

1 | **MICHIGAN DEPARTMENT OF COMMUNITY HEALTH**

2  
3 **CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR SURGICAL SERVICES**

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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 the approval of the initiation, replacement, expansion, or  
13 acquisition of a surgical service provided in a surgical facility and the delivery of these services under Part  
14 222 of the Code. Surgical services provided in a freestanding surgical outpatient facility, an ambulatory  
15 surgery center certified under title XVIII, or a surgical department of a hospital licensed under Part 215 of the  
16 Code and offering inpatient or outpatient surgical services are covered clinical services. The Department  
17 shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the  
18 Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the  
19 Michigan Compiled Laws.  
20

21 **Section 2. Definitions**

22  
23 Sec. 2. For purposes of these standards:

24 (a) "Ambulatory surgical center" or "ASC" means any distinct entity certified by Medicare as an ASC  
25 under the provisions of Title 42, Part 416 that operates exclusively for the purpose of providing surgical  
26 services to patients not requiring hospitalization.

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

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

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

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

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

37 (g) "Dedicated endoscopy or cystoscopy operating room" means a room used exclusively for  
38 endoscopy or cystoscopy cases.

39 (h) "Department" means the Michigan Department of Community Health (MDCH).

40 (i) "Emergency Room" means a designated area in a licensed hospital and recognized by the  
41 Department as having met the staffing and equipment requirements for the treatment of emergency  
42 patients.

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

44 (k) "Endoscopy case" means a single visit to an operating room during which one or more endoscopic  
45 procedures are performed.

46 (l) "Existing surgical service" means a surgical facility that, on the date an application is submitted to  
47 the Department, is part of a licensed hospital site, a licensed freestanding surgical outpatient facility, or a  
48 certified ASC.

49 (m) "Freestanding surgical outpatient facility" or "FSOF" means a health facility licensed under Part 208  
50 of the Code. It does not include a surgical outpatient facility owned and operated as a part of a licensed  
51 hospital site. A freestanding surgical outpatient facility is a health facility for purposes of Part 222 of the  
52 Code.

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

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

58 (p) "Licensed hospital site" means either:

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

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

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

65 ~~—(r) "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 ~~—(s) "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 (tr) "Offer" means to perform surgical services.

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

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

82 (wu) "Outpatient surgery" means the provision of surgical services performed in a hospital, FSOF, or  
83 ASC, requiring anesthesia or a period of post-operative observation, or both, to patients whose admission to  
84 a hospital for an overnight stay is not anticipated as being medically necessary.

85 (xv) "Procedure room" means a room in a surgical facility constructed and equipped to perform surgical  
86 procedures and not located on a sterile corridor.

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

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

90 (ii) does not involve new construction;

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

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

93 Renovation of an existing surgical service or one or more operating rooms may involve a change in the  
94 number of square feet allocated to an operating suite. The renovation of an existing surgical service or one  
95 or more operating rooms shall not be considered the initiation, expansion, replacement, or acquisition of a  
96 surgical service or one or more operating rooms.

97 ~~—(z) "Rural county" means a county not located in a metropolitan statistical area or micropolitan~~  
98 ~~statistical areas as these terms are defined under the "standards for defining metropolitan and micropolitan~~  
99 ~~statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United~~  
100 ~~States Office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in~~  
101 ~~Appendix A.~~

102 (aax) "Sterile corridor" means an area of a surgical facility designated primarily for surgical cases and  
103 surgical support staff. Access to this corridor is controlled and the corridor is not used by the general public  
104 or personnel of the surgical facility whose primary work station is not in the operating suite(s) or whose  
105 primary work tasks do not require them to be in the operating suite(s) of a surgical facility. Examples of  
106 personnel who would normally use sterile corridors include physicians, surgeons, operating room nurses,

107 laboratory or radiology personnel, and central supply or housekeeping personnel. Other terms commonly  
108 used to represent "sterile" in describing access areas include "restricted," "controlled," "limited access," or  
109 "clean."

110 | (~~bb~~y) "Surgical case" means a single visit to an operating room during which one or more surgical  
111 procedures are performed.

112 (ii) "Surgical facility" means either:

113 (i) a licensed FSOF;

114 (ii) a certified ASC; or

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

116 (jj) "Surgical service" means performing surgery in a surgical facility.

117 | (~~ee~~z) "Trauma care," for purposes of these standards, means surgical services provided to a trauma  
118 patient in a licensed hospital site that has been verified as meeting the standards of the American College of  
119 Surgeons for a Level I or II trauma center, or equivalent standards.

120 | (~~dd~~aa) "Verifiable data" means surgical data (cases and/or hours) from the most recent Annual Survey or  
121 more recent data that can be validated by the Department.

122

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

124

### 125 **Section 3. Inventory of operating rooms used to perform surgical services; surgical cases, or hours** 126 **of use; and evaluating compliance with minimum volume requirements**

127

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

134

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

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

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

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

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

142 (iv) An operating room that is or will be used, though not exclusively, to provide surgical services to  
143 patients requiring burn care or trauma care, as those terms are defined in these standards. No more than  
144 0.5 burn care and 0.5 trauma care operating rooms shall be excluded pursuant to this subdivision, and  
145 | precludes the use of the room in subsection (2)(a)(v).

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

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

153 (b) In an FSOF or ASC that is or will be used exclusively for endoscopy or cystoscopy cases, all rooms  
154 in which endoscopy or cystoscopy cases are or will be performed.

155 (c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all  
156 operating rooms in which surgery is or will be performed, excluding any operating rooms used exclusively  
157 for endoscopy or cystoscopy cases.

158

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

160 (a) In a licensed hospital site, all surgical cases, or hours of use, performed in operating rooms,  
161 including surgical cases, or hours of use, performed in an operating room identified in subsection (2)(a)(iv),  
162 but excluding the surgical cases, or hours of use, performed in operating rooms identified in subsection  
163 (2)(a)(i), (ii), and (iii).

164 (b) In an FSOF or ASC that is or will be used exclusively for endoscopy or cystoscopy cases, all  
165 endoscopy or cystoscopy cases, or hours of use, performed in the operating rooms identified in subsection  
166 (2)(b).

167 (c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all  
168 surgical cases, or hours of use, performed in the operating rooms identified in subsection (2)(c). Cases, or  
169 hours of use, performed in any operating room used exclusively for endoscopy or cystoscopy cases, shall  
170 be excluded.

#### 171 **Section 4. Requirements to initiate a surgical service**

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

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

178 (2) Subsection (1) shall not apply if the proposed project involves the initiation of a surgical service with  
179 1 or 2 operating rooms at a licensed hospital site located in a rural or micropolitan statistical area county that  
180 does not offer surgical services as of the date an application is submitted to the Department.

181 (3) An applicant shall demonstrate that it meets the requirements of Section 10(2) for the number of  
182 surgical cases projected under subsection (1).

#### 183 **Section 5. Requirements to replace a surgical service**

184 Sec. 5. To replace a surgical service or one or more operating rooms, means the development of new  
185 space (whether through new construction, purchase, lease or similar arrangement) to house one or more  
186 operating rooms operated by an applicant at the same site as the operating room(s) to be replaced. This  
187 also includes designating an OR as a dedicated endoscopy or cystoscopy OR. The term also includes  
188 relocating an existing surgical facility or one or more operating rooms to a new geographic location of an  
189 existing surgical facility or one or more operating rooms to a different location currently offering surgical  
190 services. The term does not include the renovation of an existing surgical service or one or more operating  
191 rooms. An applicant requesting to replace an existing surgical service shall demonstrate each of the  
192 following, as applicable to the proposed project.

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

194 (a) All existing operating rooms in the existing surgical facility have performed an average of at least:

195 (i) 1,042 surgical cases per year per operating room for which verifiable data is available to the  
196 Department, or

197 (ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room for  
198 which verifiable data is available to the Department, or

199 (iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average  
200 of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room for  
201 which verifiable data is available to the Department and calculated as follows:

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

213 (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average  
214 of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the  
215 facility per year per operating room for which verifiable data is available to the Department and calculated as  
216 follows:

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

220 (b) All operating rooms, existing and replaced, are projected to perform an average of at least:

221 (i) 1,042 surgical cases per year per operating room in the second twelve months of operation, and  
222 annually thereafter, or

223 (ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room in  
224 the second twelve months of operation, and annually thereafter, or

225 (iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average  
226 of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room in  
227 the second twelve months of operation, and annually thereafter and calculated as follows:

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

231 (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average  
232 of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the  
233 facility per year per operating room in the second twelve months of operation, and annually thereafter and  
234 calculated as follows:

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

238  
239 (2) An applicant proposing to replace one or more operating rooms at a licensed hospital and is located  
240 in a rural or micropolitan county or the applicant is located in a city, village, or township with a population of  
241 not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most  
242 recent federal decennial census shall demonstrate each of the following:

243 (a) The applicant has three, four, or five ORs at the licensed hospital.

244 (b) All existing operating rooms have performed an average of at least:

245 (i) 839 surgical cases per year per operating room for which verifiable data is available to the  
246 Department, or

247 (ii) 1,200 hours of use per year per operating room for which verifiable data is available to the  
248 Department.

249 (c) All operating rooms, existing and replaced, are projected to perform an average of at least:

250 (i) 839 surgical cases per year per operating room in the second twelve months of operation, and  
251 annually thereafter, or

252 (ii) 1,200 hours of use per year per operating room in the second twelve months of operation, and  
253 annually thereafter.

254  
255 (3) Subsections (1) and (2) shall not apply if the proposed project involves replacing one or more  
256 operating rooms at the same licensed hospital site if the surgical facility is located in a rural or micropolitan  
257 statistical area county and has one or two operating rooms.

258 (4) Subsections (1) and (2) shall not apply to those hospitals licensed under Part 215 of PA 368 of  
259 1978, as amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs  
260 at the surgical service has not increased as of March 31, 2003, and the location does not change.

261  
262 (5) An applicant proposing to designate an OR as a dedicated endoscopy or cystoscopy OR shall  
263 submit notification to the Department on a form provided by the Department. An applicant under this  
264 subsection shall not be required to comply with subsections (1) and (2).

265

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

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

271 (b) All existing operating rooms in the surgical facility from which one or more ORs are proposed to be  
272 relocated have performed an average of at least:

273 (i) 1,042 surgical cases per year per operating room for which verifiable data is available to the  
274 Department, or

275 (ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room for  
276 which verifiable data is available to the Department, or,

277 (iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average  
278 of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room for  
279 which verifiable data is available to the Department and calculated as follows:

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

283 (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average  
284 of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the  
285 facility per year per operating room for which verifiable data is available to the Department and calculated as  
286 follows:

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

290 (c) All operating rooms, existing and relocated, are projected to perform an average of at least:

291 (i) 1,042 surgical cases per year per operating room in the second twelve months of operation or

292 (ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room in  
293 the second twelve months of operation, and annually thereafter, or

294 (iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average  
295 of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room in  
296 the second twelve months of operation, and annually thereafter and calculated as follows:

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

300 (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average  
301 of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the  
302 facility per year per operating room in the second twelve months of operation, and annually thereafter and  
303 calculated as follows:

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

307  
308 (7) Subsection (6) shall not apply if the proposed project involves relocating one or two operating  
309 rooms within a 20-mile radius if the surgical facility is located in a rural or micropolitan statistical area county.

310 (8) An applicant proposing to relocate one or more operating rooms from one licensed hospital site to  
311 another licensed hospital site and is located in a rural or micropolitan county or the applicant is located in a  
312 city, village, or township with a population of not more than 12,000 and in a county with a population of not  
313 more than 110,000 as defined by the most recent federal decennial census shall demonstrate each of the  
314 following:

315 (a) The applicant has three, four, or five ORs at the licensed hospital.

316 (b) All existing operating rooms have performed an average of at least:

317 (i) 839 surgical cases per year per operating room for which verifiable data is available to the  
318 Department, or

- 319 (ii) 1,200 hours of use per year per operating room for which verifiable data is available to the  
320 Department.
- 321 (c) All operating rooms, existing and relocated, are projected to perform an average of at least:  
322 (i) 839 surgical cases per year per operating room in the second twelve months of operation or  
323 (ii) 1,200 hours of use per year per operating room in the second twelve months of operation.,  
324
- 325 (9) An applicant shall demonstrate that it meets the requirements of Section 10(2) for the number of  
326 surgical cases, or hours of use, projected under subsection (1), (2), (6), and (8).  
327

### 328 **Section 6. Requirements to expand an existing surgical service**

329

330 Sec. 6. To expand a surgical service means the addition of one or more operating rooms at an existing  
331 surgical service. This term also includes the change from a dedicated endoscopy or cystoscopy OR to a  
332 non-dedicated OR. An applicant proposing to add one or more operating rooms at an existing surgical  
333 service shall demonstrate each of the following as applicable, to the proposed project.  
334

335 (1) An applicant shall demonstrate the following:

336 (a) All existing operating rooms in the existing surgical facility have performed an average of at least:

337 (i) 1,216 surgical cases per year per operating room for which verifiable data is available to the  
338 Department, or  
339 (ii) 1,313 hours of use in a facility that performs only outpatient surgery per year per operating room for  
340 which verifiable data is available to the Department, or

341 (iii) a licensed hospital that provides both inpatient and outpatient surgery may use a weighted average  
342 of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room for  
343 which verifiable data is available to the Department and calculated as follows:

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

347 (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average  
348 of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the  
349 facility per year per operating room for which verifiable data is available to the Department and calculated as  
350 follows:

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

354 (b) All proposed operating rooms are projected to perform an average of at least:

355 (i) 1,042 surgical cases per year per operating room in the second twelve months of operation, or

356 (ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room in  
357 the second twelve months of operation, or

358 (iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average  
359 of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room in  
360 the second twelve months of operation, and calculated as follows:

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

364 (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average  
365 of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the  
366 facility per year per operating room in the second twelve months of operation, and calculated as follows:

367 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus  
368 the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases  
369 would equate to  $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$  OR.)  
370

371 (2) An applicant proposing to add one or more operating rooms at a licensed hospital and is located in  
372 a rural or micropolitan county or the applicant is located in a city, village, or township with a population of not  
373 more than 12,000 and in a county with a population of not more than 110,000 as defined by the most recent  
374 federal decennial census shall demonstrate each of the following:

375 (a) The applicant has two, three, or four ORs at the licensed hospital.

376 (b) All existing operating rooms have performed an average of at least:

377 (i) 979 surgical cases per year per operating room for which verifiable data is available to the  
378 Department, or

379 (ii) 1,400 hours of use per year per operating room for which verifiable data is available to the  
380 Department.

381 (c) All proposed operating rooms are projected to perform an average of at least:

382 (i) 839 surgical cases per year per operating room in the second twelve months of operation, or

383 (ii) 1,200 hours of use per year per operating room in the second twelve months of operation.  
384

385 (3) Subsections (1) and (2) shall not apply if the proposed project involves adding a second operating  
386 room in a licensed hospital site located in a rural or micropolitan statistical area county that currently has  
387 only one operating room.  
388

389 (4) An applicant shall demonstrate that it meets the requirements of Section 10(2) for the number of  
390 surgical cases, or hours of use, projected under subsections (1) and (2).  
391

### 392 **Section 7. Requirements to acquire an existing surgical service** 393

394 Sec. 7. Acquisition of a surgical service means a project involving the issuance of a new license for a  
395 hospital or a freestanding surgical outpatient facility or a new certification as an ambulatory surgical center  
396 as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an  
397 existing surgical service. An applicant proposing to acquire an existing surgical service shall demonstrate  
398 each of the following, as applicable to the proposed project.  
399

400 (1) An applicant agrees and assures to comply with all applicable project delivery requirements.  
401

402 (2) For the first application proposing to acquire an existing surgical service, for which a final decision  
403 has not been issued, on or after January 27, 1996, the existing surgical service shall not be required to be in  
404 compliance with the applicable volume requirements set forth in these standards. The surgical service shall  
405 be operating at the applicable volume requirements in the second 12 months after the effective date of the  
406 acquisition.  
407

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

412 (4) Subsection (3) shall not apply to those hospitals licensed under Part 215 of PA 368 of 1978, as  
413 amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs at the  
414 surgical service has not increased as of March 31, 2003, and the location does not change.  
415

### 416 **Section 8. Requirements for a Hybrid Operating Room/Cardiac Catheterization Laboratory (OR/CCL)** 417

418 Sec. 8. A hybrid or/ccl means an operating room located on a sterile corridor and equipped with an  
419 angiography system permitting minimally invasive procedures of the heart and blood vessels with full  
420 anesthesia capabilities. An applicant proposing to add one or more hybrid OR/CCLS at an existing surgical  
421 service shall demonstrate each of the following:  
422



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

425  
426 (2) If the hybrid OR/CCL(s) represents an increase in the number of licensed operating rooms at the  
427 facility, the applicant is in compliance with Section 6 of these standards.

428  
429 (3) If the hybrid OR/CCL(s) represents conversion of an existing operating room(s), the applicant is in  
430 compliance with the provisions of Section 5, if applicable.

431  
432 (4) The applicant meets the applicable requirements of the CON review standards for cardiac  
433 catheterization services.

434  
435 (5) Each case performed in a hybrid OR/CCL shall be included either in the surgical volume or the  
436 therapeutic cardiac catheterization volume of the facility. No case shall be counted more than once.

437  
438 **Section 9. Requirements for Medicaid Participation**

439  
440 Sec. 9. An applicant shall provide Verification of Medicaid participation. An applicant that is a new  
441 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided  
442 to the Department within six (6) months from the offering of services if a CON is approved.

443  
444 **Section 10. Project delivery requirements terms of approval for all applicants**

445  
446 Sec. 10. An applicant shall agree that, if approved, the surgical services shall be delivered in  
447 compliance with the following terms of approval:

448  
449 (1) Compliance with these standards.

450  
451 (2) Compliance with the following quality assurance standards:

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

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

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

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

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

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

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

- 475 (viii) An applicant shall provide laboratory, diagnostic imaging, pathology and pharmacy (including  
476 biologicals) services, either on-site or through contractual arrangements.
- 477 (ix) An applicant shall have written policies and procedures for advising patients of their rights.
- 478 (x) An applicant shall develop and maintain a system for the collection, storage, and use of patient  
479 records.
- 480 (xi) Surgical facilities shall have separate patient recovery and non-patient waiting areas.
- 481 (xii) Surgical facilities shall provide a functionally safe and sanitary environment for patients, personnel,  
482 and the public. Each facility shall incorporate a safety management program to maintain a physical  
483 environment free of hazards and to reduce the risk of human injury.
- 484 (B) For purposes of evaluating subsection (A), the Department shall consider it prima facie evidence as  
485 to compliance with the applicable requirements if an applicant surgical facility is accredited by the Joint  
486 Commission on the Accreditation of Healthcare Organizations, the American Osteopathic Hospital  
487 Association, or the Accreditation Association for Ambulatory Health Care, or certified by Medicare as an  
488 ambulatory surgical center.
- 489 (C) The operation of and referral of patients to the surgical facility shall be in conformance with 1978 PA  
490 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).
- 491
- 492 (3) Compliance with the following access to care requirements:
- 493 (a) The applicant, to assure appropriate utilization by all segments of the Michigan population, shall:
- 494 (b) not deny surgical services to any individual based on ability to pay or source of payment;
- 495 (c) provide surgical services to any individual based on the clinical indications of need for the service.
- 496 (d) maintain information by payer and non-paying sources to indicate the volume of care from each  
497 source provided annually. Compliance with selective contracting requirements shall not be construed as a  
498 violation of this term.
- 499 (e) An applicant shall participate in Medicaid or in Medicaid managed care products at least 12  
500 consecutive months within the first two years of operation and continue to participate annually thereafter  
501 or attest that the applicant has been unable to contract with Medicaid managed care products at current  
502 Medicaid rates.
- 503
- 504 (4) Compliance with the following monitoring and reporting requirements:
- 505 (a) Existing operating rooms shall perform an average of at least:
- 506 (i) 1,042 surgical cases per year per operating room verifiable by the Department, or
- 507 (ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room  
508 verifiable by the Department, or
- 509 (iii) Be in compliance using the applicable weighted averages under Section 5.
- 510 (b) Existing operating rooms, located in a rural or micropolitan county, or within a city, village, or  
511 township with a population of not more than 12,000 and in a county with a population of not more than  
512 110,000 as defined by the most recent Federal decennial census in a surgical service that has three, four, or  
513 five OR'S shall perform an average of at least:
- 514 (i) 839 surgical cases per year per operating room verifiable by the Department or
- 515 (ii) 1,200 hours of use per year per operating room verifiable by the Department.
- 516 (c) The applicant shall participate in a data collection System established and administered by the  
517 Department. The data may include, but is not limited to, hours of use of operating rooms, annual budget  
518 and cost information, operating schedules, and demographic, diagnostic, morbidity and mortality  
519 information, as well as the volume of care provided to patients from all payer sources. An applicant shall  
520 provide the required data on a separate basis for each licensed or certified site, in a format established by  
521 the department, and in a mutually agreed upon media. The Department may elect to verify the data through  
522 on-site review of appropriate records.
- 523 (d) The surgical service shall provide the Department with timely notice of the proposed project  
524 implementation consistent with applicable statute and promulgated rules.
- 525
- 526 (5) The agreements and assurances required by this section shall be in the form of a certification  
527 agreed to by the applicant or its authorized agent.

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**Section 11. Documentation of projections**

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

(a) The applicant shall include a description of the data source(s) used as well as an assessment of the accuracy of these data used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.

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

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

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

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

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

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

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

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

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

565

566 Sec. 12. Proposed projects reviewed under these standards shall not be subject to comparative review.

567 These CON review standards supercede and replace the CON Review Standards for Surgical Facilities

568 approved by the CON Commission on ~~April 30, 2008~~DECEMBER 15, 2011 and effective on ~~June 20,~~

569 ~~2008~~FEBRUARY 27, 2012.

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CON REVIEW STANDARDS  
FOR SURGICAL SERVICES

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

Allegan	<u>HILLSDALE</u>	<u>MASON</u>
Alpena	Houghton	Mecosta
Benzie	<u>IONIA</u>	Menominee
Branch	Isabella	<del>Midland</del>
Chippewa	Kalkaska	Missaukee
Delta	Keweenaw	St. Joseph
Dickinson	Leelanau	Shiawassee
Grand Traverse	Lenawee	Wexford
Gratiot	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	<del>onia</del>	<u>MONTCALM</u> <del>Newaygo</del>
Bay	Jackson	Muskegon
Berrien	Kalamazoo	Oakland
Calhoun	Kent	Ottawa
Cass	Lapeer	Saginaw
Clinton	Livingston	St. Clair
Eaton	Macomb	Van Buren
Genesee	<u>MIDLAND</u>	Washtenaw
Ingham	Monroe Wayne	

Source:

65-75 F.R., p. 82238-37245 (December 27, 2000)  
JUNE 28, 2010  
 Statistical Policy Office  
 Office of Information and Regulatory Affairs  
 United States Office of Management and Budget