FACILITY shall maintain a physician point of contact for the data registry.

780 (f) For primary PCI services without on-site OHS service and elective PCI services IN A HOSPITAL  
781 without on-site OHS service, catheterization lab facility requirements and collaborative cardiologists-heart  
782 surgeon relationship requirements shall conform to all SCAI/ACC Guidelines for PCI including the  
783 SCAI/ACC/AHA Expert Consensus Document. The applicant hospital shall be liable for the cost of  
784 demonstrating compliance with these criteria.

785 (g) FOR DIAGNOSTIC CARDIAC CATHETERIZATION AND ELECTIVE PCI SERVICES AT AN  
786 FEOF, CATHETERIZATION LAB FACILITY REQUIREMENTS SHALL CONFORM TO THE POSITION  
787 STATEMENT ON THE PERFORMANCE OF PERCUTANEOUS CORONARY INTERVENTION IN  
788 AMBULATORY SURGICAL CENTERS (BOX ET AL. CATHETER CARDIOVASC INTERV. 2020;1-9).  
789 THE APPLICANT FACILITY SHALL BE LIABLE FOR THE COST OF DEMONSTRATING COMPLIANCE  
790 WITH THE PRINCIPLES DOCUMENTED IN THIS POSITION STATEMENT.

791 (h) The Department shall use these thresholds and metrics in evaluating compliance: performance  
792 at a level above the 50th percentile of the statewide performance on each metric listed under subsection  
793 (d)(ii) – (v) or another level provided by the data registry designee and accepted by the Department.

794 (hi) The Department shall notify those ~~hospitals~~ FACILITIES ~~who~~ THAT fail to meet any of the  
795 minimally acceptable objective quality metric thresholds including those under subsection (d)(ii) – (v).  
796 The Department shall require these ~~hospitals~~ FACILITIES to:

- 797 (i) submit a corrective action plan within one month of notification and
- 798 (ii) demonstrate that performance has improved to meet or exceed all applicable objective quality  
799 metric thresholds, including those under subsection (d)(ii) – (v), within 12 months of notification.

800 (ij) The applicant ~~hospital~~ initiating elective PCI without on-site OHS services, WHETHER IN A  
801 HOSPITAL OR FEOF, shall have Accreditation for Cardiovascular Excellence (ACE) accreditation or an  
802 equivalent body perform an on-site review within 3, 6, and 12 months after implementation. The applicant  
803 ~~hospital~~ shall submit the summary reports of the on-site review to the Department and maintain on-going  
804 accreditation.

805

806 (6) COMPLIANCE WITH ALL OF THE FOLLOWING REQUIREMENTS FOR FSOFS PROVIDING  
807 CIED PROCEDURES:

808 (a) MAINTAIN A WRITTEN TRANSFER AGREEMENT AND PROTOCOLS WITH THE TERTIARY  
809 CARE CENTER IDENTIFIED IN SECTION 4(3)(b).

- 810 (b) MAINTAIN CARDIAC CATH LAB CAPABILITIES INCLUDING PERICARDIOCENTESIS  
 811 EQUIPMENT ON SITE.  
 812 (c) REPORT ACUTE OUTCOMES OF PROCEDURES TO A REGISTRY IDENTIFIED BY THE  
 813 DEPARTMENT.  
 814 (d) MAINTAIN DEVICE FOLLOW UP PROTOCOLS.

815  
 816 (7) Nothing in this section prohibits the Department from taking compliance action under MCL  
 817 333.22247.

818  
 819 (78) The agreements and assurances required by this section shall be in the form of a certification  
 820 agreed to by the applicant hospital or its authorized agent.

821  
 822 **Section 11. Methodology for computing cardiac catheterization equivalents**

823  
 824 Sec. 11. The following shall be used in calculating procedure equivalents and evaluating utilization of  
 825 a cardiac catheterization service and its laboratories:  
 826

Procedure Type	Description	Procedure equivalent	
		Adult	Pediatric
Diagnostic cardiac catheterization/peripheral session	Right heart catheterization, left heart catheterization, coronary angiography, coronary artery bypass graft angiography, intracoronary administration of drugs, fractional flow reserve (FFR), intra-coronary imaging [intravascular ultrasound (IVUS), optical coherence tomography (OCT)] when performed without a therapeutic procedure, cardiac biopsy, intra-cardiac echocardiography (ICE), diagnostic electrophysiology study, angiography in the peripheral arterial or venous circulation	1.5	2.7
Therapeutic cardiac catheterization session	PCI, pericardiocentesis, pacemaker implantation, ICD implantation (endovascular or subcutaneous), pacemaker/ICD generator change, pacemaker/ICD lead revision, cardiac ablation (excluding AF/VT), and/or structural heart procedure (excluding those listed below), and IABP, Impella, ECMO, or TandemHeart when this is the only therapeutic procedure	2.7	4.0
Therapeutic peripheral session	Percutaneous transluminal angioplasty (PTA), atherectomy, laser, stent implantation, IVC filter implantation or retrieval, catheter-directed ultrasound/thrombolysis, thrombectomy	2.7	4.0
Complex therapeutic session	PCI for chronic total occlusion (CTO), TAVR, mitral/pulmonary/tricuspid valve repair or replacement, paravalvular leak closure, ablation for atrial fibrillation (AF) or ventricular tachycardia (VT), pacemaker or ICD lead extraction	4.0	7.0
Prolonged therapeutic session	Cardiac therapeutic session >6 hours	6.0	7.0
Procedure equivalents from peripheral diagnostic and therapeutic procedures count toward the volume requirement for initiation of cardiac catheterization services (Section 3) and expansion of a cardiac catheterization service (Section 6).			

827  
 828 **Section 12. Documentation of projections**

829  
830 Sec. 12. An applicant ~~hospital~~ required to project volumes shall demonstrate the following as  
831 applicable to the proposed project:

832  
833 (1) The applicant ~~hospital~~ shall specify how the volume projections were developed AND SHALL  
834 INCLUDE ONLY THOSE SESSIONS PERFORMED IN A CARDIAC CATHETERIZATION  
835 LABORATORY.

836 (a) ~~Specification of the projections~~THE APPLICANT shall include a description of the data source(s)  
837 used AS WELL AS and assessment of the accuracy of the data USED TO MAKE THE PROJECTIONS.  
838 BASED ON THIS DOCUMENTATION. ~~The~~the Department shall determine if the projections are  
839 reasonable.

840 (b) THE DEPARTMENT SHALL SUBTRACT ANY PREVIOUS COMMITMENT, PURSUANT TO  
841 SUBSECTION 4(d).

842  
843 (2) An applicant hospital proposing to initiate a primary PCI service shall demonstrate and certify that  
844 the hospital treated or transferred 36 ST segment elevation AMI cases during the most recent 12-month  
845 period preceding the date the application was submitted to the Department. Cases may include  
846 thrombolytic eligible patients documented through pharmacy records showing the number of doses of  
847 thrombolytic therapy ordered and medical records of emergency transfers of AMI patients to an  
848 appropriate hospital for a primary PCI procedure.

849  
850 (3) An applicant ~~hospital~~ proposing to initiate an elective PCI service without on-site OHS services,  
851 WHETHER IN A HOSPITAL OR FSOE, shall demonstrate and certify that the ~~hospital~~PROPOSED  
852 SERVICE shall treat 200 or more patients with PCI annually using data during FROM the most recent 12-  
853 month period preceding the date the application was submitted to the Department as follows AND  
854 APPLICABLE:

855 (a) All primary PCIs performed at the applicant hospital.

856 (b) All inpatients transferred from the applicant hospital to another hospital for PCI.

857 (c) 90% of patients who received diagnostic cardiac catheterizations at the applicant ~~hospital~~  
858 FACILITY and received an elective PCI at another ~~hospital~~CARDIAC CATHETERIZATION SERVICE  
859 within 30 days of the diagnostic catheterization (based on physician commitments).

860 (d) 50% of the elective PCI procedures performed by the committing physician at another ~~hospital~~  
861 CARDIAC CATHETERIZATION SERVICE within ~~120-20 radius miles or 120 minutes travel time~~ from the  
862 applicant ~~hospital~~PROPOSED SERVICE for patients who did not receive diagnostic cardiac  
863 catheterization at the applicant ~~hospital~~FACILITY (based on physician commitments).

864 (e) An applicant hospital with current OHS services and therapeutic cardiac catheterization services  
865 that is proposing to discontinue OHS services and therapeutic cardiac catheterization services and is  
866 applying to initiate primary or elective PCI services without on-site OHS services may count all primary  
867 and elective PCI at the applicant hospital within the most recent 12-month period preceding the date the  
868 application was submitted to the Department.

869  
870 (4) IF A PROJECTED NUMBER OF SESSIONS UNDER SUBSECTION (1) OR (3) INCLUDES  
871 PROCEDURES PERFORMED AT ANOTHER EXISTING CARDIAC CATHETERIZATION SERVICE(S),  
872 AN APPLICANT SHALL DEMONSTRATE, WITH DOCUMENTATION SATISFACTORY TO THE  
873 DEPARTMENT, THAT THE UTILIZATION OF THE EXISTING CARDIAC CATHETERIZATION  
874 SERVICE(S) IS IN COMPLIANCE WITH THE VOLUME REQUIREMENTS APPLICABLE TO THAT  
875 FACILITY, AND WILL CONTINUE TO BE IN COMPLIANCE WITH THE VOLUME REQUIREMENTS  
876 APPLICABLE TO THAT FACILITY SUBSEQUENT TO THE INITIATION, EXPANSION, OR  
877 REPLACEMENT OF THE CARDIAC CATHETERIZATION SERVICES PROPOSED BY AN APPLICANT.  
878 ONLY EXCESS PROCEDURE EQUIVALENTS EQUAL TO OR GREATER THAN WHAT IS BEING  
879 COMMITTED PURSUANT TO THIS SUBSECTION MAY BE USED TO DOCUMENT PROJECTIONS  
880 UNDER THIS SUBSECTION. IN DEMONSTRATING COMPLIANCE WITH THIS SUBSECTION, AN  
881 APPLICANT SHALL PROVIDE EACH OF THE FOLLOWING:

882 (a) THE NAME OF EACH PHYSICIAN THAT PERFORMED CARDIAC CATHETERIZATION  
883 SESSION TO BE TRANSFERRED TO THE APPLICANT CARDIAC CATHETERIZATION FACILITY.  
884 (b) THE NUMBER OF CARDIAC CATHETERIZATION SESSIONS EACH PHYSICIAN IDENTIFIED  
885 IN SUBDIVISION (a) PERFORMED DURING THE MOST RECENT 12-MONTH PERIOD FOR WHICH  
886 VERIFIABLE DATA IS AVAILABLE.  
887 (c) THE LOCATION(S) AT WHICH THE CARDIAC CATHETERIZATION SESSIONS TO BE  
888 TRANSFERRED WERE PERFORMED, INCLUDING EVIDENCE THAT THE EXISTING LOCATION AND  
889 THE PROPOSED LOCATION ARE WITHIN 20 MILES OF EACH OTHER.  
890 (d) A WRITTEN COMMITMENT FROM EACH PHYSICIAN IDENTIFIED IN SUBDIVISION (a) THAT  
891 HE OR SHE WILL PERFORM AT LEAST THE VOLUME OF CARDIAC CATHETERIZATION SESSIONS  
892 TO BE TRANSFERRED TO THE APPLICANT CARDIAC CATHETERIZATION SERVICE FOR NO LESS  
893 THAN 3 YEARS SUBSEQUENT TO THE INITIATION, EXPANSION, OR REPLACEMENT OF THE  
894 CARDIAC CATHETERIZATION SERVICE PROPOSED BY AN APPLICANT.  
895 (e) THE NUMBER OF CARDIAC CATHETERIZATION SESSIONS PERFORMED AT THE  
896 EXISTING CARDIAC CATHETERIZATION SERVICE FROM WHICH CARDIAC CATHETERIZATION  
897 SESSIONS WILL BE TRANSFERRED DURING THE MOST RECENT 12-MONTH PERIOD PRIOR TO  
898 THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT FOR WHICH VERIFIABLE  
899 DATA IS AVAILABLE.  
900 (f) SUBSECTION 4(d) SHALL NOT APPLY IF THE PROPOSED PROJECT INVOLVES THE  
901 INITIATION OF A CARDIAC CATHETERIZATION SERVICE AT A NEW FSOFF AT A NEW  
902 GEOGRAPHICAL SITE UTILIZING THE HISTORICAL CARDIAC CATHETERIZATION PROCEDURE  
903 EQUIVALENTS OF THE APPLICANT AND THE NEW SERVICE IS OWNED BY THE SAME  
904 APPLICANT. THE APPLICANT FACILITY COMMITTING CARDIAC CATHETERIZATION SESSIONS  
905 DATA HAS COMPLETED THE DEPARTMENTAL FORM THAT CERTIFIES THE CARDIAC  
906 CATHETERIZATION SESSIONS WERE PERFORMED AT THE COMMITTING FACILITY AND THE  
907 CARDIAC CATHETERIZATION PROCEDURE EQUIVALENTS WILL BE TRANSFERRED TO THE  
908 PROPOSED CARDIAC CATHETERIZATION SERVICE FOR NO LESS THAN THREE YEARS  
909 SUBSEQUENT TO THE INITIATION OF THE CARDIAC CATHETERIZATION SERVICE PROPOSED  
910 BY THE APPLICANT.

### 911 **Section 13. Comparative reviews; Effect on prior CON Review Standards**

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914 Sec. 13. Proposed projects reviewed under these standards shall not be subject to comparative  
915 review. These CON Review Standards supersede and replace the CON Review Standards for Cardiac  
916 Catheterization Services approved by the CON Commission on ~~June 11, 2015~~ September 20, 2018 and  
917 effective on ~~September 14, 2015~~ December 26, 2018.  
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Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

75 F.R., p. 37245 (June 28, 2010)  
Statistical Policy Office  
Office of Information and Regulatory Affairs  
United States Office of Management and Budget