

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR SURGICAL SERVICES

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

Section 1. Applicability

Sec. 1. (1) These standards are requirements for the approval of the initiation, replacement, expansion, or acquisition of a surgical service provided in a surgical facility and the delivery of these services under Part 222 of the Code. Surgical services provided in a freestanding surgical outpatient facility, an ambulatory surgery center certified under title XVIII, or a surgical department of a hospital licensed under Part 215 of the Code and offering inpatient or outpatient surgical services are covered clinical services. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

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

(a) "Ambulatory surgical center" or "ASC" means any distinct entity certified by Medicare as an ASC under the provisions of Title 42, Part 416 that operates exclusively for the purpose of providing surgical services IN A CON-APPROVED OPERATING ROOM to patients not requiring hospitalization, AND DEFINED AS A HEALTH FACILITY FOR PURPOSES OF PART 222 OF THE CODE.

(b) "Burn care" means surgical services provided to burn patients in a licensed hospital site that has been verified as meeting the "Guidelines for Development and Operation of Burn Centers" issued by the American Burn Association in March 1988, or equivalent standards for a burn center.

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

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

(e) "CRITICAL ACCESS HOSPITAL" OR "CAH" MEANS A HOSPITAL DESIGNATED BY CMS PURSUANT TO 42 CFR 485.606.

(f) "Cystoscopy" means direct visual examination of the urinary tract with a cystoscope.

(g) "Cystoscopy case" means a single visit to an operating room during which one or more cystoscopic procedures are performed.

(h) "DEDICATED DIALYSIS ACCESS CENTER" MEANS A FSOE OR ASC USED EXCLUSIVELY FOR DIALYSIS ACCESS CASES.

(i) "Dedicated endoscopy or cystoscopy operating room" means a room used exclusively for endoscopy or cystoscopy cases. (j) "Department" means the Michigan Department of Health and Human Services (MDHHS)

(k) "DIALYSIS ACCESS" MEANS THE PHYSICAL CONDUIT BEING USED TO ACCESS THE PATIENT IN ORDER TO PROVIDE DIALYSIS.

(l) "DIALYSIS ACCESS CASE" MEANS A SINGLE VISIT TO AN OPERATING ROOM DURING THE PERFORMANCE OF ONE OR MORE PROCEDURES FOR A PATIENT TO ESTABLISH OR MAINTAIN DIALYSIS ACCESS FOR THE PURPOSE OF PROVIDING HEMODIALYSIS OR PERITONEAL DIALYSIS FOR THE TREATMENT OF ADVANCED CHRONIC KIDNEY DISEASE, END STAGE RENAL DISEASE OR OTHER QUALIFYING CONDITION REQUIRING DIALYSIS. THESE PROCEDURES MAY INCLUDE VENOGRAPHY, FLUOROSCOPIC GUIDANCE OF CENTRAL VENOUS DIALYSIS ACCESS DEVICES, VASCULAR CATHETER PLACEMENT, REPAIR, REMOVAL, AND REPLACEMENT, VASCULAR CATHETER THROMBOLYSIS, REMOVAL OF OBSTRUCTIONS,

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55 FISTULAGRAMS, ANGIOPLASTY, ANGIOGRAM, STENT PLACEMENT, PERCUTANEOUS
56 THROMBECTOMY, PERCUTANEOUS FISTULA CREATION, PERCUTANEOUS PERITONEAL
57 DIALYSIS CATHETER PLACEMENT, REPAIR, REMOVAL, AND REPLACEMENT.

58 (m) "Emergency Room" means a designated area in a licensed hospital and recognized by the
59 Department as having met the staffing and equipment requirements for the treatment of emergency
60 patients.

61 (n) "Endoscopy" means visual inspection of any portion of the body by means of an endoscope.

62 (o) "Endoscopy case" means a single visit to an operating room during which one or more endoscopic
63 procedures are performed.

64 (p) "Existing surgical service" means a surgical facility that, on the date an application is submitted to
65 the Department, is part of a licensed hospital site, a licensed freestanding surgical outpatient facility, or a
66 certified ASC.

67 (q) "Freestanding surgical outpatient facility" or "FSOF" means a health facility licensed under Part 208
68 of the Code AND PROVIDES OUTPATIENT SURGICAL SERVICES IN A CON-APPROVED
69 OPERATING ROOM. It does not include a surgical outpatient facility owned and operated as a part of a
70 licensed hospital site. A freestanding surgical outpatient facility is a health facility for purposes of Part 222 of
71 the Code.

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

73 (s) "Hours of use" means the actual time in hours, and parts thereof, an operating room is used to
74 provide surgical services. It is the time from when a patient enters an operating room until that same patient
75 leaves that same room. It excludes any pre- or post-operative room set-up or clean-up preparations, or any
76 time a patient spends in pre- or post-operative areas including a recovery room.

77 (t) "Licensed hospital site" means either:

78 (i) in the case of a single site hospital, the location of the hospital authorized by license and listed on
79 that licensee's certificate of licensure or

80 (ii) in the case of a hospital with multiple sites, the location of each separate and distinct inpatient site
81 as authorized by licensure.

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

84 (v) "MEDICARE DEPENDENT HOSPITAL" OR "MDH" MEANS A HOSPITAL DESIGNED BY CMS
85 PURSUANT TO 42 CFR 412.108.

86 (w) "Offer" means to perform surgical services.

87 (x) "Operating room" or "OR" means a room in a surgical facility constructed and equipped to perform
88 surgical cases and located on a sterile corridor. The term also includes a room constructed and equipped to
89 perform surgical cases on a nonsterile corridor if the room is located in an FSOF or ASC that is used
90 exclusively for endoscopy or cystoscopy cases. This term does not include procedure rooms.

91 (y) "Operating suite," for purposes of these standards, means an area in a surgical facility that is
92 dedicated to the provision of surgery. An operating suite includes operating rooms, pre- and post-operative
93 patient areas, clean and soiled utility and linen areas, and other support areas associated with the provision
94 of surgery.

95 (z) "Outpatient surgery" means the provision of surgical services performed in a hospital, FSOF, or
96 ASC, requiring anesthesia or a period of postoperative observation, or both, to patients whose admission to
97 a hospital for an overnight stay is not anticipated- as being medically necessary.

98 (aa) "Procedure room" means a room in a surgical facility constructed and equipped to perform surgical
99 procedures and not located on a sterile corridor. PROCEDURES CONDUCTED IN PROCEDURE ROOMS
100 ARE NOT CONSIDERED SURGICAL CASES.

101 (bb) "Renovate an existing surgical service or one or more operating rooms" means a project that:

102 (i) involves the renovation, remodeling, or modernization of an operating suite of a hospital, FSOF, or
103 ASC;

104 (ii) does not involve new construction;

105 (iii) does not involve a change in the physical location within the surgical facility at the same site; and

106 (iv) does not result in an increase in the number of operating rooms at an existing surgical facility.

107 Renovation of an existing surgical service or one or more operating rooms may involve a change in the
108 number of square feet allocated to an operating suite. The renovation of an existing surgical service or one

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109 or more operating rooms shall not be considered the initiation, expansion, replacement, or acquisition of a
110 surgical service or one or more operating rooms.

111 (cc) "SOLE COMMUNITY HOSPITAL" OR "SCH" MEANS A HOSPITAL DESIGNATED BY CMS
112 PURSUANT TO 42 CFR 412.92.

113 (dd) "Sterile corridor" means an area of a surgical facility designated primarily for surgical cases and
114 surgical support staff. Access to this corridor is controlled and the corridor is not used by the general public
115 or personnel of the surgical facility whose primary work station is not in the operating suite(s) or whose
116 primary work tasks do not require them to be in the operating suite(s) of a surgical facility. Examples of
117 personnel who would normally use sterile corridors include physicians, surgeons, operating room nurses,
118 laboratory or radiology personnel, and central supply or housekeeping personnel. Other terms commonly
119 used to represent "sterile" in describing access areas include "restricted," "controlled," "limited access," or
120 "clean."

121 (ee) "Surgical case" means a single visit to an operating room during which one or more surgical
122 procedures are performed IN A CON-APPROVED OPERATING ROOM.

123 (ff) "Surgical facility" means either:

124 (i) a licensed FSOF;

125 (ii) a certified ASC; or

126 (iii) a licensed hospital site authorized to provide inpatient or outpatient surgery.

127 (gg) "Surgical service" means performing surgery in a surgical facility.

128 (hh) "Trauma care," for purposes of these standards, means surgical services provided to a trauma patient in
129 a licensed hospital site that has been verified as meeting the standards of the American College of
130 Surgeons for a Level I or II trauma center, or equivalent standards.

131 (ii) "Verifiable data" means surgical data (cases and/or hours) from the most recent Annual Survey or more
132 recent data that can be validated by the Department.

133

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

135

136 Section 3. Inventory of operating rooms used to perform surgical services; surgical cases, or hours 137 of use; and evaluating compliance with minimum volume requirements

138

139 Sec. 3. (1) The Department shall use the number of operating rooms and verifiable data pursuant to
140 subsection (2) to determine the number of surgical cases, hours of use, or both, as applicable, pursuant to
141 subsection (3) for purposes of evaluating compliance with the actual and proposed volume requirements set
142 forth in the applicable sections of these standards. Compliance with CON minimum volume requirements
143 established by these standards shall be determined based on the average number of surgical cases, hours
144 of use, or both, per operating room of the surgical service as permitted by these standards.

145

146 (2) The number of operating rooms for each type of surgical facility shall be determined as follows:

147 (a) In a licensed hospital site, all operating rooms in which surgery is or will be performed excluding:

148 (i) A delivery room(s) if that room is located in an area of a licensed hospital site designated primarily
149 for obstetrical services.

150 (ii) An operating room that is or will be used exclusively for endoscopy or cystoscopy cases.

151 (iii) An operating room in which a fixed lithotripter is or will be located and utilized. A mobile lithotripter
152 shall not be considered as an operating room.

153 (iv) An operating room that is or will be used, though not exclusively, to provide surgical services to
154 patients requiring burn care or trauma care, as those terms are defined in these standards. No more than
155 0.5 burn care and 0.5 trauma care operating rooms shall be excluded pursuant to this subdivision, and
156 precludes the use of the room in subsection (2)(a)(v).

157 (v) An operating room that is or will be used exclusively to provide surgical services to patients
158 requiring burn care or trauma care, as those terms are defined in these standards. No more than 1 burn
159 care and 1 trauma care operating room shall be excluded pursuant to this subdivision, and precludes the
160 use of the room in subsection (2)(a)(iv).

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161 (vi) A hybrid ORCCL shall have 0.5 excluded for each room meeting the requirements of section of
162 these standards. A surgical facility will not be limited to the number of hybrid ORCCLs within a single
163 licensed facility.

164 (b) In an FSOF or ASC that is or will be used exclusively for endoscopy, cystoscopy, OR DIALYSIS
165 ACCESS cases all rooms in which endoscopy, cystoscopy, OR DIALYSIS ACCESS cases are or will be
166 performed.

167 (c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy, cystoscopy OR
168 DIALYSIS ACCESS cases, all operating rooms in which surgery is or will be performed, excluding any
169 operating rooms used exclusively for endoscopy, cystoscopy, OR DIALYSIS ACCESS cases.

170
171 (3) The number of surgical cases, or hours of use, shall be determined as follows:

172 (a) In a licensed hospital site, all surgical cases, or hours of use, performed in operating rooms,
173 including surgical cases, or hours of use, performed in an operating room identified in subsections (2)(a)(iv),
174 (v), and (vi) but excluding the surgical cases, or hours of use, performed in operating rooms identified in
175 subsection (2)(a)(i), (ii), and (iii).

176 (b) In an FSOF or ASC that is or will be used exclusively for endoscopy, cystoscopy, OR DIALYSIS
177 ACCESS cases, all endoscopy, cystoscopy, OR DIALYSIS ACCESS cases, or hours of use, performed in
178 the operating rooms identified in subsection (2)(b).

179 (c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy, cystoscopy, OR
180 DIALYSIS ACCESS cases, all surgical cases, or hours of use, performed in the operating rooms identified in
181 subsection (2)(c). Cases, or hours of use, performed in any operating room used exclusively for endoscopy,
182 cystoscopy, OR DIALYSIS ACCESS cases, shall be excluded.

183 184 Section 4. Requirements to initiate a surgical service

185 Sec. 4. To initiate a surgical service means to begin operation of a surgical facility at a site that has not
186 offered surgical services within the 12-month period immediately preceding the date an application is
187 submitted to the Department. An applicant proposing to initiate a surgical service shall demonstrate the
188 following, as applicable to the proposed project.

189
190 (1) Each proposed operating room shall perform an average of at least 1,128 surgical cases per year
191 per operating room in the second 12 months of operation.

192
193 (2) Subsection (1) shall not apply if the proposed project involves the initiation of a surgical service with
194 1 or 2 operating rooms at a licensed hospital THAT IS A CRITICAL ACCESS HOSPITAL, SOLE
195 COMMUNITY HOSPITAL, OR MEDICARE DEPENDENT HOSPITAL, OR A LICENSED HOSPITAL site
196 located in a rural or micropolitan statistical area county that does not offer surgical services as of the date an
197 application is submitted to the Department.

198
199 (3) An applicant shall demonstrate that it meets the requirements of Section 11(2) for the number of
200 surgical cases projected under subsection (1).

201 (a) Section 11(2)(d) shall not apply if the proposed project involves the initiation of a surgical service at
202 a new FSOF or a new ASC at a new geographical site utilizing the historical surgical cases of the applicant
203 and the new service is owned by the same applicant.

204 (4) AN APPLICANT PROPOSING TO INITIATE A DEDICATED DIALYSIS ACCESS CENTER
205 SHALL ONLY USE DIALYSIS ACCESS CASES IN ACCORDANCE WITH SECTION 11 (1)(e).

206 207 Section 5. Requirements to replace a surgical service

208
209 Sec. 5. To replace a surgical service or one or more operating rooms, means:

210 (i) THE development of new space (whether through new construction, purchase, lease or similar
211 arrangement) to house one or more operating rooms operated by an applicant at the same site as the
212 operating room(s) to be replaced;

213 (ii) DESIGNATING an OR as a dedicated endoscopy or cystoscopy OR;

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214 (iii) RELOCATING an existing surgical facility WITH one or more operating rooms to a new geographic
215 location of THAT existing surgical facility; or

216 (iv) RELOCATING one or more operating rooms OF AN EXISTING SURGICAL FACILITY to a different
217 GEOGRAPHIC location currently offering surgical services AS ANOTHER EXISTING SURGICAL
218 FACILITY.

219 (v) The term does not include the renovation of an existing surgical service or one or more operating
220 rooms.

221 (vi) An applicant requesting to replace an existing surgical service shall demonstrate each of the
222 following, as applicable to the proposed project.

223

224 (1) An applicant proposing to replace shall demonstrate:

225 (a) All existing operating rooms in the existing surgical facility have performed an average of at least
226 THE FOLLOWING, UTILIZING THE MOST RECENT 12 MONTHS OF DATA WHICH IS VERIFIABLE BY
227 THE DEPARTMENT:

228 (i) 1,042 surgical cases per operating room, or

229 (ii) 1,125 hours of use in a facility that performs only outpatient surgery, per operating room or

230 (iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average
231 of inpatient hours of use and outpatient hours of use, as billed by the facility, per operating room and
232 calculated as follows:

233 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus
234 the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours
235 would equate to $375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00$ OR.), or

236 (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average
237 of INPATIENT hours of use and OUTPATIENT surgical cases, as billed by the facility, per operating room
238 and calculated as follows:

239 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus
240 the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases
241 would equate to $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$ OR.)

242

243

244 (2) An applicant proposing to replace one or more operating rooms at a licensed hospital and is located
245 in a rural or micropolitan county or the applicant is located in a city, village, or township with a population of
246 not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most
247 recent federal decennial census OR THE APPLICANT IS A CRITICAL ACCESS HOSPITAL, SOLE
248 COMMUNITY HOSPITAL, OR MEDICARE DEPENDENT HOSPITAL shall demonstrate each of the
249 following:

250 (a) The applicant has LESS THAN SIX ORS at the licensed hospital.

251 (b) All existing operating rooms have performed an average of at least ONE OF THE FOLLOWING
252 UTILIZING THE MOST RECENT 12 MONTHS OF DATA VERIFIABLE BY THE DEPARTMENT:

253 (i) 839 surgical cases per operating room, or

254 (ii) 906 hours of use per operating room.

255

256

257 (3) Subsections (1) and (2) shall not apply if the proposed project involves replacing one or more
258 operating rooms at the same licensed hospital site IS A CRITICAL ACCESS HOSPITAL, SOLE
259 COMMUNITY HOSPITAL, OR MEDICARE DEPENDENT HOSPITAL, OR if the surgical facility is located in
260 a rural or micropolitan statistical area county and has one or two operating rooms.

261

262 (4) Subsections (1) and (2) shall not apply to those hospitals licensed under Part 215 of PA 368 of
263 1978, as amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs
264 at the surgical service has not increased as of March 31, 2003, and the location does not change.

265

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266 (5) An applicant proposing to designate an OR as a dedicated endoscopy or cystoscopy OR shall
267 submit notification to the Department on a form provided by the Department. An applicant under this
268 subsection shall not be required to comply with subsections (1) and (2).
269

270 (6) An applicant proposing to relocate an existing surgical service or one or more operating rooms shall
271 demonstrate each of the following, as applicable:

272 (a) The proposed new site is within a 10-mile radius of the site at which an existing surgical service is
273 located if an existing surgical service is located in a metropolitan statistical area county, or a 20-mile radius if
274 an existing surgical service is located in a rural or micropolitan statistical area county.

275 (b) All existing operating rooms in the surgical facility from which one or more ORs are proposed to be
276 relocated have performed an average of at least **ONE OF THE FOLLOWING UTILIZING THE MOST**
277 **RECENT 12 MONTHS OF DATA VERIFIABLE BY THE DEPARTMENT:**

278 (i) 1,042 surgical cases per operating room, or

279 (ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room or,

280 (iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average
281 of inpatient hours of use and outpatient hours of use, as billed by the facility, per operating room and
282 calculated as follows:

283 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus
284 the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours
285 would equate to $375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00$ OR.), or

286 (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average
287 of **INPATIENT** hours of use and **OUTPATIENT** surgical cases, as billed by the facility, per operating room
288 calculated as follows:

289 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus
290 the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases
291 would equate to $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$ OR.)

292 (v) **AN EXISTING SURGICAL FACILITY APPLICANT THAT IS PROPOSING TO RELOCATE ONE**
293 **OR MORE OPERATING ROOMS TO ANOTHER EXISTING SURGICAL FACILITY IS NOT REQUIRED**
294 **TO MEET SUBSECTIONS 5(6)(B)(I)-(IV).**

295 (vi) **THE RELOCATED OPERATING ROOMS SHALL BE LICENSED TO THE RECEIVING EXISTING**
296 **SURGICAL FACILITY AND THE APPLICANT SHALL AGREE TO DECREASE THEIR TOTAL NUMBER**
297 **OF OPERATING ROOMS, AS APPLICABLE.**

298 (c) All operating rooms, existing and relocated, **AT THE RECEIVING EXISTING SURGICAL FACILITY,**
299 are projected to perform an average of at least **THE FOLLOWING IN THE SECOND TWELVE MONTHS**
300 **OF OPERATIONS:**

301 (i) 1,042 surgical cases per operating room or

302 (ii) 1,125 hours of use in a facility that performs only outpatient surgery per operating room, and
303 annually thereafter, or

304 (iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average
305 of inpatient hours of use and outpatient hours of use, as billed by the facility, per operating room,, and
306 annually thereafter and calculated as follows:

307 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus
308 the outpatient **SURGICAL** hours divided by 1,125. (For example: Using 375 inpatient hours and 844
309 outpatient hours would equate to $375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00$ OR.) or

310 (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average
311 of **INPATIENT** hours of use and **OUTPATIENT** surgical cases, as billed by the facility, per operating room,
312 and annually thereafter and calculated as follows:

313 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus
314 the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases
315 would equate to $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$ OR.)

316 (d) **THE EXISTING SURGICAL SERVICE FROM WHICH THE OPERATING ROOMS ARE BEING**
317 **RELOCATED, AND THE EXISTING SURGICAL SERVICE RECEIVING THE OPERATING ROOMS,**
318 **SHALL NOT REQUIRE ANY OWNERSHIP RELATIONSHIP.**
319

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(7) Subsection (6) shall not apply if the proposed project involves relocating one or two operating rooms within a 20-mile radius if the surgical facility IS A CRITICAL ACCESS HOSPITAL, SOLE COMMUNITY HOSPITAL, OR MEDICARE DEPENDENT HOSPITAL, OR is located in a rural or micropolitan statistical area county.

(8) An applicant proposing to relocate AN EXISTING SURGICAL SERVICE OR one or more operating rooms from one licensed hospital site to another licensed hospital site and is located in a rural or micropolitan county or the applicant is located in a city, village, or township with a population of not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most recent federal decennial census OR THE APPLICANT IS A CRITICAL ACCESS HOSPITAL, SOLE COMMUNITY HOSPITAL, OR MEDICARE DEPENDENT HOSPITAL, shall demonstrate each of the following:

(a) The applicant has LESS THAN SIX ORS at the licensed hospital FROM WHICH ONE OR MORE OPERATING ROOMS ARE PROPOSED TO BE RELOCATED.

(b) All existing operating rooms have performed an average of at least ONE OF THE FOLLOWING UTILIZING THE MOST RECENT 12 MONTHS OF DATA THAT IS VERIFIABLE BY THE DEPARTMENT:

(i) 839 surgical cases per operating room, or

(ii) 906 hours of use per operating room,

(iii) AN EXISTING LICENSED HOSPITAL THAT IS PROPOSING TO RELOCATE ONE OR MORE OPERATING ROOMS TO ANOTHER EXISTING LICENSED HOSPITAL IS NOT REQUIRED TO MEET SUBSECTIONS 5(8)(b)(i)-(ii),

(iv) THE RELOCATED OPERATING ROOMS SHALL BE LICENSED TO THE RECEIVING EXISTING LICENSED HOSPITAL AND THE APPLICANT SHALL AGREE TO DECREASE THEIR TOTAL NUMBER OF OPERATING ROOMS, AS APPLICABLE.

(c) All operating rooms, existing and relocated, AT THE RECEIVING LICENSED HOSPITAL are projected to perform an average of at least THE FOLLOWING IN THE SECOND TWELVE MONTHS OF OPERATIONS:

(i) 839 surgical cases per operating room or

(ii) 906 hours of use per operating room.

(d) THE EXISTING LICENSED HOSPITAL FROM WHICH THE OPERATING ROOMS ARE BEING RELOCATED, AND THE EXISTING LICENSED HOSPITAL RECEIVING THE OPERATING ROOMS, SHALL NOT REQUIRE ANY OWNERSHIP RELATIONSHIP.

(9) An applicant shall demonstrate that it meets the requirements of Section 11(2) for the number of surgical cases, or hours of use, projected under subsections (6) and (8).

Section 6. Requirements to expand an existing surgical service

Sec. 6. To expand a surgical service means the addition of one or more operating rooms at an existing surgical service. This term also includes the change from a dedicated endoscopy or cystoscopy OR to a non-dedicated OR. An applicant proposing to add one or more operating rooms at an existing surgical service shall demonstrate each of the following as applicable, to the proposed project.

(1) An applicant shall demonstrate the following:

(a) All existing operating rooms in the existing surgical facility have performed an average of at least ONE OF THE FOLLOWING UTILIZING THE MOST RECENT 12 MONTHS OF DATA THAT IS VERIFIABLE BY THE DEPARTMENT:

(i) 1,216 surgical cases per operating room, or

(ii) 1,313 hours of use in a facility that performs only outpatient surgery per operating room, or

(iii) a licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use, as billed by the facility per year, per operating room, calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,750 plus the outpatient hours divided by 1,313. (For example: Using 438 inpatient hours and 985 outpatient hours would equate to $438/1,750 + 985/1,313 = 0.25 + 0.75 = 1.00$ OR), or

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374 (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average
375 of **INPATIENT** hours of use and **OUTPATIENT** surgical cases, as billed by the facility, per operating room
376 calculated as follows:

377 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,750 plus
378 the outpatient cases divided by 1,216. (For example: Using 438 inpatient hours and 912 outpatient cases
379 would equate to $438/1,750 + 912/1,216 = 0.25 + 0.75 = 1.00$ OR.)

380 **(v) ALL EXPANSION VOLUME UNDER THIS SUBSECTION MUST BE BASED ON EXISTING**
381 **SURGICAL CASES AND/OR HOURS PERFORMED IN EXISTING OPERATING ROOMS, NOT**
382 **PROPOSED, PROJECTED CASES BASED ON A TREND OF INCREASED VOLUME AT A FACILITY.**

383 (b) All proposed operating rooms, **INCLUDING EXISTING OPERATING ROOMS**, are projected to
384 perform an average of at least **THE FOLLOWING IN THE SECOND TWELVE MONTHS OF**
385 **OPERATIONS:**

386 (i) 1,042 surgical cases per operating room or

387 (ii) 1,125 hours of use in a facility that performs only outpatient surgery per operating room, or

388 (iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average
389 of inpatient hours of use and outpatient hours of use as billed by the facility per operating room calculated as
390 follows:

391 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus
392 the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours
393 would equate to $375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00$ OR.), or

394 (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average
395 of **INPATIENT** hours of use and **OUTPATIENT** surgical cases, as billed by the facility, calculated as follows:

396 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus
397 the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases
398 would equate to $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$ OR.)

399 **(c) AN APPLICANT WHOSE EXISTING OPERATING ROOMS IN THE EXISTING SURGICAL**
400 **FACILITY HAVE PERFORMED AN AVERAGE OF AT LEAST 1650 SURGICAL CASES OR 1750 HOURS**
401 **OF USE PER OPERATING ROOM IN THE PREVIOUS 12 MONTHS FOR WHICH VERIFIABLE DATA IS**
402 **AVAILABLE SHALL QUALIFY TO ADD ONE (1) ADDITIONAL OPERATING ROOM AND SHALL NOT BE**
403 **SUBJECT TO SUBSECTIONS (a) OR (b) ABOVE.**

404
405 (2) An applicant proposing to add one or more operating rooms at a licensed hospital located in a rural
406 or micropolitan county or in a city, village, or township with a population of not more than 12,000 and in a
407 county with a population of not more than 110,000 as defined by the most recent federal decennial census,
408 **OR THE APPLICANT IS A CRITICAL ACCESS HOSPITAL, SOLE COMMUNITY HOSPITAL, OR**
409 **MEDICARE DEPENDENT HOSPITAL**, shall demonstrate each of the following:

410 (a) The applicant has **LESS THAN SIX ORS** at the licensed hospital.

411 (b) All existing operating rooms have performed an average of at least **ONE OF THE FOLLOWING**
412 **UTILIZING THE MOST RECENT 12 MONTHS OF DATA VERIFIABLE BY THE DEPARTMENT:**

413 (i) 979 surgical cases per operating room, or

414 (ii) **1,057** hours of use per operating room..

415 (c) All proposed operating rooms, **INCLUDING EXISTING OPERATING ROOMS**, are projected to
416 perform an average of at least **THE FOLLOWING IN THE SECOND TWELVE MONTHS OF**
417 **OPERATIONS:**

418 (i) 839 surgical cases per operating room, or

419 (ii) **906** hours of use per operating room.

420
421 (3) Subsections (1) and (2) shall not apply if the proposed project involves adding a second operating
422 room in a licensed hospital site located in a rural or micropolitan statistical area county that currently has
423 only one operating room.

424
425 (4) An applicant shall demonstrate that it meets the requirements of Section 11(2) for the number of
426 surgical cases, or hours of use, projected under subsections (1) and (2).

427

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428 (5) FOR AN APPLICANT PROPOSING TO ADD ONE OR MORE OPERATING ROOMS TO A
429 DEDICATED DIALYSIS ACCESS CENTER THAT APPLICANT SHALL ONLY USE DIALYSIS ACCESS
430 CASES SUBJECT TO SECTION 11 (1)(e).
431

432 **Section 7. Requirements to acquire an existing surgical service**

433
434 Sec. 7. Acquisition of a surgical service means a project involving the issuance of a new license for a
435 hospital or a freestanding surgical outpatient facility or a new certification as an ambulatory surgical center
436 as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an
437 existing surgical service. An applicant proposing to acquire an existing surgical service shall demonstrate
438 each of the following, as applicable to the proposed project.
439

440 (1) An applicant agrees and assures to comply with all applicable project delivery requirements.
441

442 (2) For the first application proposing to acquire an existing surgical service, for which a final decision
443 has not been issued, on or after January 27, 1996, the existing surgical service shall not be required to be in
444 compliance with the applicable volume requirements set forth in these standards. The surgical service shall
445 be operating at the applicable volume requirements in the second 12 months after the effective date of the
446 acquisition.
447

448 (3) For any application proposing to acquire an existing surgical service except the first application, for
449 which a final decision has not been issued, on or after January 27, 1996, the existing surgical service shall
450 be required to be in compliance with the applicable volume requirements on the date the application is
451 submitted to the Department.

452 (4) Subsection (3) shall not apply to those hospitals licensed under Part 215 of PA 368 of 1978, as
453 amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs at the
454 surgical service has not increased as of March 31, 2003, and the location does not change.
455

456 **Section 8. Requirements for a Hybrid Operating Room/Cardiac Catheterization Laboratory (OR/CCL)**

457
458 Sec. 8. A hybrid or/ccl means an operating room located on a sterile corridor and equipped with an
459 angiography system permitting minimally invasive procedures of the heart and blood vessels with full
460 anesthesia capabilities. An applicant proposing to add one or more hybrid OR/CCLS at an existing surgical
461 service shall demonstrate each of the following:
462

463 (1) The applicant operates an open heart surgery service which is in full compliance with the current
464 con review standards for open heart surgery services.
465

466 (2) If the hybrid OR/CCL(s) represents an increase in the number of licensed operating rooms at the
467 facility, the applicant is in compliance with Section 6 of these standards.
468

469 (3) If the hybrid OR/CCL(s) represents conversion of an existing operating room(s), the applicant is in
470 compliance with the provisions of Section 5, if applicable.
471

472 (4) The applicant meets the applicable requirements of the CON review standards for cardiac
473 catheterization services.

474 (5) Each case performed in a hybrid OR/CCL shall be included either in the surgical volume or the
475 therapeutic cardiac catheterization volume of the facility. No case shall be counted more than once.
476

477 **Section 9. Requirements for Medicaid Participation**

478
479 Sec. 9. An applicant shall provide Verification of **THE FACILITY'S** Medicaid participation. An
480 applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid
481 participation will be provided to the Department within six (6) months from the offering of services if a

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482 CON is approved. AN INDIVIDUAL PHYSICIAN'S NATIONAL PROVIDER IDENTIFIER (NPI) NUMBER
483 SHALL NOT SUFFICE AS PROOF OF A FACILITY'S MEDICAID PARTICIPATION.
484

485 Section 10. Project delivery requirements terms of approval for all applicants 486

487 Sec. 10. An applicant shall agree that, if approved, the surgical services shall be delivered in
488 compliance with the following terms of approval:
489

490 (1) Compliance with these standards.
491

492 (2) (a) Compliance with the following quality assurance standards:

493 (i) The designation of ORs as defined by the standards shall not be changed without prior notification
494 to the Department.

495 (ii) Surgical facilities shall have established policies for the selection of patients and delineate
496 procedures which may be performed in that particular facility.

497 (iii) Surgical facilities shall have provisions for handling all types of in-house emergencies, including
498 cardiopulmonary resuscitation.

499 (iv) Surgical facilities performing outpatient surgery shall have policies which allow for hospitalization of
500 patients when necessary. All surgeons who perform surgery within the facility shall have evidence of
501 admitting privileges or of written arrangements with other physicians for patient admissions at a local
502 hospital. The surgical facility shall have an established procedure, including a transfer agreement that
503 provides for the immediate transfer of a patient requiring emergency care beyond the capabilities of the
504 surgical facility to a hospital that is capable of providing the necessary inpatient services and is located
505 within 30 minutes of the surgical facility. If no hospital is located within 30 minutes of the surgical facility, an
506 applicant shall have a transfer agreement with the nearest hospital having such capability.

507 (v) An applicant shall have written policies and procedures regarding the administration of a surgical
508 facility.

509 (vi) An applicant shall have written position descriptions which include minimum education, licensing, or
510 certification requirements for all personnel employed at the surgical facility.

511 (vii) An applicant shall have a process for credentialing individuals authorized to perform surgery or
512 provide anesthesia services at a surgical facility. An applicant's credentialing process shall insure that the
513 selection and appointment of individuals to the staff of a surgical facility does not discriminate on the basis of
514 licensure, registration, or professional education as doctors of medicine, osteopathic medicine and surgery,
515 podiatric medicine and surgery, or dentistry.

516 (viii) An applicant shall provide laboratory, diagnostic imaging, pathology and pharmacy (including
517 biologicals) services, either on-site or through contractual arrangements.

518 (ix) An applicant shall have written policies and procedures for advising patients of their rights.

519 (x) An applicant shall develop and maintain a system for the collection, storage, and use of patient
520 records.

521 (xi) Surgical facilities shall have separate patient recovery and non-patient waiting areas.

522 (xii) Surgical facilities shall provide a functionally safe and sanitary environment for patients, personnel,
523 and the public. Each facility shall incorporate a safety management a physical environment free of hazards
524 and to reduce the risk of human injury.

525 (b) For purposes of evaluating subsection (a), the Department shall consider it prima facie evidence as
526 to compliance with the applicable requirements if an applicant surgical facility is accredited by the Joint
527 Commission on the Accreditation of Healthcare Organizations, or the Accreditation Association for
528 Ambulatory Health Care, or certified by Medicare as an ambulatory surgical center.

529 (c) The operation of and referral of patients to the surgical facility shall be in conformance with 1978 PA
530 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).
531

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

533 (a) The applicant, to assure appropriate utilization by all segments of the Michigan population, shall:

534 (b) not deny surgical services to any individual based on ability to pay or source of payment;

535 (c) provide surgical services to any individual based on the clinical indications of need for the service.

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536 (d) maintain information by payer and non-paying sources to indicate the volume of care from each
537 source provided annually. Compliance with selective contracting requirements shall not be construed as a
538 violation of this term.

539 (e) An applicant shall participate in Medicaid or in Medicaid managed care products at least 12
540 consecutive months within the first two years of operation and continue to participate annually thereafter
541 or attest that the applicant has been unable to contract with Medicaid managed care products at current
542 Medicaid rates.

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

544 (a) Existing operating rooms shall perform an average of at least:

545 (i) 1,042 surgical cases per year per operating room verifiable by the Department, or

546 (ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room
547 verifiable by the Department, or

548 (iii) Be in compliance using the applicable weighted averages under Section 5.

549 (b) Existing operating rooms, located in a rural or micropolitan county, or within a city, village, or
550 township with a population of not more than 12,000 and in a county with a population of not more than
551 110,000 as defined by the most recent Federal decennial census **OR THE FACILITY IS A CRITICAL**
552 **ACCESS HOSPITAL, SOLE COMMUNITY HOSPITAL, OR MEDICARE DEPENDENT HOSPITAL** in a
553 surgical service that has **LESS THAN 6 OR's** shall perform an average of at least:

554 (i) 839 surgical cases per year per operating room verifiable by the Department or

555 (ii) **906** hours of use ~~per year~~ per operating room verifiable by the Department.

556 (c) The applicant shall participate in a data collection System established and administered by the
557 Department. The data may include, but is not limited to, hours of use of operating rooms, annual budget
558 and cost information, operating schedules, and demographic, diagnostic, morbidity and mortality
559 information, as well as the volume of care provided to patients from all payer sources. An applicant shall
560 provide the required data on a separate basis for each licensed or certified site, in a format established by
561 the department, and in a mutually agreed upon media. The Department may elect to verify the data through
562 on-site review of appropriate records. **MINIMUM VOLUME REQUIREMENTS SHALL NOT APPLY IF THE**
563 **LICENSED HOSPITAL HAS LESS THAN 3 ORS AND IS A CRITICAL ACCESS HOSPITAL, SOLE**
564 **COMMUNITY HOSPITAL, OR MEDICARE DEPENDENT HOSPITAL, OR IS LOCATED IN A RURAL OR**
565 **MICROPOLITAN COUNTY.**

566 (d) The surgical service shall provide the Department with timely notice of the proposed project
567 implementation consistent with applicable statute and promulgated rules.

568 **(e) THE APPLICANT SHALL PROVIDE NOTICE TO THE DEPARTMENT OF ANY PLANNED**
569 **DECREASE OR DISCONTINUATION OF SERVICE(S) NO LATER THAN 30 DAYS AFTER THE**
570 **PLANNED DECREASE OR DISCONTINUATION OF THE SERVICE(S).**

571
572
573 (5) The agreements and assurances required by this section shall be in the form of a certification
574 agreed to by the applicant or its authorized agent.

575 **Section 11. Documentation of projections**

576
577
578 Sec. 11. (1) An applicant required to project volumes of service shall specify how the volume
579 projections were developed and shall include only those surgical cases performed in an OR.

580 (a) The applicant shall include a description of the data source(s) used as well as an assessment of the
581 accuracy of these data used to make the projections. **THE PROJECTIONS MUST USE MOST RECENT 12**
582 **MONTHS OF DATA VERIFIABLE BY THE DEPARTMENT. IF THE APPLICANT IS NOT UTILIZING**
583 **ANNUAL SURVEY DATA, THEN THEY MUST PROVIDE A DETAILED LIST OF SURGICAL CASES FOR**
584 **EACH COMMITTING FACILITY.** Based on this documentation, the Department shall determine if the
585 projections are reasonable.

586 (b) The Department shall subtract any previous commitment, pursuant to subsection 2(d).

587 **(c) AN APPLICANT COMMITTING CASES FROM A HOSPITAL TO AN FSOFF OR ASC**
588 **APPLICATION, SHALL NOT UTILIZE INPATIENT CASE COMMITMENTS (OR HOURS OF USE) IN**
589 **THE CON APPLICATION FOR PROJECTIONS.**

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590 (d) THE DEPARTMENT SHALL ACCEPT PROJECTIONS THAT INCLUDE APPLYING A
591 SPECIFIED PERCENTAGE OF PROJECTED FUTURE GROWTH IF THAT PERCENTAGE IS LESS
592 THAN OR EQUAL TO THE AVERAGE ANNUAL PERCENTAGE OF GROWTH SEEN AT THE
593 APPLICANT'S FACILITY OVER THE PREVIOUS 5 YEARS.

594 (e) IF AN APPLICANT IS APPLYING FOR A DEDICATED DIALYSIS ACCESS CENTER, THAT
595 APPLICANT SHALL ONLY USE DIALYSIS ACCESS CASES FOR PROJECTED VOLUME. FOR THE
596 PURPOSES TO INITIATE OR EXPAND SURGICAL SERVICES FOR A DEDICATED DIALYSIS ACCESS
597 CENTER, AN APPLICANT MAY USE DIALYSIS ACCESS CASES THAT WERE PERFORMED
598 OUTSIDE OF AN OR AS LONG AS THE DIALYSIS ACCESS CASES WERE PERFORMED IN A
599 FACILITY CERTIFIED BY THE JOINT COMMISSION FOR DIALYSIS ACCESS CASES.

600 (f) AN APPLICANT FACILITY THAT IS NOT OR WILL NOT BE USED EXCLUSIVELY FOR
601 DIALYSIS ACCESS CASES SHALL NOT UTILIZE ANY DIALYSIS ACCESS CASES PERFORMED AT A
602 DEDICATED DIALYSIS ACCESS CENTER IN THE CON APPLICATION FOR PROJECTIONS.

603
604 (2) If a projected number of surgical cases, or hours of use, under subsection (1) includes surgical
605 cases, or hours of use, performed at another existing surgical facility(s), an applicant shall demonstrate, with
606 documentation satisfactory to the Department, that the utilization of the existing surgical facility(s) is in
607 compliance with the volume requirements applicable to that facility, and will continue to be in compliance
608 with the volume requirements (cases and/or hours) applicable to that facility subsequent to the initiation,
609 expansion, or replacement of the surgical services proposed by an applicant. In demonstrating compliance
610 with this subsection, an applicant shall provide each of the following:

611 (a) The name of each physician that performed surgical cases to be transferred to the applicant
612 surgical facility.

613 (b) The number of surgical cases each physician, identified in subdivision (a), performed during the
614 most recent 12-month period for which verifiable data is available.

615 (c) The location(s) at which the surgical cases to be transferred were performed, including evidence
616 that the existing location and the proposed location are within 20 miles of each other.

617 (d) A written commitment from each physician, identified in subdivision (a), that he or she will perform
618 at least the volume of surgical cases to be transferred to the applicant surgical facility for no less than 3
619 years subsequent to the initiation, expansion, or replacement of the surgical service proposed by an
620 applicant.

621 (e) Subsection 11(2)(d) shall not apply if the proposed project involves the initiation of a surgical service
622 at a new FSOF or a new ASC at a new geographical site utilizing the historical surgical cases of the
623 applicant and the new service is owned by the same applicant. The applicant facility committing surgical
624 data has completed the departmental form that certifies the surgical cases were performed at the
625 committing facility and the surgical cases will be transferred to the proposed surgical facility for no less than
626 three years subsequent to the initiation of the surgical service proposed by the applicant.

627 (f) The number of surgical cases performed, at the existing surgical facility from which surgical cases
628 will be transferred, during the most recent 12-month period prior to the date an application is submitted to
629 the Department for which verifiable annual survey data is available.

630
631 (3) An applicant, other than an applicant proposing to initiate a surgical service, may utilize hours of
632 use in documenting compliance with the applicable sections of these standards, if an applicant provides
633 documentation, satisfactory to the Department, from the surgical facility from which the hours of use are
634 being transferred.

635 **Section 12. Effect on prior CON review standards; comparative reviews**

636
637
638 Sec. 12. Proposed projects reviewed under these standards shall not be subject to comparative review.
639 These CON review standards **supersede** and replace the CON Review Standards for Surgical Facilities
640 approved by the CON Commission on **September 21, 2017** and effective on **November 17, 2017**.

Department Recommendation

APPENDIX A

642
643
644 Rural Michigan counties are as follows:

645			
646	Alcona	Gogebic	Ogemaw
647	Alger	Huron	Ontonagon
648	Antrim	Iosco	Osceola
649	Arenac	Iron	Oscoda
650	Baraga	Lake	Otsego
651	Charlevoix	Luce	Presque Isle
652	Cheboygan	Mackinac	Roscommon
653	Clare	Manistee	Sanilac
654	Crawford	Montmorency	Schoolcraft
655	Emmet	Newaygo	Tuscola
656	Gladwin	Oceana	

657
658 Micropolitan statistical area Michigan counties are as follows:

659			
660	Allegan	Hillsdale	Mason
661	Alpena	Houghton	Mecosta
662	Benzie	Ionia	Menominee
663	Branch	Isabella	Missaukee
664	Chippewa	Kalkaska	St. Joseph
665	Delta	Keweenaw	Shiawassee
666	Dickinson	Leelanau	Wexford
667	Grand Traverse	Lenawee	
668	Gratiot	Marquette	

669
670 Metropolitan statistical area Michigan counties are as follows:

671			
672	Barry	Jackson	Muskegon
673	Bay	Kalamazoo	Oakland
674	Berrien	Kent	Ottawa
675	Calhoun	Lapeer	Saginaw
676	Cass	Livingston	St. Clair
677	Clinton	Macomb	Van Buren
678	Eaton	Midland	Washtenaw
679	Genesee	Monroe	Wayne
680	Ingham	Montcalm	

681 Source:

682
683 75 F.R., p. 37245 (June 28, 2010)
684 Statistical Policy Office
685 Office of Information and Regulatory Affairs
686 United States Office of Management and Budget