

1 MICHIGAN DEPARTMENT OF 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.)

9  
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) "CMS" MEANS THE CENTERS FOR MEDICARE & MEDICAID SERVICES OF THE U.S.**  
33 **DEPARTMENT OF HEALTH AND HUMAN SERVICES.**

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

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

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

39 (gh) "Dedicated endoscopy or cystoscopy operating room" means a room used exclusively for  
40 endoscopy or cystoscopy cases.

41 **(i) "DEDICATED VASCULAR ACCESS OPERATING ROOM" MEANS A ROOM USED**  
42 **EXCLUSIVELY FOR VASCULAR ACCESS SURGICAL CASES**

43 (hj) "Department" means the Michigan Department of Health and Human Services (MDHHS).

44 (ij) "Emergency Room" means a designated area in a licensed hospital and recognized by the  
45 Department as having met the staffing and equipment requirements for the treatment of emergency  
46 patients.

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

48 (kl) "Endoscopy case" means a single visit to an operating room during which one or more endoscopic  
49 procedures are performed.

50 **(m) "ESRD FACILITY" MEANS A FACILITY THAT IS CERTIFIED FOR PARTICIPATION IN THE**  
51 **MEDICARE PROGRAM AS A PROVIDER OF TREATMENT AND SERVICES TO INDIVIDUALS WITH**  
52 **END-STAGE RENAL DISEASE PURSUANT TO SECTION 1881(C) OF THE SOCIAL SECURITY ACT.**

- 53       ~~(ln)~~ "Existing surgical service" means a surgical facility that, on the date an application is submitted to  
54 the Department, is part of a licensed hospital site, a licensed freestanding surgical outpatient facility, or a  
55 certified ASC.
- 56       ~~(mo)~~ "Freestanding surgical outpatient facility" or "FSOF" means a health facility licensed under Part 208  
57 of the Code. It does not include a surgical outpatient facility owned and operated as a part of a licensed  
58 hospital site. A freestanding surgical outpatient facility is a health facility for purposes of Part 222 of the  
59 Code.
- 60       ~~(np)~~ "Hospital" means a health facility licensed under Part 215 of the Code.
- 61       ~~(eq)~~ "Hours of use" means the actual time in hours, and parts thereof, an operating room is used to  
62 provide surgical services. It is the time from when a patient enters an operating room until that same patient  
63 leaves that same room. It excludes any pre- or post-operative room set-up or clean-up preparations, or any  
64 time a patient spends in pre- or post-operative areas including a recovery room.
- 65       ~~(pr)~~ "Licensed hospital site" means either:  
66       (i) in the case of a single site hospital, the location of the hospital authorized by license and listed on  
67 that licensee's certificate of licensure or  
68       (ii) in the case of a hospital with multiple sites, the location of each separate and distinct inpatient site  
69 as authorized by licensure.
- 70       ~~(es)~~ "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6  
71 and 1396r-8 to 1396v.
- 72       ~~(ft)~~ "Offer" means to perform surgical services.
- 73       ~~(su)~~ "Operating room" or "OR" means a room in a surgical facility constructed and equipped to perform  
74 surgical cases and located on a sterile corridor. The term also includes a room constructed and equipped to  
75 perform surgical cases on a nonsterile corridor if the room is located in an FSOF or ASC that is used  
76 exclusively for endoscopy or cystoscopy cases. This term does not include procedure rooms.
- 77       ~~(tv)~~ "Operating suite," for purposes of these standards, means an area in a surgical facility that is  
78 dedicated to the provision of surgery. An operating suite includes operating rooms, pre- and post-operative  
79 patient areas, clean and soiled utility and linen areas, and other support areas associated with the provision  
80 of surgery.
- 81       ~~(uw)~~ "Outpatient surgery" means the provision of surgical services performed in a hospital, FSOF, or  
82 ASC, requiring anesthesia or a period of post-operative observation, or both, to patients whose admission to  
83 a hospital for an overnight stay is not anticipated as being medically necessary.
- 84       ~~(vx)~~ "Procedure room" means a room in a surgical facility constructed and equipped to perform surgical  
85 procedures and not located on a sterile corridor.
- 86       ~~(wy)~~ "Renovate an existing surgical service or one or more operating rooms" means a project that:  
87       (i) involves the renovation, remodeling, or modernization of an operating suite of a hospital, FSOF, or  
88 ASC;  
89       (ii) does not involve new construction;  
90       (iii) does not involve a change in the physical location within the surgical facility at the same site; and  
91       (iv) does not result in an increase in the number of operating rooms at an existing surgical facility.  
92 Renovation of an existing surgical service or one or more operating rooms may involve a change in the  
93 number of square feet allocated to an operating suite. The renovation of an existing surgical service or one  
94 or more operating rooms shall not be considered the initiation, expansion, replacement, or acquisition of a  
95 surgical service or one or more operating rooms.
- 96       ~~(xz)~~ "Sterile corridor" means an area of a surgical facility designated primarily for surgical cases and  
97 surgical support staff. Access to this corridor is controlled and the corridor is not used by the general public  
98 or personnel of the surgical facility whose primary work station is not in the operating suite(s) or whose  
99 primary work tasks do not require them to be in the operating suite(s) of a surgical facility. Examples of  
100 personnel who would normally use sterile corridors include physicians, surgeons, operating room nurses,  
101 laboratory or radiology personnel, and central supply or housekeeping personnel. Other terms commonly  
102 used to represent "sterile" in describing access areas include "restricted," "controlled," "limited access," or  
103 "clean."
- 104       ~~(yaa)~~ "Surgical case" means a single visit to an operating room during which one or more surgical  
105 procedures are performed.

- 106 (bb) "Surgical facility" means either:  
107 (i) a licensed FSOF;  
108 (ii) a certified ASC; or  
109 (iii) a licensed hospital site authorized to provide inpatient or outpatient surgery.  
110 (jcc) "Surgical service" means performing surgery in a surgical facility.  
111 (zdd) "Trauma care," for purposes of these standards, means surgical services provided to a trauma  
112 patient in a licensed hospital site that has been verified as meeting the standards of the American College of  
113 Surgeons for a Level I or II trauma center, or equivalent standards.  
114 (ee) "VASCULAR ACCESS SURGICAL CASE" MEANS A SINGLE CLINICAL ENCOUNTER DURING  
115 WHICH ONE OR MORE VASCULAR ACCESS SURGICAL PROCEDURES ARE PERFORMED FOR A  
116 PATIENT WITH END STAGE RENAL DISEASE AND SUCH SURGICAL PROCEDURES ARE  
117 NECESSARY OR APPROPRIATE FOR MAINTAINING VASCULAR ACCESS FOR RENAL DIALYSIS  
118 INCLUDING WITHOUT LIMITATION VENOGRAPHY, CATHETER PLACEMENT, REPAIR, REMOVAL  
119 AND REPLACEMENT, CATHETER THROMBOLYSIS, REMOVAL OF OBSTRUCTIONS FOR VASCULAR  
120 ACCESS, FISTULAGRAMS, ANGIOPLASTY, STENT PLACEMENT, PERCUTANEOUS  
121 THROMBECTOMY, TRANSLUMINAL BALLOON ANGIOPLASTY OF EXTREMITIES, GUIDANCE FOR  
122 VASCULAR ACCESS AND FLUOROSCOPIC GUIDANCE OF CENTRAL VENOUS ACCESS DEVICES  
123 OR ANY COMBINATION OF THE FOREGOING OR DIRECTLY RELATED PROCEDURES.  
124 (aaff) "Verifiable data" means surgical data (cases and/or hours) from the most recent Annual Survey or  
125 more recent data that can be validated by the Department.  
126  
127 (2) Terms defined in the Code have the same meanings when used in these standards.  
128

129 **Section 3. Inventory of operating rooms used to perform surgical services; surgical cases, or hours**  
130 **of use; and evaluating compliance with minimum volume requirements**  
131

132 Sec. 3. (1) The Department shall use the number of operating rooms and verifiable data pursuant to  
133 subsection (2) to determine the number of surgical cases, hours of use, or both, as applicable, pursuant to  
134 subsection (3) for purposes of evaluating compliance with the actual and proposed volume requirements set  
135 forth in the applicable sections of these standards. Compliance with CON minimum volume requirements  
136 established by these standards shall be determined based on the average number of surgical cases, hours  
137 of use, or both, per operating room of the surgical service as permitted by these standards.  
138

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

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

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

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

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

146 (iv) An operating room that is or will be used, though not exclusively, to provide surgical services to  
147 patients requiring burn care or trauma care, as those terms are defined in these standards. No more than  
148 0.5 burn care and 0.5 trauma care operating rooms shall be excluded pursuant to this subdivision, and  
149 precludes the use of the room in subsection (2)(a)(v).

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

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

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

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

162  
163 (3) The number of surgical cases, or hours of use, shall be determined as follows:

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

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

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

#### 175 176 **Section 4. Requirements to initiate a surgical service**

177  
178 Sec. 4. To initiate a surgical service means to begin operation of a surgical facility at a site that has not  
179 offered surgical services within the 12-month period immediately preceding the date an application is  
180 submitted to the Department. An applicant proposing to initiate a surgical service shall demonstrate the  
181 following, as applicable to the proposed project.

182  
183 (1) Each proposed operating room shall perform an average of at least 1,128 surgical cases per year  
184 per operating room **OR 1,128 VASCULAR ACCESS SURGICAL CASES PER OPERATING ROOM, AS**  
185 **APPLICABLE**, in the second 12 months of operation.

186  
187 (2) Subsection (1) shall not apply if the proposed project involves the initiation of a surgical service with  
188 1 or 2 operating rooms at a licensed hospital site located in a rural or micropolitan statistical area county that  
189 does not offer surgical services as of the date an application is submitted to the Department.

190  
191 (3) An applicant shall demonstrate that it meets the requirements of Section 11(2) for the number of  
192 surgical cases projected under subsection (1).

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

196  
197 (4) **AN APPLICANT THAT IS APPLYING TO INITIATE A SURGICAL SERVICE FOR ONE OR MORE**  
198 **OPERATING ROOMS TO BE USED EXCLUSIVELY FOR VASCULAR ACCESS SURGICAL CASES**  
199 **SHALL DEMONSTRATE THE FOLLOWING:**

200 (a) **THE APPLICANT CURRENTLY OPERATES AN ESRD FACILITY.**

201 (b) **THE SURGICAL SERVICE SHALL BE USED ONLY FOR VASCULAR ACCESS SURGICAL**  
202 **CASES.**

203 (c) **THE APPLICANT SHALL OBTAIN ACCREDITATION FROM THE JOINT COMMISSION, THE**  
204 **ACCREDITATION ASSOCIATION FOR AMBULATORY HEALTH CARE OR ANOTHER ACCREDITING**  
205 **BODY APPROVED BY CMS FOR PURPOSES OF MEDICARE CERTIFICATION UNDER SECTION**  
206 **1865(a) OF THE SOCIAL SECURITY ACT WITHIN SIX (6) MONTHS AFTER BEGINNING OPERATION**  
207 **OF THE SURGICAL SERVICE AND AT ALL TIMES THEREAFTER.**

208 (d) **THE APPLICANT SHALL PARTICIPATE IN THE MEDICARE PROGRAM AND BE CERTIFIED AS**  
209 **AN AMBULATORY SURGICAL CENTER WITHIN SIX (6) MONTHS AFTER BEGINNING OPERATION OF**  
210 **THE SURGICAL SERVICE AND ANNUALLY THEREAFTER.**

211 (e) THE APPLICANT SHALL HAVE A POLICY AND PROCEDURE FOR ASSURING PROMPT  
212 ACCESS FOR ANY ESRD PATIENT IN NEED OF A VASCULAR ACCESS SURGICAL CASE PROVIDED  
213 THAT THE ESRD PATIENT IS CLINICALLY APPROPRIATE FOR TREATMENT IN AN AMBULATORY  
214 SURGICAL CENTER.

215 (f) A SURGICAL SERVICE WITH ONE OR MORE OPERATING ROOMS EXCLUSIVELY FOR  
216 VASCULAR ACCESS SURGICAL CASES SHALL EMPLOY OR CONTRACT WITH AN  
217 INTERVENTIONAL RADIOLOGIST, NEPHROLOGIST, VASCULAR SURGEON, OR OTHER PHYSICIAN  
218 TRAINED TO PROVIDE VASCULAR ACCESS PROCEDURES FOR CLINICAL OVERSIGHT OF THE  
219 SURGICAL SERVICE.

## 220 221 **Section 5. Requirements to replace a surgical service**

222  
223 Sec. 5. To replace a surgical service or one or more operating rooms, means the development of new  
224 space (whether through new construction, purchase, lease or similar arrangement) to house one or more  
225 operating rooms operated by an applicant at the same site as the operating room(s) to be replaced. This  
226 also includes designating an OR as a dedicated endoscopy or cystoscopy OR. The term also includes  
227 relocating an existing surgical facility or one or more operating rooms to a new geographic location of an  
228 existing surgical facility or one or more operating rooms to a different location currently offering surgical  
229 services. The term does not include the renovation of an existing surgical service or one or more operating  
230 rooms. An applicant requesting to replace an existing surgical service shall demonstrate each of the  
231 following, as applicable to the proposed project.

232  
233 (1) An applicant proposing to replace shall demonstrate:

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

235 (i) 1,042 surgical cases per year per operating room for which verifiable data is available to the  
236 Department, or  
237 (ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room for  
238 which verifiable data is available to the Department, or

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

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

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

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

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

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

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

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

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

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

267 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus  
268 the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases  
269 would equate to  $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$  OR.)  
270

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

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

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

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

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

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

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

284 (ii) 1,200 hours of use per year per operating room in the second twelve months of operation, and  
285 annually thereafter.  
286

287 (3) Subsections (1) and (2) shall not apply if the proposed project involves replacing one or more  
288 operating rooms at the same licensed hospital site if the surgical facility is located in a rural or micropolitan  
289 statistical area county and has one or two operating rooms.  
290

291 (4) Subsections (1) and (2) shall not apply to those hospitals licensed under Part 215 of PA 368 of  
292 1978, as amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs  
293 at the surgical service has not increased as of March 31, 2003, and the location does not change.  
294

295 (5) An applicant proposing to designate an OR as a dedicated endoscopy or cystoscopy OR shall  
296 submit notification to the Department on a form provided by the Department. An applicant under this  
297 subsection shall not be required to comply with subsections (1) and (2).  
298

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

340  
341 (7) Subsection (6) shall not apply if the proposed project involves relocating one or two operating  
342 rooms within a 20-mile radius if the surgical facility is located in a rural or micropolitan statistical area county.  
343

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

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

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

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

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

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

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

357 (ii) 1,200 hours of use per year per operating room in the second twelve months of operation.,  
358

359 (9) An applicant shall demonstrate that it meets the requirements of Section 11(2) for the number of  
360 surgical cases, or hours of use, projected under subsection (1), (2), (6), and (8).  
361

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

363  
364 Sec. 6. To expand a surgical service means the addition of one or more operating rooms at an existing  
365 surgical service. This term also includes the change from a dedicated endoscopy or cystoscopy OR to a  
366 non-dedicated OR. An applicant proposing to add one or more operating rooms at an existing surgical  
367 service shall demonstrate each of the following as applicable, to the proposed project.  
368

- 369 (1) An applicant shall demonstrate the following:
- 370 (a) All existing operating rooms in the existing surgical facility have performed an average of at least:
- 371 (i) 1,216 surgical cases per year per operating room for which verifiable data is available to the
- 372 Department, or
- 373 (ii) 1,313 hours of use in a facility that performs only outpatient surgery per year per operating room for
- 374 which verifiable data is available to the Department, or
- 375 (iii) a licensed hospital that provides both inpatient and outpatient surgery may use a weighted average
- 376 of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room for
- 377 which verifiable data is available to the Department and calculated as follows:
- 378 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,750 plus
- 379 the outpatient hours divided by 1,313. (For example: Using 438 inpatient hours and 985 outpatient hours
- 380 would equate to  $438/1,750 + 985/1,313 = 0.25 + 0.75 = 1.00$  OR), or
- 381 (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average
- 382 of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the
- 383 facility per year per operating room for which verifiable data is available to the Department and calculated as
- 384 follows:
- 385 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,750 plus
- 386 the outpatient cases divided by 1,216. (For example: Using 438 inpatient hours and 912 outpatient cases
- 387 would equate to  $438/1,750 + 912/1,216 = 0.25 + 0.75 = 1.00$  OR.)
- 388 (b) All proposed operating rooms are projected to perform an average of at least:
- 389 (i) 1,042 surgical cases per year per operating room in the second twelve months of operation, or
- 390 (ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room in
- 391 the second twelve months of operation, or
- 392 (iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average
- 393 of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room in
- 394 the second twelve months of operation, and calculated as follows:
- 395 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus
- 396 the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours
- 397 would equate to  $375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00$  OR.), or
- 398 (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average
- 399 of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the
- 400 facility per year per operating room in the second twelve months of operation, and calculated as follows:
- 401 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus
- 402 the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases
- 403 would equate to  $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$  OR.)
- 404
- 405 (2) An applicant proposing to add one or more operating rooms at a licensed hospital and is located in
- 406 a rural or micropolitan county or the applicant is located in a city, village, or township with a population of not
- 407 more than 12,000 and in a county with a population of not more than 110,000 as defined by the most recent
- 408 federal decennial census shall demonstrate each of the following:
- 409 (a) The applicant has two, three, or four ORs at the licensed hospital.
- 410 (b) All existing operating rooms have performed an average of at least:
- 411 (i) 979 surgical cases per year per operating room for which verifiable data is available to the
- 412 Department, or
- 413 (ii) 1,400 hours of use per year per operating room for which verifiable data is available to the
- 414 Department.
- 415 (c) All proposed operating rooms are projected to perform an average of at least:
- 416 (i) 839 surgical cases per year per operating room in the second twelve months of operation, or
- 417 (ii) 1,200 hours of use per year per operating room in the second twelve months of operation.
- 418
- 419 (3) Subsections (1) and (2) shall not apply if the proposed project involves adding a second operating
- 420 room in a licensed hospital site located in a rural or micropolitan statistical area county that currently has
- 421 only one operating room.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**Section 9. Requirements for Medicaid Participation**

473 Sec. 9. An applicant shall provide Verification of Medicaid participation. An applicant that is a new  
474 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided  
475 to the Department within six (6) months from the offering of services if a CON is approved.  
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477 **Section 10. Project delivery requirements terms of approval for all applicants**  
478

479 Sec. 10. An applicant shall agree that, if approved, the surgical services shall be delivered in  
480 compliance with the following terms of approval:  
481

482 (1) Compliance with these standards.  
483

484 (2) Compliance with the following quality assurance standards:  
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486 (i) The designation of ORs as defined by the standards shall not be changed without prior notification  
487 to the Department.

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

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

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

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

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

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

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

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

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

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

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

518 (B) For purposes of evaluating subsection (A), the Department shall consider it prima facie evidence as  
519 to compliance with the applicable requirements if an applicant surgical facility is accredited by the Joint  
520 Commission on the Accreditation of Healthcare Organizations, the American Osteopathic Hospital  
521 Association, or the Accreditation Association for Ambulatory Health Care, or certified by Medicare as an  
522 ambulatory surgical center.

523 (C) The operation of and referral of patients to the surgical facility shall be in conformance with 1978 PA  
524 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

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

- 526 (a) The applicant, to assure appropriate utilization by all segments of the Michigan population, shall:  
 527 (b) not deny surgical services to any individual based on ability to pay or source of payment;  
 528 (c) provide surgical services to any individual based on the clinical indications of need for the service.  
 529 (d) maintain information by payer and non-paying sources to indicate the volume of care from each  
 530 source provided annually. Compliance with selective contracting requirements shall not be construed as a  
 531 violation of this term.  
 532 (e) An applicant shall participate in Medicaid or in Medicaid managed care products at least 12  
 533 consecutive months within the first two years of operation and continue to participate annually thereafter  
 534 or attest that the applicant has been unable to contract with Medicaid managed care products at current  
 535 Medicaid rates.  
 536  
 537 (4) Compliance with the following monitoring and reporting requirements:  
 538 (a) Existing operating rooms shall perform an average of at least:  
 539 (i) 1,042 surgical cases per year per operating room verifiable by the Department, or  
 540 (ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room  
 541 verifiable by the Department, or  
 542 (iii) Be in compliance using the applicable weighted averages under Section 5.  
 543 (b) Existing operating rooms, located in a rural or micropolitan county, or within a city, village, or  
 544 township with a population of not more than 12,000 and in a county with a population of not more than  
 545 110,000 as defined by the most recent Federal decennial census in a surgical service that has three, four, or  
 546 five OR'S shall perform an average of at least:  
 547 (i) 839 surgical cases per year per operating room verifiable by the Department or  
 548 (ii) 1,200 hours of use per year per operating room verifiable by the Department.  
 549 (c) The applicant shall participate in a data collection System established and administered by the  
 550 Department. The data may include, but is not limited to, hours of use of operating rooms, annual budget  
 551 and cost information, operating schedules, and demographic, diagnostic, morbidity and mortality  
 552 information, as well as the volume of care provided to patients from all payer sources. An applicant shall  
 553 provide the required data on a separate basis for each licensed or certified site, in a format established by  
 554 the department, and in a mutually agreed upon media. The Department may elect to verify the data through  
 555 on-site review of appropriate records.  
 556 (d) The surgical service shall provide the Department with timely notice of the proposed project  
 557 implementation consistent with applicable statute and promulgated rules.  
 558

- 559 (5) AN APPLICANT APPROVED TO INITIATE A SURGICAL SERVICE EXCLUSIVELY FOR  
 560 VASCULAR ACCESS SURGICAL CASES ALSO MUST MAINTAIN COMPLIANCE WITH THE  
 561 FOLLOWING REQUIREMENTS:  
 562 (a) THE APPLICANT SHALL OBTAIN ACCREDITATION FROM THE JOINT COMMISSION, THE  
 563 ACCREDITATION ASSOCIATION FOR AMBULATORY HEALTH CARE OR ANOTHER ACCREDITING  
 564 BODY APPROVED BY CMS FOR PURPOSES OF MEDICARE CERTIFICATION UNDER SECTION  
 565 1865(a) OF THE SOCIAL SECURITY ACT WITHIN SIX (6) MONTHS AFTER BEGINNING OPERATION  
 566 OF THE SURGICAL SERVICE AND AT ALL TIMES THEREAFTER.  
 567 (b) THE APPLICANT SHALL PARTICIPATE IN THE MEDICARE PROGRAM AND BE CERTIFIED AS  
 568 AN AMBULATORY SURGICAL CENTER WITHIN SIX (6) MONTHS AFTER BEGINNING OPERATION OF  
 569 THE SURGICAL SERVICE AND ANNUALLY THEREAFTER.  
 570 (c) THE SURGICAL SERVICE SHALL BE USED ONLY FOR VASCULAR ACCESS SURGICAL  
 571 CASES UNLESS THE APPLICANT HAS OBTAINED CON APPROVAL FOR ANY OPERATING ROOMS  
 572 THAT ARE NOT DEDICATED EXCLUSIVELY TO VASCULAR ACCESS SURGICAL CASES.  
 573 (d) THE APPLICANT SHALL HAVE A POLICY AND PROCEDURE FOR ASSURING PROMPT  
 574 ACCESS FOR ANY ESRD PATIENT IN NEED OF A VASCULAR ACCESS SURGICAL CASE PROVIDED  
 575 THAT THE ESRD PATIENT IS CLINICALLY APPROPRIATE FOR TREATMENT IN AN AMBULATORY  
 576 SURGICAL CENTER.  
 577 (e) A SURGICAL SERVICE WITH ONE OR MORE OPERATING ROOMS EXCLUSIVELY FOR  
 578 VASCULAR ACCESS SURGICAL CASES SHALL EMPLOY OR CONTRACT WITH AN

579 INTERVENTIONAL RADIOLOGIST, NEPHROLOGIST, VASCULAR SURGEON, OR OTHER PHYSICIAN  
580 TRAINED TO PROVIDE VASCULAR ACCESS PROCEDURES FOR CLINICAL OVERSIGHT OF THE  
581 SURGICAL SERVICE.

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583 (6) The agreements and assurances required by this section shall be in the form of a certification  
584 agreed to by the applicant or its authorized agent.

#### 585 586 **Section 11. Documentation of projections**

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588 Sec. 11. (1) An applicant required to project volumes of service shall specify how the volume  
589 projections were developed and shall include only those surgical cases performed in an OR UNLESS THE  
590 APPLICANT PROPOSES A SURGICAL SERVICE OR ONE OR MORE OPERATING ROOMS TO BE  
591 USED EXCLUSIVELY FOR VASCULAR ACCESS SURGICAL CASES.

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

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

596 (c) AN APPLICANT PROPOSING TO INITIATE A SURGICAL SERVICE OR ONE OR MORE  
597 OPERATING ROOMS TO BE USED EXCLUSIVELY FOR VASCULAR ACCESS SURGICAL CASES MAY  
598 INCLUDE ONLY VASCULAR ACCESS SURGICAL CASES IN THE PROJECTIONS REQUIRED UNDER  
599 THIS SECTION.

600 (d) DEDICATED VASCULAR ACCESS SURGICAL CASES PERFORMED IN DEDICATED  
601 VASCULAR ACCESS OPERATING ROOMS SHALL ONLY BE USED TO PROJECT VOLUME FOR  
602 DEDICATED VASCULAR ACCESS OPERATING ROOMS.

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

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

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

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

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

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

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

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

635

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

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

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

640 approved by the CON Commission on September ~~25~~21, ~~2014~~2017 and effective on ~~December~~

641 ~~22~~NOVEMBER 17, ~~2014~~2017.

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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