

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.)
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) "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 FSOF 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).

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.)

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

385
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 (1) An applicant agrees and assures to comply with all applicable project delivery requirements.
- 393
394 (2) For the first application proposing to acquire an existing surgical service, for which a final decision
395 has not been issued, on or after January 27, 1996, the existing surgical service shall not be required to be in
396 compliance with the applicable volume requirements set forth in these standards. The surgical service shall
397 be operating at the applicable volume requirements in the second 12 months after the effective date of the
398 acquisition.
- 399
400 (3) For any application proposing to acquire an existing surgical service except the first application, for
401 which a final decision has not been issued, on or after January 27, 1996, the existing surgical service shall
402 be required to be in compliance with the applicable volume requirements on the date the application is
403 submitted to the Department.
- 404 (4) Subsection (3) shall not apply to those hospitals licensed under Part 215 of PA 368 of 1978, as
405 amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs at the
406 surgical service has not increased as of March 31, 2003, and the location does not change.

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

408
409
410 Sec. 8. A hybrid or/ccl means an operating room located on a sterile corridor and equipped with an
411 angiography system permitting minimally invasive procedures of the heart and blood vessels with full
412 anesthesia capabilities. An applicant proposing to add one or more hybrid OR/CCLS at an existing surgical
413 service shall demonstrate each of the following:
414
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