

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,
13 EXPANSION, OR ACQUISITION OF CARDIAC CATHETERIZATION services, AND THE DELIVERY OF
14 THESE SERVICES under Part 222 of the Code. PURSUANT TO Part 222 of the Code CARDIAC
15 CATHETERIZATION SERVICES ARE A COVERED CLINICAL SERVICE. The Department shall use
16 THESE STANDARDS in applying Section 22225(1) of the Code, being Section 333.22225(1) of the
17 Michigan Compiled Laws AND Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the
18 Michigan Compiled Laws.
19

20 **Section 2. Definitions**

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

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24 across the atrial septum and withdrawn to create an enlarged atrial opening.

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

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

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

43 (E) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to
44 Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

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

47 (G) "Department" means the Michigan Department of Community Health (MDCH).

48 (H) "Diagnostic cardiac catheterization service" means providing diagnostic-only cardiac
49 catheterizations on an organized, regular basis, in a laboratory. The term includes, but is not limited to:
50 the intra coronary administration of drugs; left heart catheterization; right heart catheterization; coronary
51 angiography; diagnostic electrophysiology studies; and cardiac biopsies (echo-guided or fluoroscopic).
52 For purposes of these standards, the term also includes balloon atrial septostomy procedure in a hospital
53 that provides pediatric diagnostic cardiac catheterization services. This term also includes cardiac

54 permanent pacemaker/ICD device implantations in a hospital that does not provide therapeutic cardiac
55 catheterization services.

56 (I) "Electrophysiology study" means a study of the electrical conduction activity of the heart and
57 characterization of atrial and ventricular arrhythmias, obtained by means of a cardiac catheterization
58 procedure. The term also includes the implantation of permanent pacemakers and defibrillators.

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

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

63 (o) " (L) " Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6
64 and 1396r-8 to 1396v.

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

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

73 (O) "On-site open heart surgery services" means a facility that does have a CON to perform
74 open heart surgery services and does perform open heart surgery services in the existing hospital.

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

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

83 (R) "Procedure equivalent" means a unit of measure that reflects the relative average length of time
84 one patient spends in one session in a cardiac catheterization laboratory based on the type of procedures
85 being performed.

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87 (S) "Rural county" means a county not located in a metropolitan statistical area or micropolitan
88 statistical areas as those terms are defined under the "standards for defining metropolitan and
89 micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of
90 the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as
91 shown in Appendix A.

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

99
100 (2) Terms defined in the Code have the same meanings when used in these standards.

101 **Section 3. Requirements TO INITIATE A CARDIAC CATHETERIZATION SERVICE**

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104 Sec. 3. To initiate a cardiac catheterization service means to begin performing cardiac catheterization
105 procedures at a hospital that does not perform cardiac catheterization procedures as of the date an
106 application is submitted to the Department. AN APPLICANT PROPOSING TO INITIATE CARDIAC

107 CATHETERIZATION SERVICES SHALL DEMONSTRATE THE FOLLOWING, AS APPLICABLE TO
108 THE PROPOSED PROJECT.

109
110 (1) Cardiac catheterization procedures shall be performed in a cardiac catheterization laboratory
111 located within a hospital, and have within, or immediately available to the room, dedicated emergency
112 equipment to manage cardiovascular emergencies.

113
114 (2) An applicant proposing to initiate an adult diagnostic cardiac catheterization service in a new
115 single laboratory shall project the following volume of procedure equivalents, as applicable, will be
116 performed in the second 12 months of operation after initiation of the service, and annually thereafter:

117 (a) For a hospital located in a rural or micropolitan statistical area county, a minimum of 500
118 procedure equivalents which shall include the 300 procedure equivalents in the category of adult
119 diagnostic cardiac catheterization.

120 (b) For a hospital located in a metropolitan statistical area county, a minimum of 750 procedure
121 equivalents which shall include the 300 procedure equivalents in the category of adult diagnostic cardiac
122 catheterization.

123 (3) An applicant proposing to initiate an adult diagnostic cardiac catheterization service in 2 or more
124 laboratories shall project a minimum of 1,000 procedure equivalents per laboratory which shall include
125 300 procedure equivalents in the category of adult diagnostic cardiac catheterization in the second 12
126 months of operation after initiation of the service, and annually thereafter.

127
128 (4) AN APPLICANT PROPOSING TO PERFORM ADULT THERAPEUTIC CARDIAC
129 CATHETERIZATION PROCEDURES SHALL DEMONSTRATE ALL OF THE FOLLOWING:

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

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

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

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

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

144
145 (5) AN APPLICANT PROPOSING TO INITIATE A PEDIATRIC CARDIAC CATHETERIZATION
146 SERVICE AT A HOSPITAL THAT WILL PERFORM CARDIAC CATHETERIZATION PROCEDURES IS
147 REQUIRED TO HAVE EACH OF THE FOLLOWING AS OUTLINED IN THE AMERICAN ACADEMY OF
148 PEDIATRICS (AAP), GUIDELINES FOR PEDIATRIC CARDIOVASCULAR CENTERS (MARCH 2002):

149 (A) A BOARD CERTIFIED PEDIATRIC CARDIOLOGIST WITH TRAINING IN PEDIATRIC
150 CATHETERIZATION PROCEDURES TO DIRECT THE PEDIATRIC CATHETERIZATION
151 LABORATORY;

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

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

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

155 (E) AN APPLICANT PROPOSING TO INITIATE A PEDIATRIC CARDIAC CATHETERIZATION
156 SERVICE AT A HOSPITAL THAT CURRENTLY PERFORMS CARDIAC CATHETERIZATION
157 PROCEDURES SHALL PROJECT THAT A MINIMUM OF 600 PROCEDURE EQUIVALENTS IN THE
158 CATEGORY OF PEDIATRIC CARDIAC CATHETERIZATIONS WILL BE PERFORMED IN THE
159 SECOND 12 MONTHS OF OPERATION AFTER INITIATION OF THE PEDIATRIC CARDIAC
160 CATHETERIZATION SERVICE, AND ANNUALLY THEREAFTER.

161
162 (6) An applicant proposing to initiate primary PCI service without on-site open heart surgery services
163 shall submit documentation demonstrating all of the following:
164 (a) The applicant's adult diagnostic cardiac catheterization service performed a minimum of 400
165 diagnostic procedures (excluding diagnostic electrophysiology studies and right heart catheterizations)
166 during the most recent 12 months preceding the date the application was submitted to the Department.
167 (b) The interventional cardiologists (at least two) to perform the primary PCI are experienced
168 interventionalists who have each performed at least 75 interventions annually as the primary operator at
169 an open heart surgery facility during the most recent 24 months preceding the date the application was
170 submitted to the Department, and annually thereafter.
171 (c) The nursing and technical catheterization laboratory staff: are experienced in handling acutely ill
172 patients and comfortable with interventional equipment; have acquired experience in dedicated
173 interventional laboratories at an open heart surgery facility; and participate in an un-interrupted 24-hour,
174 365-day call schedule. Competency should be documented annually.
175 (d) The catheterization laboratory is well-equipped, with optimal imaging systems, resuscitative
176 equipment, intra-aortic balloon pump (IABP) support, and must be well-stocked with a broad array of
177 interventional equipment.
178 (e) The cardiac care unit nurses are adept in hemodynamic monitoring and IABP management.
179 Competency should be documented annually.
180 (f) A written agreement with an open heart surgery facility that includes:
181 (i) Involvement in credentialing criteria and recommendations for physicians approved to perform
182 primary PCI;
183 (ii) Provision for ongoing cross-training for professional and technical staff involved in the provision of
184 primary PCI to ensure familiarity with interventional equipment; and competency should be documented
185 annually;
186 (iii) Provision for ongoing cross training for Emergency Department, Catheterization Laboratory and
187 Critical Care Unit staff to ensure experience in handling the high acuity status of primary PCI patient
188 candidates and competency should be documented annually;
189 (iv) Regularly held joint cardiology/cardiac surgery conferences to include review of all primary PCI
190 cases;
191 (v) Development and ongoing review of patient selection criteria for primary PCI patients and
192 implementation of those criteria;
193 (vi) A mechanism to provide for appropriate patient transfers between facilities and an agreed plan for
194 prompt care;
195 (vii) Written protocols, signed by the applicant and the open heart surgery facility, must be in place,
196 with provisions for the implementation for immediate and efficient transfer (within 1 hour from cardiac
197 catheterization laboratory to evaluation on site in the open heart surgical facility) of patients requiring
198 surgical evaluation and/or intervention 365 days a year, the protocols shall be reviewed/tested on a
199 regular (quarterly) basis; and
200 (viii) Consultation on facilities, equipment, staffing, ancillary services, and policies and procedures for
201 the provision of interventional procedures.
202 (g) A written protocol must be established and maintained for case selection for the performance of
203 primary PCI that is consistent with current practice guidelines set forth by the American College of
204 Cardiology and the American Heart Association.
205 (h) A system to ensure prompt and efficient identification of potential primary PCI patients and rapid
206 transfer from the Emergency Department to the Catheterization Laboratory must be developed and
207 maintained so that door-to-balloon targets are met.
208 (i) Because primary PCI must be available to emergency patients 24 hours per day, 365 days a
209 year, at least two physicians credentialed to perform primary PCI must commit to functioning as a
210 coordinated group willing and able to provide this service at the hospital on a 24-hour per day, 365 day
211 per year call schedule, with ability to be on-site and available to operate within 30 minutes of identifying
212 the need for primary PCI. These physicians must be credentialed at the facility and actively collaborate
213 with administrative and clinical staff in establishing and implementing protocols, call schedules, and
214 quality assurance procedures pertaining to primary PCI designed to meet the requirements for this
215 certification and in keeping with the current guidelines for the provision of primary PCI promulgated by the
216 American College of Cardiology and American Heart Association.

217
218 (J) An applicant shall project a minimum of 48 primary PCI procedures will be performed in the
219 second 12 months of operation after initiation of service, and annually thereafter. Primary PCI volume
220 shall be projected by documenting, as outlined in Section 13, and certifying that the applicant treated or
221 transferred enough ST segment elevation AML cases during the most recent 12 months preceding the
222 date the application was submitted to the Department to maintain 48 primary PCI cases annually.
223 Factors that may be considered in projecting primary PCI volume are the number of thrombolytic eligible
224 patients per year seen in the Emergency Department (as documented through hospital pharmacy records
225 showing the number of doses of thrombolytic therapy ordered for AML in the Emergency Department)
226 and/or documentation of emergency transfers to an open heart surgery facility for primary PCI.
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228 **Section 4. Requirements to replace AN EXISTING cardiac catheterization laboratory**

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230 Sec. 4. REPLACE/UPGRADE MEANS ANY EQUIPMENT CHANGE THAT INVOLVES A CAPITAL
231 EXPENDITURE OF \$500,000 OR MORE IN ANY CONSECUTIVE 24-MONTH PERIOD WHICH
232 RESULTS IN THE APPLICANT OPERATING THE SAME NUMBER OF CARDIAC CATHETERIZATION
233 LABORATORIES BEFORE AND AFTER PROJECT COMPLETION. An applicant, other than a hospital
234 that provides only pediatric cardiac catheterization services, proposing to replace/upgrade its only
235 laboratory, shall demonstrate that it meets each of the following, as applicable:
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237 (1) An applicant proposing to replace equipment shall demonstrate that the existing equipment to be
238 replaced is fully depreciated according to generally accepted accounting principles, or EITHER OF THE
239 FOLLOWING:

240 (A) The existing equipment poses a threat to the safety of the PATIENTS.

241 (B) THE REPLACEMENT EQUIPMENT offers technological improvements THAT enhance quality of
242 care, increase efficiency, and reduce operating costs AND PATIENT CHARGES.
243

244 (2) THE APPLICANT AGREES THAT THE EQUIPMENT TO BE REPLACED WILL BE REMOVED
245 FROM SERVICE ON OR BEFORE BEGINNING OPERATION OF THE REPLACEMENT EQUIPMENT.
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247 (3) AN APPLICANT PROPOSING TO REPLACE A CARDIAC CATHETERIZATION SERVICE TO A
248 NEW SITE SHALL DEMONSTRATE THE FOLLOWING:

249 (A) THE PROPOSED SITE IS WITHIN A XX-MILE RADIUS OF THE EXISTING SITE FOR A
250 METROPOLITAN STATISTICAL AREA COUNTY OR A XX-MILE RADIUS FOR A RURAL OR
251 MICROPOLITAN STATISTICAL AREA COUNTY.

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

255 (C) THE EXISTING CARDIAC CATHETERIZATION SERVICE HAS BEEN IN OPERATION FOR AT
256 LEAST 36 MONTHS AS OF THE DATE OF THE APPLICATION SUBMITTED TO THE DEPARTMENT..
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258 **Section 5. Requirements to expand a cardiac catheterization service**

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260 Sec. 5. EXPANDING A CARDIAC CATHETERIZATION SERVICE MEANS EITHER AN INCREASE
261 IN THE NUMBER OF CARDIAC CATHETERIZATION LABORATORIES AT A HOSPITAL OR
262 EXPANDING THE TYPES OF CARDIAC CATHETERIZATION PROCEDURES AUTHORIZED TO BE
263 PERFORMED INCLUDING ADULT OR PEDIATRIC, DIAGNOSTIC OR THERAPEUTIC AT A HOSPITAL
264 THAT CURRENTLY PERFORMS CARDIAC CATHETERIZATION PROCEDURES. An applicant
265 proposing to add a laboratory to an existing cardiac catheterization service shall demonstrate the
266 following:
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268 (1) An average of 1,500 procedure equivalents per room per year was performed in each existing
269 cardiac catheterization laboratory in the hospital during the most recent 12-month period preceding the
270 date the application was submitted to the Department.

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Section 6. REQUIREMENTS TO ACQUIRE A CARDIAC CATHETERIZATION SERVICE

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

(1) AN APPLICATION FOR THE FIRST ACQUISITION OF AN EXISTING CARDIAC CATHETERIZATION SERVICE AFTER <INSERT EFFECTIVE DATE OF THESE STANDARDS> SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE APPLICABLE VOLUME REQUIREMENTS ON THE DATE OF ACQUISITION. THE CARDIAC CATHETERIZATION SERVICE SHALL BE OPERATING AT XXX PROCEDURE EQUIVALENTS IN THE SECOND 12 MONTHS AFTER THE DATE THE SERVICE IS ACQUIRED, AND ANNUALLY THEREAFTER.

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

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

SECTION 7. REQUIREMENT FOR MEDICAID PARTICIPATION

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

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

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

(1) COMPLIANCE WITH THESE STANDARDS.

(2) COMPLIANCE WITH THE FOLLOWING QUALITY ASSURANCE REQUIREMENTS:

(A) THE APPROVED SERVICES SHALL BE STAFFED WITH SUFFICIENT MEDICAL, NURSING, TECHNICAL AND OTHER PERSONNEL TO PERMIT REGULAR SCHEDULED HOURS OF OPERATION AND CONTINUOUS 24-HOUR ON-CALL AVAILABILITY.

(B) THE MEDICAL STAFF AND GOVERNING BODY SHALL RECEIVE AND REVIEW AT LEAST ANNUAL REPORTS DESCRIBING THE ACTIVITIES OF THE CARDIAC CATHETERIZATION SERVICE INCLUDING: COMPLICATION RATES (INCLUDING EMERGENCY SURGICAL PROCEDURES);

325 MORBIDITY AND MORTALITY DATA; SUCCESS RATES AND THE NUMBER OF PROCEDURES
326 PERFORMED.

327 (C) EACH PHYSICIAN CREDENTIALLED BY A HOSPITAL TO PERFORM ADULT THERAPEUTIC
328 CARDIAC CATHETERIZATION PROCEDURES SHALL PERFORM, AS THE PRIMARY OPERATOR, A
329 MINIMUM OF 75 ADULT THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES PER YEAR IN
330 THE SECOND 12 MONTHS AFTER BEING CREDENTIALLED TO PERFORM PROCEDURES AT THE
331 APPLICANT HOSPITAL, AND ANNUALLY THEREAFTER. THE ANNUAL CASE LOAD FOR A
332 PHYSICIAN MEANS ADULT THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES
333 PERFORMED BY THAT PHYSICIAN IN ANY HOSPITAL OR IN ANY COMBINATION OF HOSPITALS.
334 THE APPLICANT SHALL BE RESPONSIBLE FOR REPORTING TO THE DEPARTMENT, ON AN
335 ANNUAL BASIS, THE NAME AND THE NUMBER OF ADULT THERAPEUTIC CARDIAC
336 CATHETERIZATION PROCEDURES PERFORMED BY EACH PHYSICIAN CREDENTIALLED TO
337 PERFORM ADULT THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES.

338 (D) EACH PHYSICIAN CREDENTIALLED BY A HOSPITAL TO PERFORM PEDIATRIC
339 DIAGNOSTIC CARDIAC CATHETERIZATIONS SHALL PERFORM, AS THE PRIMARY OPERATOR, A
340 MINIMUM OF 50 PEDIATRIC DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES PER YEAR
341 IN THE SECOND 12 MONTHS AFTER BEING CREDENTIALLED TO PERFORM PROCEDURES AT
342 THE APPLICANT HOSPITAL, AND ANNUALLY THEREAFTER. THE ANNUAL CASE LOAD FOR A
343 PHYSICIAN MEANS PEDIATRIC DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES
344 PERFORMED BY THAT PHYSICIAN IN ANY HOSPITAL OR IN ANY COMBINATION OF HOSPITALS.
345 THE APPLICANT SHALL BE RESPONSIBLE FOR REPORTING TO THE DEPARTMENT, ON AN
346 ANNUAL BASIS, THE NAME AND THE NUMBER OF PEDIATRIC DIAGNOSTIC CARDIAC
347 CATHETERIZATION PROCEDURES PERFORMED BY EACH PHYSICIAN CREDENTIALLED TO
348 PERFORM PEDIATRIC DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES.

349 (E) EACH PHYSICIAN CREDENTIALLED BY A HOSPITAL TO PERFORM PEDIATRIC
350 THERAPEUTIC CARDIAC CATHETERIZATIONS SHALL PERFORM, AS A PRIMARY OPERATOR, A
351 MINIMUM OF 25 PEDIATRIC THERAPEUTIC CARDIAC CATHETERIZATIONS PER YEAR IN THE
352 SECOND 12 MONTHS AFTER BEING CREDENTIALLED TO PERFORM PROCEDURES AT THE
353 APPLICANT HOSPITAL, AND ANNUALLY THEREAFTER. THE ANNUAL CASE LOAD FOR A
354 PHYSICIAN MEANS PEDIATRIC THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES
355 PERFORMED BY THAT PHYSICIAN IN ANY HOSPITAL OR IN ANY COMBINATION OF HOSPITALS.
356 THE APPLICANT SHALL BE RESPONSIBLE FOR REPORTING TO THE DEPARTMENT, ON AN
357 ANNUAL BASIS, THE NAME AND THE NUMBER OF PEDIATRIC THERAPEUTIC CARDIAC
358 CATHETERIZATION PROCEDURES PERFORMED BY EACH PHYSICIAN CREDENTIALLED TO
359 PERFORM PEDIATRIC THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES.

360 (F) FOR PURPOSES OF EVALUATING SUBDIVISIONS (V) OR (VI), A DIAGNOSTIC CARDIAC
361 CATHETERIZATION FOLLOWED BY A THERAPEUTIC CARDIAC CATHETERIZATION (INCLUDING
362 ELECTROPHYSIOLOGY STUDIES) IN THE SAME SESSION SHALL BE CONSIDERED BOTH 1
363 DIAGNOSTIC PROCEDURE AND 1 THERAPEUTIC PROCEDURE. TWO PHYSICIANS, ONE
364 CREDENTIALLED TO PERFORM DIAGNOSTIC CARDIAC CATHETERIZATIONS AND ONE
365 CREDENTIALLED TO PERFORM THERAPEUTIC CARDIAC CATHETERIZATIONS, EACH MAY BE
366 CONSIDERED TO HAVE PERFORMED EITHER 1 DIAGNOSTIC OR 1 THERAPEUTIC
367 CATHETERIZATION IF BOTH WERE INVOLVED IN PERFORMING A DIAGNOSTIC CARDIAC
368 CATHETERIZATION PROCEDURE FOLLOWED BY A THERAPEUTIC PROCEDURE IN THE SAME
369 SESSION.

370 (G) AN APPLICANT PROPOSING TO OFFER AN ADULT DIAGNOSTIC CARDIAC
371 CATHETERIZATION SERVICE SHALL HAVE A MINIMUM OF TWO (2) APPROPRIATELY TRAINED
372 PHYSICIANS ON ITS ACTIVE HOSPITAL STAFF. FOR PURPOSES OF EVALUATING THIS
373 SUBSECTION, THE DEPARTMENT SHALL CONSIDER IT PRIMA FACIE EVIDENCE OF
374 APPROPRIATE TRAINING IF THE STAFF PHYSICIANS:

375 (I) ARE TRAINED CONSISTENT WITH THE RECOMMENDATIONS OF THE AMERICAN
376 COLLEGE OF CARDIOLOGY;

377 (II) ARE CREDENTIALLED BY THE HOSPITAL TO PERFORM ADULT DIAGNOSTIC CARDIAC
378 CATHETERIZATIONS; AND

379 (III) HAVE EACH PERFORMED A MINIMUM OF 100 ADULT DIAGNOSTIC CARDIAC
380 CATHETERIZATIONS IN THE PRECEDING 12 MONTHS.
381 HOWEVER, THE APPLICANT MAY SUBMIT AND THE DEPARTMENT MAY ACCEPT OTHER
382 EVIDENCE THAT THE STAFF PHYSICIANS PERFORMING ADULT DIAGNOSTIC CARDIAC
383 CATHETERIZATIONS ARE APPROPRIATELY TRAINED.
384 (H) AN APPLICANT PROPOSING TO OFFER AN ADULT THERAPEUTIC CARDIAC
385 CATHETERIZATION SERVICE SHALL HAVE A MINIMUM OF TWO (2) APPROPRIATELY TRAINED
386 PHYSICIANS ON ITS ACTIVE HOSPITAL STAFF. FOR PURPOSES OF EVALUATING THIS
387 SUBSECTION, THE DEPARTMENT SHALL CONSIDER IT PRIMA FACIE EVIDENCE OF
388 APPROPRIATE TRAINING IF THE STAFF PHYSICIANS:
389 (I) ARE TRAINED CONSISTENT WITH THE RECOMMENDATIONS OF THE AMERICAN
390 COLLEGE OF CARDIOLOGY;
391 (II) ARE CREDENTIALLED BY THE HOSPITAL TO PERFORM ADULT THERAPEUTIC CARDIAC
392 CATHETERIZATIONS; AND
393 (III) HAVE EACH PERFORMED A MINIMUM OF 75 ADULT THERAPEUTIC CARDIAC
394 CATHETERIZATION PROCEDURES IN THE PRECEDING 12 MONTHS.
395 HOWEVER, THE APPLICANT MAY SUBMIT AND THE DEPARTMENT MAY ACCEPT OTHER
396 EVIDENCE THAT THE STAFF PHYSICIANS PERFORMING ADULT THERAPEUTIC CARDIAC
397 CATHETERIZATIONS ARE APPROPRIATELY TRAINED.
398 (I) AN APPLICANT PROPOSING TO OFFER A PEDIATRIC CARDIAC CATHETERIZATION
399 SERVICE SHALL DEMONSTRATE AN APPROPRIATELY TRAINED PHYSICIAN(S) SHALL BE ON
400 THE ACTIVE HOSPITAL STAFF TO PERFORM DIAGNOSTIC OR THERAPEUTIC, AS APPLICABLE,
401 PEDIATRIC CARDIAC CATHETERIZATIONS. FOR PURPOSES OF EVALUATING THIS
402 SUBSECTION, THE DEPARTMENT SHALL CONSIDER IT PRIMA FACIE EVIDENCE OF
403 APPROPRIATE TRAINING IF THE STAFF PHYSICIAN(S) IS:
404 (I) BOARD CERTIFIED OR BOARD ELIGIBLE IN PEDIATRIC CARDIOLOGY BY THE AMERICAN
405 BOARD OF PEDIATRICS;
406 (II) CREDENTIALLED BY THE HOSPITAL TO PERFORM DIAGNOSTIC OR THERAPEUTIC, AS
407 APPLICABLE, PEDIATRIC CARDIAC CATHETERIZATIONS; AND
408 (III) TRAINED CONSISTENTLY WITH THE RECOMMENDATIONS OF THE AMERICAN COLLEGE
409 OF CARDIOLOGY.
410 HOWEVER, THE APPLICANT MAY SUBMIT AND THE DEPARTMENT MAY ACCEPT OTHER
411 EVIDENCE THAT THE STAFF PHYSICIAN(S) PERFORMING PEDIATRIC CARDIAC
412 CATHETERIZATIONS IS APPROPRIATELY TRAINED.
413 (J) A CARDIAC CATHETERIZATION SERVICE SHALL BE DIRECTED BY AN APPROPRIATELY
414 TRAINED PHYSICIAN. FOR PURPOSES OF EVALUATING THIS SUBSECTION, THE DEPARTMENT
415 SHALL CONSIDER IT PRIMA FACIE EVIDENCE OF APPROPRIATE TRAINING AND EXPERIENCE
416 OF THE CARDIAC CATHETERIZATION SERVICE DIRECTOR IF THE PHYSICIAN IS BOARD
417 CERTIFIED IN CARDIOLOGY, CARDIOVASCULAR RADIOLOGY OR RADIOLOGY, ADULT OR
418 PEDIATRIC, AS APPLICABLE. THE DIRECTOR OF AN ADULT CARDIAC CATHETERIZATION
419 SERVICE SHALL HAVE PERFORMED AT LEAST 200 CATHETERIZATIONS PER YEAR DURING
420 EACH OF THE 5 PRECEDING YEARS. HOWEVER, THE APPLICANT MAY SUBMIT AND THE
421 DEPARTMENT MAY ACCEPT OTHER EVIDENCE THAT THE CARDIAC CATHETERIZATION
422 SERVICE DIRECTOR IS APPROPRIATELY TRAINED.
423 (K) AN APPROVED CARDIAC CATHETERIZATION SERVICE SHALL BE OPERATED
424 CONSISTENTLY WITH THE RECOMMENDATIONS OF THE AMERICAN COLLEGE OF
425 CARDIOLOGY.
426
427 (3) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:
428 (A) THE CARDIAC CATHETERIZATION SERVICES SHALL ACCEPT REFERRALS FOR CARDIAC
429 CATHETERIZATION SERVICES FROM ALL APPROPRIATELY LICENSED PRACTITIONERS.
430 (B) THE CARDIAC CATHETERIZATION SERVICE SHALL PARTICIPATE IN MEDICAID AT LEAST
431 12 CONSECUTIVE MONTHS WITHIN THE FIRST TWO YEARS OF OPERATION AND CONTINUE TO
432 PARTICIPATE ANNUALLY THEREAFTER.

433 (C) THE CARDIAC CATHETERIZATION SERVICE SHALL NOT DENY CARDIAC
434 CATHETERIZATION SERVICES TO ANY INDIVIDUAL BASED ON ABILITY TO PAY OR SOURCE OF
435 PAYMENT.

436 (D) THE OPERATION OF AND REFERRAL OF PATIENTS TO THE CARDIAC CATHETERIZATION
437 SERVICE SHALL BE IN COMFROMANCE WITH 1978 PA 368, SEC. 16221, AS AMENDED BY 1986 PA
438 319; MCL 333.1621; MSA 14.15 (16221).

439
440 (4) COMPLIANCE WITH THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:

441 (A) THE APPROVED SERVICES SHALL BE OPERATING AT THE APPLICABLE REQUIRED
442 VOLUMES WITHIN THE TIME PERIOD SPECIFIED IN THESE STANDARDS, AND ANNUALLY
443 THEREAFTER.

444 (B) THE APPLICANT SHALL PARTICIPATE IN A DATA COLLECTION NETWORK ESTABLISHED
445 AND ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE. THE DATA MAY INCLUDE, BUT IS
446 NOT LIMITED TO, ANNUAL BUDGET AND COST INFORMATION, OPERATING SCHEDULES, AND
447 DEMOGRAPHIC, DIAGNOSTIC, MORBIDITY AND MORTALITY INFORMATION, AS WELL AS THE
448 VOLUME OF CARE PROVIDED TO PATIENTS FROM ALL PAYOR SOURCES AND OTHER DATA
449 REQUESTED BY THE DEPARTMENT OR ITS DESIGNEE AND APPROVED BY THE COMMISSION.
450 THE APPLICANT SHALL PROVIDE THE REQUIRED DATA ON A SEPARATE BASIS FOR EACH
451 SEPARATE AND DISTINCT SITE OR UNIT AS REQUIRED BY THE DEPARTMENT, IN A FORMAT
452 ESTABLISHED BY THE DEPARTMENT AND IN A MUTUALLY AGREED UPON MEDIA. THE
453 DEPARTMENT MAY ELECT TO VERIFY THE DATA THROUGH ON-SITE REVIEW OF APPROPRIATE
454 RECORDS.

455 (C) THE APPLICANT SHALL PARTICIPATE IN A QUALITY IMPROVEMENT DATA REGISTRY
456 ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE. THE DEPARTMENT OR ITS DESIGNEE
457 SHALL REQUIRE THAT THE APPLICANT SUBMIT A SUMMARY REPORT AS REQUIRED BY THE
458 DEPARTMENT. THE APPLICANT SHALL PROVIDE THE REQUIRED DATA IN A FORMAT
459 ESTABLISHED BY THE DEPARTMENT OR ITS DESIGNEE. THE APPLICANT SHALL BE LIABLE FOR
460 THE COST OF DATA SUBMISSION AND ON-SITE REVIEWS IN ORDER FOR THE DEPARTMENT TO
461 VERIFY AND MONITOR VOLUMES AND ASSURE QUALITY. AN APPLICANT SHALL BECOME A
462 MEMBER OF THE DATA REGISTRY UPON INITIATION OF THE SERVICE AND CONTINUE TO
463 PARTICIPATE ANNUALLY THEREAFTER.

464 (D) THE CARDIAC CATHETERIZATION SERVICE SHALL PROVIDE THE DEPARTMENT WITH
465 TIMELY NOTICE OF THE PROPOSED PROJECT IMPLEMENTATION CONSISTENT WITH
466 APPPLICABLE STATUTE AND PROMULGATED RULES.

467 (E) EQUIPMENT THAT IS REPLACED SHALL BE REMOVED FROM THE CARDIAC
468 CATHETERIZATION SERVICE.

469
470 (5) COMPLIANCE WITH THE FOLLOWING PRIMARY PCI REQUIREMENTS, IF APPLICABLE:

471 (A) SHALL IMMEDIATELY REPORT TO THE DEPARTMENT ANY CHANGES IN THE
472 INTERVENTIONAL CARDIOLOGISTS WHO PERFORM THE PRIMARY PCI PROCEDURES.

473 (B) COMPLIANCE WITH REQUIREMENTS OF THE STANDARDS SET FORTH IN SECTION 5(1).

474 (C) THE APPLICANT SHALL HAVE PERFORMED A MINIMUM OF 48 PRIMARY PCI
475 PROCEDURES AT THE FACILITY IN THE PRECEDING 12 MONTHS AND ANNUALLY THEREAFTER.

476 (D) THE APPLICANT SHALL PARTICIPATE IN A DATA REGISTRY, ADMINISTERED BY THE
477 DEPARTMENT OR ITS DESIGNEE. THE DEPARTMENT OR ITS DESIGNEE SHALL REQUIRE THAT
478 THE APPLICANT SUBMIT DATA ON ALL CONSECUTIVE CASES OF PRIMARY PCI AS IS
479 NECESSARY TO COMPREHENSIVELY ASSESS AND PROVIDE COMPARATIVE ANALYSES OF
480 CASE SELECTION, PROCESSES AND OUTCOME OF CARE, AND TREND IN EFFICIENCY. THE
481 APPLICANT SHALL PROVIDE THE REQUIRED DATA IN A FORMAT ESTABLISHED BY THE
482 DEPARTMENT OR ITS DESIGNEE. THE APPLICANT SHALL BE LIABLE FOR THE COST OF DATA
483 SUBMISSION AND ON-SITE REVIEWS IN ORDER FOR THE DEPARTMENT TO VERIFY AND
484 MONITOR VOLUMES AND ASSURE QUALITY.

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486 (6) THE AGREEMENTS AND ASSURANCES REQUIRED BY THIS SECTION SHALL BE IN THE
 487 FORM OF A CERTIFICATION AGREED TO BY THE APPLICANT OR ITS AUTHORIZED AGENT.
 488

489 **Section9. Methodology for computing cardiac catheterization equivalents – procedures and**
 490 **weights**

491
 492 Sec..9. (1) The following procedure equivalents shall be used in calculating and evaluating utilization
 493 of a cardiac catheterization laboratory:
 494
 495

| PROCEDURE TYPE | PROCEDURE EQUIVALENT | |
|---|---|---|
| | Adult | Pediatric |
| Diagnostic cardiac catheterization | 1.0 | 3.0 |
| Therapeutic cardiac catheterization | 1.5 | 3.0 |
| Therapeutic,other (PFO/ASD/Valvuloplasty,LVAD) | 2.5 | 3.5 |
| Diagnostic, peripheral ¹ | 1.0 | 2.0 |
| Therapeutic, peripheral – Carotid, Subclavian, Renal, Iliac, Mesenteric | 1.5 | 2.5 |
| Therapeutic, peripheral – Superficial Femoral Artery | 2.5 | 2.5 |
| Therapeutic, peripheral – Infrapopliteal | 3.0 | 3.0 |
| Therapeutic, peripheral – Aorta | 4.0 | 4.0 |
| Diagnostic, electro physiology (EP) | 2.0 | 3.5 |
| Therapeutic, EP – Permanent Pacemaker, ICD | 2.5 | 5.0 |
| Therapeutic, EP – Ablation Non-AF | 3.0 | 5.0 |
| Therapeutic, EP – Ablation AF or VT | 4.0 | 6.0 |
| Therapeutic, EP – Cardioversion | 1.0 | 1.0 |
| Other procedures (IVC Filter, Temporary Venous Pacemaker, IABP, other radiological procedures) | 1.0 | 2.0 |
| Multiple procedures within the same session (diagnostic and/or therapeutic) | The sum of procedure weights minus 0.5 for each procedure after the first procedure | The sum of procedure weights minus 0.5 for each procedure after the first procedure |
| ¹ Excludes selective common femoral angiography when performed as part of a diagnostic or therapeutic cardiac catheterization for a possible closure device. | | |

496
 497 (2) For purposes of evaluating whether an applicant meets applicable volume requirements set forth
 498 in these standards, cardiac catheterization procedures per laboratory must be met exclusive of the intra-
 499 vascular catheterization procedures when considering expansion or replace/upgrade. The peripheral
 500 non-cardiac procedures shall count toward the total volume requirements for procedures, but the
 501 minimum volumes remain the same for initiation of cardiac catheterization services.

502 (a) Intra-vascular catheterization is a medical diagnostic or therapeutic procedure during which a
 503 catheter is inserted into an artery in a patient. Subsequently, the free end of the catheter is manipulated
 504 by a physician to travel along the course of a non-coronary artery. X-rays and an electronic image
 505 intensifier are used as aids in placing the catheter tip into the desired position. When the catheter is in
 506 place, the physician is able to perform various diagnostic studies and/or therapeutic procedures in the
 507 artery. Intra-vascular catheterization shall not include "float catheters" or "hemodynamic monitoring
 508 catheters" which are performed, and/or are used at the bedside for the purposes of monitoring or
 509 administering hemodynamic medication.
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Section 10. Documentation of projections

Sec. 10. An applicant required to project volumes of service under sections 4, 5, 6, and 7 shall specify how the volume projections were developed. This specification of the projections shall include a description of the data source(s) used, assessments of the accuracy of these data, and the statistical method used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.

Section 11. COMPARATIVE REVIEWS; Effect on prior CON Review Standards

Sec. 11. PROPOSED PROJECTS REVIEWED UNDER THESE STANDARDS SHALL NOT BE SUBJECT TO COMPARATIVE REVIEW. These CON Review Standards supercede and replace the CON Standards for Cardiac Catheterization Services approved by the CON Commission on DECEMBER 11, 2007 and effective on FEBRUARY 25, 2008.

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Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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