

1 **MICHIGAN DEPARTMENT OF COMMUNITY HEALTH AND HUMAN SERVICES**

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**

11  
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~~ **AND HUMAN SERVICES**  
40 **(MDCHMDHHS).**

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

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

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

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

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

- 54 (n) "Hospital" means a health facility licensed under Part 215 of the Code.
- 55 (o) "Hours of use" means the actual time in hours, and parts thereof, an operating room is used to  
56 provide surgical services. It is the time from when a patient enters an operating room until that same patient  
57 leaves that same room. It excludes any pre- or post-operative room set-up or clean-up preparations, or any  
58 time a patient spends in pre- or post-operative areas including a recovery room.
- 59 (p) "Licensed hospital site" means either:
- 60 (i) in the case of a single site hospital, the location of the hospital authorized by license and listed on  
61 that licensee's certificate of licensure or
- 62 (ii) in the case of a hospital with multiple sites, the location of each separate and distinct inpatient site  
63 as authorized by licensure.
- 64 (q) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6  
65 and 1396r-8 to 1396v.
- 66 (r) "Offer" means to perform surgical services.
- 67 (s) "Operating room" or "OR" means a room in a surgical facility constructed and equipped to perform  
68 surgical cases and located on a sterile corridor. The term also includes a room constructed and equipped to  
69 perform surgical cases on a nonsterile corridor if the room is located in an FSOF or ASC that is used  
70 exclusively for endoscopy or cystoscopy cases. This term does not include procedure rooms.
- 71 (t) "Operating suite," for purposes of these standards, means an area in a surgical facility that is  
72 dedicated to the provision of surgery. An operating suite includes operating rooms, pre- and post-operative  
73 patient areas, clean and soiled utility and linen areas, and other support areas associated with the provision  
74 of surgery.
- 75 (u) "Outpatient surgery" means the provision of surgical services performed in a hospital, FSOF, or  
76 ASC, requiring anesthesia or a period of post-operative observation, or both, to patients whose admission to  
77 a hospital for an overnight stay is not anticipated as being medically necessary.
- 78 (v) "Procedure room" means a room in a surgical facility constructed and equipped to perform surgical  
79 procedures and not located on a sterile corridor.
- 80 (w) "Renovate an existing surgical service or one or more operating rooms" means a project that:
- 81 (i) involves the renovation, remodeling, or modernization of an operating suite of a hospital, FSOF, or  
82 ASC;
- 83 (ii) does not involve new construction;
- 84 (iii) does not involve a change in the physical location within the surgical facility at the same site; and  
85 (iv) does not result in an increase in the number of operating rooms at an existing surgical facility.
- 86 Renovation of an existing surgical service or one or more operating rooms may involve a change in the  
87 number of square feet allocated to an operating suite. The renovation of an existing surgical service or one  
88 or more operating rooms shall not be considered the initiation, expansion, replacement, or acquisition of a  
89 surgical service or one or more operating rooms.
- 90 (x) "Sterile corridor" means an area of a surgical facility designated primarily for surgical cases and  
91 surgical support staff. Access to this corridor is controlled and the corridor is not used by the general public  
92 or personnel of the surgical facility whose primary work station is not in the operating suite(s) or whose  
93 primary work tasks do not require them to be in the operating suite(s) of a surgical facility. Examples of  
94 personnel who would normally use sterile corridors include physicians, surgeons, operating room nurses,  
95 laboratory or radiology personnel, and central supply or housekeeping personnel. Other terms commonly  
96 used to represent "sterile" in describing access areas include "restricted," "controlled," "limited access," or  
97 "clean."
- 98 (y) "Surgical case" means a single visit to an operating room during which one or more surgical  
99 procedures are performed.
- 100 (ii) "Surgical facility" means either:
- 101 (i) a licensed FSOF;
- 102 (ii) a certified ASC; or
- 103 (iii) a licensed hospital site authorized to provide inpatient or outpatient surgery.
- 104 (jj) "Surgical service" means performing surgery in a surgical facility.

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

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

110  
111 (2) Terms defined in the Code have the same meanings when used in these standards.  
112

### 113 **Section 3. Inventory of operating rooms used to perform surgical services; surgical cases, or hours** 114 **of use; and evaluating compliance with minimum volume requirements** 115

116 Sec. 3. (1) The Department shall use the number of operating rooms and verifiable data pursuant to  
117 subsection (2) to determine the number of surgical cases, hours of use, or both, as applicable, pursuant to  
118 subsection (3) for purposes of evaluating compliance with the actual and proposed volume requirements set  
119 forth in the applicable sections of these standards. Compliance with CON minimum volume requirements  
120 established by these standards shall be determined based on the average number of surgical cases, hours  
121 of use, or both, per operating room of the surgical service as permitted by these standards.  
122

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

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

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

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

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

130 (iv) An operating room that is or will be used, though not exclusively, to provide surgical services to  
131 patients requiring burn care or trauma care, as those terms are defined in these standards. No more than  
132 0.5 burn care and 0.5 trauma care operating rooms shall be excluded pursuant to this subdivision, and  
133 precludes the use of the room in subsection (2)(a)(v).

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

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

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

143 (c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all  
144 operating rooms in which surgery is or will be performed, excluding any operating rooms used exclusively  
145 for endoscopy or cystoscopy cases.  
146

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

148 (a) In a licensed hospital site, all surgical cases, or hours of use, performed in operating rooms,  
149 including surgical cases, or hours of use, performed in an operating room identified in subsection S (2)(a)(iv),  
150 (v), AND (vi) but excluding the surgical cases, or hours of use, performed in operating rooms identified in  
151 subsection (2)(a)(i), (ii), and (iii).

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

155 (c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all  
156 surgical cases, or hours of use, performed in the operating rooms identified in subsection (2)(c). Cases, or

157 hours of use, performed in any operating room used exclusively for endoscopy or cystoscopy cases, shall  
158 be excluded.

159  
160 **Section 4. Requirements to initiate a surgical service**

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

165  
166 (1) Each proposed operating room shall perform an average of at least 1,128 surgical cases per year  
167 per operating room in the second 12 months of operation.

168  
169 (2) Subsection (1) shall not apply if the proposed project involves the initiation of a surgical service with  
170 1 or 2 operating rooms at a licensed hospital site located in a rural or micropolitan statistical area county that  
171 does not offer surgical services as of the date an application is submitted to the Department.

172  
173 (3) An applicant shall demonstrate that it meets the requirements of Section 4011(2) for the number of  
174 surgical cases projected under subsection (1).

175 (a) SECTION 11(2)(d) SHALL NOT APPLY IF THE PROPOSED PROJECT INVOLVES THE  
176 INITIATION OF A SURGICAL SERVICE AT A NEW FSOE OR A NEW ASC AT A NEW GEOGRAPHICAL  
177 SITE UTILIZING THE HISTORICAL SURGICAL CASES OF THE APPLICANT AND THE NEW SERVICE  
178 IS OWNED BY THE SAME APPLICANT.

179  
180 **Section 5. Requirements to replace a surgical service**

181  
182 Sec. 5. To replace a surgical service or one or more operating rooms, means the development of new  
183 space (whether through new construction, purchase, lease or similar arrangement) to house one or more  
184 operating rooms operated by an applicant at the same site as the operating room(s) to be replaced. This  
185 also includes designating an OR as a dedicated endoscopy or cystoscopy OR. The term also includes  
186 relocating an existing surgical facility or one or more operating rooms to a new geographic location of an  
187 existing surgical facility or one or more operating rooms to a different location currently offering surgical  
188 services. The term does not include the renovation of an existing surgical service or one or more operating  
189 rooms. An applicant requesting to replace an existing surgical service shall demonstrate each of the  
190 following, as applicable to the proposed project.

191  
192 (1) An applicant proposing to replace shall demonstrate:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

229  
230 (2) An applicant proposing to replace one or more operating rooms at a licensed hospital and is located  
231 in a rural or micropolitan county or the applicant is located in a city, village, or township with a population of  
232 not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most  
233 recent federal decennial census shall demonstrate each of the following:

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

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

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

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

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

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

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

245  
246 (3) Subsections (1) and (2) shall not apply if the proposed project involves replacing one or more  
247 operating rooms at the same licensed hospital site if the surgical facility is located in a rural or micropolitan  
248 statistical area county and has one or two operating rooms.

249  
250 (4) Subsections (1) and (2) shall not apply to those hospitals licensed under Part 215 of PA 368 of  
251 1978, as amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs  
252 at the surgical service has not increased as of March 31, 2003, and the location does not change.

253  
254 (5) An applicant proposing to designate an OR as a dedicated endoscopy or cystoscopy OR shall  
255 submit notification to the Department on a form provided by the Department. An applicant under this  
256 subsection shall not be required to comply with subsections (1) and (2).

257  
258 (6) An applicant proposing to relocate an existing surgical service or one or more operating rooms shall  
259 demonstrate each of the following, as applicable:

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

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

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

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

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

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

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

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

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

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

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

286 (iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average  
287 of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room in  
288 the second twelve months of operation, and annually thereafter and 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 hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours  
291 would equate to  $375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00$  OR.) or

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

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

299  
300 (7) Subsection (6) shall not apply if the proposed project involves relocating one or two operating  
301 rooms within a 20-mile radius if the surgical facility is located in a rural or micropolitan statistical area county.  
302

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

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

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

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

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

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

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

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

317

318 (9) An applicant shall demonstrate that it meets the requirements of Section 4011(2) for the number of  
319 surgical cases, or hours of use, projected under subsection (1), (2), (6), and (8).

320

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

322

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

327

328 (1) An applicant shall demonstrate the following:

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

330 (i) 1,216 surgical cases per year per operating room for which verifiable data is available to the  
331 Department, or

332 (ii) 1,313 hours of use in a facility that performs only outpatient surgery per year per operating room for  
333 which verifiable data is available to the Department, or

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

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

340 (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average  
341 of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the  
342 facility per year per operating room for which verifiable data is available to the Department and calculated as  
343 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 cases divided by 1,216. (For example: Using 438 inpatient hours and 912 outpatient cases  
346 would equate to  $438/1,750 + 912/1,216 = 0.25 + 0.75 = 1.00$  OR.)

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

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

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

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

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

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

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

363

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

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

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

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

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

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

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

376 (ii) 1,200 hours of use per year per operating room in the second twelve months of operation.  
377

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

381  
382 (4) An applicant shall demonstrate that it meets the requirements of Section 4011(2) for the number of  
383 surgical cases, or hours of use, projected under subsections (1) and (2).  
384

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

386  
387 Sec. 7. Acquisition of a surgical service means a project involving the issuance of a new license for a  
388 hospital or a freestanding surgical outpatient facility or a new certification as an ambulatory surgical center  
389 as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an  
390 existing surgical service. An applicant proposing to acquire an existing surgical service shall demonstrate  
391 each of the following, as applicable to the proposed project.  
392

393 (1) An applicant agrees and assures to comply with all applicable project delivery requirements.  
394

395 (2) For the first application proposing to acquire an existing surgical service, for which a final decision  
396 has not been issued, on or after January 27, 1996, the existing surgical service shall not be required to be in  
397 compliance with the applicable volume requirements set forth in these standards. The surgical service shall  
398 be operating at the applicable volume requirements in the second 12 months after the effective date of the  
399 acquisition.  
400

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

405 (4) Subsection (3) shall not apply to those hospitals licensed under Part 215 of PA 368 of 1978, as  
406 amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs at the  
407 surgical service has not increased as of March 31, 2003, and the location does not change.  
408

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

410  
411 Sec. 8. A hybrid or/ccl means an operating room located on a sterile corridor and equipped with an  
412 angiography system permitting minimally invasive procedures of the heart and blood vessels with full  
413 anesthesia capabilities. An applicant proposing to add one or more hybrid OR/CCLS at an existing surgical  
414 service shall demonstrate each of the following:  
415



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

418  
419 (2) If the hybrid OR/CCL(s) represents an increase in the number of licensed operating rooms at the  
420 facility, the applicant is in compliance with Section 6 of these standards.

421  
422 (3) If the hybrid OR/CCL(s) represents conversion of an existing operating room(s), the applicant is in  
423 compliance with the provisions of Section 5, if applicable.

424  
425 (4) The applicant meets the applicable requirements of the CON review standards for cardiac  
426 catheterization services.

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

429  
430 **Section 9. Requirements for Medicaid Participation**

431  
432 Sec. 9. An applicant shall provide Verification of Medicaid participation. An applicant that is a new  
433 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided  
434 to the Department within six (6) months from the offering of services if a CON is approved.

435  
436 **Section 10. Project delivery requirements terms of approval for all applicants**

437  
438 Sec. 10. An applicant shall agree that, if approved, the surgical services shall be delivered in  
439 compliance with the following terms of approval:

440  
441 (1) Compliance with these standards.

442  
443 (2) Compliance with the following quality assurance standards:

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

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

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

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

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

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

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

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

- 469 (ix) An applicant shall have written policies and procedures for advising patients of their rights.  
470 (x) An applicant shall develop and maintain a system for the collection, storage, and use of patient  
471 records.  
472 (xi) Surgical facilities shall have separate patient recovery and non-patient waiting areas.  
473 (xii) Surgical facilities shall provide a functionally safe and sanitary environment for patients, personnel,  
474 and the public. Each facility shall incorporate a safety management program to maintain a physical  
475 environment free of hazards and to reduce the risk of human injury.  
476 (B) For purposes of evaluating subsection (A), the Department shall consider it prima facie evidence as  
477 to compliance with the applicable requirements if an applicant surgical facility is accredited by the Joint  
478 Commission on the Accreditation of Healthcare Organizations, the American Osteopathic Hospital  
479 Association, or the Accreditation Association for Ambulatory Health Care, or certified by Medicare as an  
480 ambulatory surgical center.  
481 (C) The operation of and referral of patients to the surgical facility shall be in conformance with 1978 PA  
482 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).  
483  
484 (3) Compliance with the following access to care requirements:  
485 (a) The applicant, to assure appropriate utilization by all segments of the Michigan population, shall:  
486 (b) not deny surgical services to any individual based on ability to pay or source of payment;  
487 (c) provide surgical services to any individual based on the clinical indications of need for the service.  
488 (d) maintain information by payer and non-paying sources to indicate the volume of care from each  
489 source provided annually. Compliance with selective contracting requirements shall not be construed as a  
490 violation of this term.  
491 (e) An applicant shall participate in Medicaid or in Medicaid managed care products at least 12  
492 consecutive months within the first two years of operation and continue to participate annually thereafter  
493 or attest that the applicant has been unable to contract with Medicaid managed care products at current  
494 Medicaid rates.  
495  
496 (4) Compliance with the following monitoring and reporting requirements:  
497 (a) Existing operating rooms shall perform an average of at least:  
498 (i) 1,042 surgical cases per year per operating room verifiable by the Department, or  
499 (ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room  
500 verifiable by the Department, or  
501 (iii) Be in compliance using the applicable weighted averages under Section 5.  
502 (b) Existing operating rooms, located in a rural or micropolitan county, or within a city, village, or  
503 township with a population of not more than 12,000 and in a county with a population of not more than  
504 110,000 as defined by the most recent Federal decennial census in a surgical service that has three, four, or  
505 five OR'S shall perform an average of at least:  
506 (i) 839 surgical cases per year per operating room verifiable by the Department or  
507 (ii) 1,200 hours of use per year per operating room verifiable by the Department.  
508 (c) The applicant shall participate in a data collection System established and administered by the  
509 Department. The data may include, but is not limited to, hours of use of operating rooms, annual budget  
510 and cost information, operating schedules, and demographic, diagnostic, morbidity and mortality  
511 information, as well as the volume of care provided to patients from all payer sources. An applicant shall  
512 provide the required data on a separate basis for each licensed or certified site, in a format established by  
513 the department, and in a mutually agreed upon media. The Department may elect to verify the data through  
514 on-site review of appropriate records.  
515 (d) The surgical service shall provide the Department with timely notice of the proposed project  
516 implementation consistent with applicable statute and promulgated rules.  
517  
518 (5) The agreements and assurances required by this section shall be in the form of a certification  
519 agreed to by the applicant or its authorized agent.  
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## Section 11. Documentation of projections

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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) SUBSECTION 11(2)(d) SHALL NOT APPLY IF THE PROPOSED PROJECT INVOLVES THE INITIATION OF A SURGICAL SERVICE AT A NEW FSOF OR A NEW ASC AT A NEW GEOGRAPHICAL SITE UTILIZING THE HISTORICAL SURGICAL CASES OF THE APPLICANT AND THE NEW SERVICE IS OWNED BY THE SAME APPLICANT. THE APPLICANT FACILITY COMMITTING SURGICAL DATA HAS COMPLETED THE DEPARTMENTAL FORM THAT CERTIFIES THE SURGICAL CASES WERE PERFORMED AT THE COMMITTING FACILITY AND THE SURGICAL CASES WILL BE TRANSFERRED TO THE PROPOSED SURGICAL FACILITY FOR NO LESS THAN THREE YEARS SUBSEQUENT TO THE INITIATION OF THE SURGICAL SERVICE PROPOSED BY THE APPLICANT.

(ef) 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.

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

Sec. 12. Proposed projects reviewed under these standards shall not be subject to comparative review. These CON review standards supercede and replace the CON Review Standards for Surgical Facilities approved by the CON Commission on December 15, 2011~~SEPTEMBER 25, 2014~~ and effective on February 27, 2012~~DECEMBER 22, 2014~~.

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Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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