

1 MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

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

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5
6 (By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of
7 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being
8 sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)
9

10 **Section 1. Applicability**

11
12 Sec. 1. ~~(1)~~ These standards are requirements for THE approval ~~and delivery of services for all projects~~
13 ~~approved and Certificates of Need issued~~ OF THE INITIATION, REPLACEMENT, EXPANSION, OR
14 ACQUISITION OF A SURGICAL SERVICE PROVIDED IN A SURGICAL FACILITY AND THE DELIVERY
15 OF THESE SERVICES under Part 222 of the Code ~~that involve the initiation, expansion, replacement,~~
16 ~~relocation, or acquisition of surgical services provided in a surgical facility.~~

17
18 ~~(2)~~ PURSUANT TO PART 222 OF THE CODE, Surgical Surgical services provided in a freestanding
19 surgical outpatient facility, an ambulatory surgery center certified under title XVIII, or a surgical department
20 of a hospital licensed under Part 215 of the Code and offering inpatient or outpatient surgical services are
21 covered clinical services ~~for purposes of Part 222 of the Code.~~

22
23 ~~(3)~~ A "freestanding surgical outpatient facility" is a health facility for purposes of Part 222 of the Code.

24
25 ~~(4)~~ The Department shall use ~~sections 3, 4, 5, 6, 7, 8, and 11, as applicable,~~ THESE STANDARDS in
26 applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws. AND

27
28 ~~(5)~~ The Department shall use Section 10, as applicable, in applying Section 22225(2)(c) of the
29 Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.
30

31 **Section 2. Definitions**

32
33 Sec. 2. ~~(1)~~ For purposes of these standards:

34 ~~(a)~~ "Acquisition of a surgical service" means a project involving the issuance of a new license for a
35 hospital or a freestanding surgical outpatient facility or a new certification as an ambulatory surgical center
36 as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an
37 existing surgical service.

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

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

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

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

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

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

51 ~~(hg)~~ "Dedicated endoscopy or cystoscopy operating room" means a room used exclusively for
52 endoscopy or cystoscopy cases.

53 ~~(ih)~~ "Department" means the Michigan Department of Community Health (MDCH).

54 | (ji) "Emergency Room" means a designated area in a licensed hospital and recognized by the
55 | Department as having met the staffing and equipment requirements for the treatment of emergency
56 | patients.

57 | (kj) "Endoscopy" means visual inspection of any portion of the body by means of an endoscope.

58 | (lk) "Endoscopy case" means a single visit to an operating room during which one or more endoscopic
59 | procedures are performed.

60 | (ml) "Existing surgical service" means a surgical facility that, on the date an application is submitted to
61 | the Department, is part of a licensed hospital site, a licensed freestanding surgical outpatient facility, or a
62 | certified ASC.

63 | ~~(n) "Expand a surgical service" means the addition of one or more operating rooms at an existing
64 | surgical service. This term also includes the change from a dedicated endoscopy or cystoscopy OR to a
65 | non-dedicated OR.~~

66 | ~~(om) "Freestanding surgical outpatient facility" or "FSOF" means a health facility licensed under Part 208
67 | of the Code. It does not include a surgical outpatient facility owned and operated as a part of a licensed
68 | hospital site. A freestanding surgical outpatient facility is a health facility for purposes of Part 222 of the
69 | Code.~~

70 | (pn) "Hospital" means a health facility licensed under Part 215 of the Code.

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

75 | ~~(r) "Initiate a surgical service" means to begin operation of a surgical facility at a site that has not
76 | offered surgical services within the 12-month period immediately preceding the date an application is
77 | submitted to the Department. The term does not include the relocation of a surgical service or one or more
78 | operating rooms meeting the requirements of Section 7.~~

79 | (sp) "Licensed hospital site" means either:
80 | (i) in the case of a single site hospital, the location of the hospital authorized by license and listed on
81 | that licensee's certificate of licensure or
82 | (ii) in the case of a hospital with multiple sites, the location of each separate and distinct inpatient site
83 | as authorized by licensure.

84 | (tq) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6
85 | and 1396r-8 to 1396v.

86 | (ur) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as
87 | that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by
88 | the statistical policy office of the office of information and regulatory affairs of the United States office of
89 | management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

90 | (vs) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as
91 | that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by
92 | the statistical policy office of the office of information and regulatory affairs of the United States office of
93 | management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

94 | (wt) "Offer" means to perform surgical services.

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

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

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

106 | (~~ax~~) "Procedure room" means a room in a surgical facility constructed and equipped to perform surgical
107 | procedures and not located on a sterile corridor.

108 | ~~—(bb) "Relocate a surgical service or one or more operating rooms" means changing the geographic~~
109 | ~~location of an existing surgical facility or one or more operating rooms to a different location currently~~
110 | ~~offering surgical services within the relocation zone.~~

111 | ~~—(cc) "Relocation zone," for purposes of these standards, means a site that is within a 10-mile radius of~~
112 | ~~the site at which an existing surgical service is located if an existing surgical service is located in a~~
113 | ~~metropolitan statistical area county, or a 20-mile radius if an existing surgical service is located in a rural or~~
114 | ~~micropolitan statistical area county.~~

115 | (~~edy~~) "Renovate an existing surgical service or one or more operating rooms" means a project that:
116 | (i) involves the renovation, remodeling, or modernization of an operating suite of a hospital, FSOF, or
117 | ASC;
118 | (ii) does not involve new construction;
119 | (iii) does not involve a change in the physical location within the surgical facility at the same site; and
120 | (iv) does not result in an increase in the number of operating rooms at an existing surgical facility.

121 | Renovation of an existing surgical service or one or more operating rooms may involve a change in the
122 | number of square feet allocated to an operating suite. The renovation of an existing surgical service or one
123 | or more operating rooms shall not be considered the initiation, expansion, replacement, ~~relocation,~~ or
124 | acquisition of a surgical service or one or more operating rooms.

125 | ~~—(ee) "Replace a surgical service or one or more operating rooms" means the development of new space~~
126 | ~~(whether through new construction, purchase, lease or similar arrangement) to house one or more operating~~
127 | ~~rooms currently operated by an applicant at the same site as the operating room(s) to be replaced. This~~
128 | ~~term also includes designating an OR as a dedicated endoscopy or cystoscopy OR. The term does not~~
129 | ~~include the renovation of an existing surgical service or one or more operating rooms.~~

130 | (~~ffz~~) "Rural county" means a county not located in a metropolitan statistical area or micropolitan
131 | statistical areas as those terms are defined under the "standards for defining metropolitan and micropolitan
132 | statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United
133 | States Office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in
134 | Appendix A.

135 | (~~ggaa~~) "Sterile corridor" means an area of a surgical facility designated primarily for surgical cases and
136 | surgical support staff. Access to this corridor is controlled and the corridor is not used by the general public
137 | or personnel of the surgical facility whose primary work station is not in the operating suite(s) or whose
138 | primary work tasks do not require them to be in the operating suite(s) of a surgical facility. Examples of
139 | personnel who would normally use sterile corridors include physicians, surgeons, operating room nurses,
140 | laboratory or radiology personnel, and central supply or housekeeping personnel. Other terms commonly
141 | used to represent "sterile" in describing access areas include "restricted," "controlled," "limited access," or
142 | "clean."

143 | (~~hbb~~) "Surgical case" means a single visit to an operating room during which one or more surgical
144 | procedures are performed.

145 | (ii) "Surgical facility" means either:
146 | (i) a licensed FSOF;
147 | (ii) a certified ASC; or
148 | (iii) a licensed hospital site authorized to provide inpatient or outpatient surgery.
149 | (jj) "Surgical service" means performing surgery in a surgical facility.

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

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

155 |
156 | (2) The definitions in Part 222 shall apply to these standards.
157 |

158 **Section 3. Inventory of operating rooms used to perform surgical services; surgical cases, or hours**
159 **of use; and evaluating compliance with minimum volume requirements**
160

161 Sec. 3. (1) The Department shall use the number of operating rooms and verifiable data pursuant to
162 subsection (2) to determine the number of surgical cases, hours of use, or both, as applicable, pursuant to
163 subsection (3) for purposes of evaluating compliance with the actual and proposed volume requirements set
164 forth in the applicable sections of these standards. Compliance with CON minimum volume requirements
165 established by these standards shall be determined based on the average number of surgical cases, hours
166 of use, or both, per operating room of the surgical service as permitted by these standards.
167

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

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

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

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

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

175 (iv) An operating room that is or will be used, though not exclusively, to provide surgical services to
176 patients requiring burn care or trauma care, as those terms are defined in these standards. No more than
177 0.5 burn care and 0.5 trauma care operating rooms shall be excluded pursuant to this subdivision.

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

180 (c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all
181 operating rooms in which surgery is or will be performed, excluding any operating rooms used exclusively
182 for endoscopy or cystoscopy cases.
183

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

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

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

192 (c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all
193 surgical cases, or hours of use, performed in the operating rooms identified in subsection (2)(c). Cases, or
194 hours of use, performed in any operating room used exclusively for endoscopy or cystoscopy cases, shall
195 be excluded.
196

197 **Section 4. Requirements ~~for approval for applicants proposing to initiate a surgical service~~**
198

199 Sec. 4. ~~(1) An applicant proposing to~~ To initiate a surgical service means to begin operation of a surgical
200 facility at a site that has not offered surgical services within the 12-month period immediately preceding the
201 date an application is submitted to the Department. The term does not include the relocation of a surgical
202 service or one or more operating rooms. AN APPLICANT PROPOSING TO INITIATE A SURGICAL
203 SERVICE shall demonstrate THE FOLLOWING, AS APPICABLE TO THE PROPOSED PROJECT.
204

205 (1) that eEach proposed operating room shall perform an average of at least 1,128 surgical cases per
206 year per operating room in the second 12 months of operation, ~~and annually thereafter.~~
207

208 (2) Subsection (1) shall not apply if the proposed project involves the initiation of a surgical service with
209 1 or 2 operating rooms at a licensed hospital site located in a rural or micropolitan statistical area county that
210 does not offer surgical services as of the date an application is submitted to the Department.

211
212 (3) An applicant shall demonstrate that it meets the requirements of Section 140(2) for the number of
213 surgical cases projected under subsection (1).
214

215 Section 5. Requirements to replace a surgical service

216
217 Sec. 5. TO replace a surgical service or one or more operating rooms, means the development of new
218 space (whether through new construction, purchase, lease or similar arrangement) to house one or more
219 operating rooms operated by an applicant at the same site as the operating room(s) to be replaced. This
220 also includes designating an OR as a dedicated endoscopy or cystoscopy OR. The term also includes
221 relocating an existing surgical facility or one or more operating rooms to a different NEW GEOGRAPHIC
222 location of an existing surgical facility or one or more operating rooms to a different location currently
223 offering surgical services within the relocation zone. The term does not include the renovation of an existing
224 surgical service or one or more operating rooms. AN APPLICANT REQUESTING TO REPLACE AN
225 EXISTING SURGICAL SERVICE SHALL DEMONSTRATE EACH OF THE FOLLOWING, AS
226 APPLICABLE TO THE PROPOSED PROJECT.
227

228 (1) AN APPLICANT PROPOSING TO REPLACE SHALL DEMONSTRATE:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

285 _____
286 (4) Subsections (1) and (2) shall not apply to those hospitals licensed under Part 215 of PA 368 of
287 1978, as amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs
288 at the surgical service has not increased as of March 31, 2003, and the location does not change.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

335
336 (7) Subsection (6) shall not apply if the proposed project involves relocating one or two operating
337 rooms within a 20-mile radiusthe relocation zone, if the surgical facility is located in a rural or micropolitan
338 statistical area county.

339
340 (8) An applicant proposing to relocate one or more operating rooms from one licensed hospital site to
341 another licensed hospital site and is located in a rural or micropolitan county or the applicant is located in a
342 city, village, or township with a population of not more than 12,000 and in a county with a population of not
343 more than 110,000 as defined by the most recent federal decennial census shall demonstrate each of the
344 following:

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

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

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

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

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

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

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

354
355 (9) An applicant shall demonstrate that it meets the requirements of Section 10(2) for the number of
356 surgical cases, or hours of use, projected under subsection (1), (2), (6), and (8).

357
358 **Section 56. Requirements ~~for approval for surgical services proposing~~ to expand an existing**
359 **surgical service**

360
361 Sec. 56. (1)–TO expand a surgical service means the addition of one or more operating rooms at an
362 existing surgical service. This term also includes the change from a dedicated endoscopy or cystoscopy OR
363 to a non-dedicated OR. An applicant proposing to add one or more operating rooms at an existing surgical
364 service shall demonstrate each of the following AS APPLICABLE, TO THE PROPOSED PROJECT.

365
366 (a1) AN APPLICANT SHALL DEMONSTRATE THE FOLLOWING:

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

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

421 (3) Subsections (1) and (2) shall not apply if the proposed project involves adding a second operating
422 room in a licensed hospital site located in a rural or micropolitan statistical area county that currently has
423 only one operating room.
424

425 (4) An applicant shall demonstrate that it meets the requirements of Section 140(2) for the number of
426 surgical cases, or hours of use, projected under subsections (1) and (2).
427

428 **Section 6. Requirements for approval for facilities proposing to replace a surgical service or one or**
429 **more operating rooms**
430

431 ~~Sec. 6. (1) An applicant proposing to replace an existing surgical service or one or more operating~~
432 ~~rooms at the same site shall demonstrate each of the following:~~

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

434 ~~—(i) 1,042 surgical cases per year per operating room for which verifiable data is available to the~~
435 ~~Department, or~~

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

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

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

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

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

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

452 ~~—(i) 1,042 surgical cases per year per operating room in the second twelve months of operation, and~~
453 ~~annually thereafter, or~~

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

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

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

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

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

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

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

- 474 ~~—(b) All existing operating rooms have performed an average of at least:~~
475 ~~—(i) 839 surgical cases per year per operating room for which verifiable data is available to the~~
476 ~~Department, or~~
477 ~~—(ii) 1,200 hours of use per year per operating room for which verifiable data is available to the~~
478 ~~Department.~~
479 ~~—(c) All operating rooms, existing and replaced, are projected to perform an average of at least:~~
480 ~~—(i) 839 surgical cases per year per operating room in the second twelve months of operation, and~~
481 ~~annually thereafter, or~~
482 ~~—(ii) 1,200 hours of use per year per operating room in the second twelve months of operation, and~~
483 ~~annually thereafter.~~
484
485 ~~—(3) Subsections (1) and (2) shall not apply if the proposed project involves replacing one or more~~
486 ~~operating rooms at the same licensed hospital site, if the surgical facility is located in a rural or micropolitan~~
487 ~~statistical area county and has one or two operating rooms.~~
488
489 ~~—(4) Subsections (1) and (2) shall not apply to those hospitals licensed under Part 215 of PA 368 of~~
490 ~~1978, as amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs~~
491 ~~at the surgical service has not increased as of March 31, 2003, and the location does not change.~~
492
493 ~~—(5) An applicant proposing to designate an OR as a dedicated endoscopy or cystoscopy OR shall~~
494 ~~submit notification to the Department on a form provided by the Department. An applicant under this~~
495 ~~subsection shall not be required to comply with subsections (1) and (2).~~
496

497 **Section 7. Requirements for approval for applicants proposing to relocate an existing surgical**
498 **service or one or more operating rooms**
499

500 ~~—Sec. 7. An applicant proposing to relocate an existing surgical service or one or more operating rooms~~
501 ~~shall demonstrate each of the following, as applicable:~~
502

503 ~~—(1) The proposed relocation will not result in an increase in the total number of operating rooms~~
504 ~~operated by an applicant at the existing and proposed sites unless an applicant can demonstrate~~
505 ~~compliance with the applicable requirements of Section 5.~~
506

507 ~~—(2) The proposed new site is located within the relocation zone.~~
508

509 ~~—(3) All existing operating rooms in the surgical facility from which one or more ORs are proposed to be~~
510 ~~relocated have performed an average of at least:~~

511 ~~—(a) 1,042 surgical cases per year per operating room for which verifiable data is available to the~~
512 ~~Department, or~~

513 ~~—(b) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room for~~
514 ~~which verifiable data is available to the Department, or,~~

515 ~~—(c) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average~~
516 ~~of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room for~~
517 ~~which verifiable data is available to the Department and calculated as follows:~~

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

521 ~~—(d) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average~~
522 ~~of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the~~
523 ~~facility per year per operating room for which verifiable data is available to the Department and calculated as~~
524 ~~follows:~~

525 ~~—(i) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus~~
526 ~~the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases~~
527 ~~would equate to $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$ OR.)~~
528

529 ~~—(4) All operating rooms, existing and relocated, are projected to perform an average of at least:~~

530 ~~—(a) 1,042 surgical cases per year per operating room in the second twelve months of operation, and~~
531 ~~annually thereafter, or~~

532 ~~—(b) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room in~~
533 ~~the second twelve months of operation, and annually thereafter, or~~

534 ~~—(c) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average~~
535 ~~of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room in~~
536 ~~the second twelve months of operation, and annually thereafter and calculated as follows:~~

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

540 ~~—(d) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average~~
541 ~~of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the~~
542 ~~facility per year per operating room in the second twelve months of operation, and annually thereafter and~~
543 ~~calculated as follows:~~

544 ~~—(i) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus~~
545 ~~the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases~~
546 ~~would equate to $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$ OR.)~~
547

548 ~~—(5) Subsections (3) and (4) shall not apply if the proposed project involves relocating one or two~~
549 ~~operating rooms within the relocation zone, if the surgical facility is located in a rural or micropolitan~~
550 ~~statistical area county.~~

551

552 ~~—(6) An applicant proposing to relocate one or more operating rooms from one licensed hospital site to~~
553 ~~another licensed hospital site and is located in a rural or micropolitan county or the applicant is located in a~~
554 ~~city, village, or township with a population of not more than 12,000 and in a county with a population of not~~
555 ~~more than 110,000 as defined by the most recent federal decennial census shall demonstrate each of the~~
556 ~~following:~~

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

558 ~~—(b) All existing operating rooms have performed an average of at least:~~

559 ~~—(i) 839 surgical cases per year per operating room for which verifiable data is available to the~~
560 ~~Department, or~~

561 ~~—(ii) 1,200 hours of use per year per operating room for which verifiable data is available to the~~
562 ~~Department.~~

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

564 ~~—(i) 839 surgical cases per year per operating room in the second twelve months of operation, and~~
565 ~~annually thereafter, or~~

566 ~~—(ii) 1,200 hours of use per year per operating room in the second twelve months of operation, and~~
567 ~~annually thereafter.~~

568

569 ~~—(7) An applicant shall demonstrate that it meets the requirements of Section 11(2) for the number of~~
570 ~~surgical cases, or hours of use, projected under subsection (4) and (6).~~

571

572 **Section 87. Requirements for approval for applicants proposing to acquire an existing surgical**
573 **service**

574

575 Sec. 87. Acquisition of a surgical service means a project involving the issuance of a new license for a
576 hospital or a freestanding surgical outpatient facility or a new certification as an ambulatory surgical center
577 as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an

578 existing surgical service. An applicant proposing to acquire an existing surgical service shall demonstrate
579 each of the following, as applicable TO THE PROPOSED PROJECT.

580
581 ~~(1) The acquisition will not result in an increase in the number of operating rooms at the surgical service to~~
582 ~~be acquired unless an applicant can demonstrate compliance with the applicable requirements of Section 5.~~

583
584 ~~—(2) The location of the surgical service does not change as a result of the acquisition unless an~~
585 ~~applicant can demonstrate compliance with the applicable requirements of Section 7.~~

586
587 (31) An applicant agrees and assures to comply with all applicable project delivery requirements.

588
589 (42) For the first application ~~for proposed proposing TO acquisition of~~ ACQUIRE an existing surgical
590 service, for which a final decision has not been issued, on or after January 27, 1996, ~~an-THE~~ existing
591 surgical service ~~to be acquired~~ shall not be required to be in compliance with the APPLICABLE volume
592 requirements ~~applicable to the seller/lessor on the date the acquisition occurs~~ SET FORTH IN THESE
593 STANDARDS. The surgical service shall be operating at the applicable volume requirements in the second
594 12 months after the effective date of the acquisition, ~~and annually thereafter.~~

595
596 (53) For any application ~~for proposed acquisition of~~ PROPOSING TO ACQUIRE an existing surgical
597 service except the first application, for which a final decision has not been issued, on or after January 27,
598 1996, THE EXISTING SURGICAL SERVICE ~~an applicant~~ shall be required to document BE IN compliance
599 with the APPLICABLE volume requirements ~~applicable to the existing surgical service~~ on the date ~~an-THE~~
600 application is submitted to the Department.

601
602 (64) Subsection (53) shall not apply to those hospitals licensed under Part 215 of PA 368 of 1978, as
603 amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs at the
604 surgical service has not increased as of March 31, 2003, and the location does not change.

605 606 **Section 98. Requirements for approval -- all applicants** MEDICAID PARTICIPATION

607
608 Sec. 98. An applicant shall provide VERIFICATION evidence OF MEDICAID PARTICIPATION of
609 participation in Medicaid or in Medicaid managed care products or attestation that the applicant has been
610 unable to contract at current Medicaid rates at the time the application is submitted to the Department.
611 By providing a signed affidavit, an applicant that is an ASC or FSOF shall demonstrate a willingness to
612 participate when accepted by Medicaid. An applicant that is initiating a a new service or is a new provider
613 not currently enrolled in Medicaid shall provide CERTIFY a signed affidavit stating that proof of Medicaid
614 participation will be provided to the Department within six (6) months from the offering of services if a
615 CON is approved. ~~If the required documentation is not submitted with the application on the designated~~
616 ~~application date, the application will be deemed filed on the first applicable designated application date~~
617 ~~after all required documentation is received by the Department.~~

618 619 **Section 409. Project delivery requirements -- terms of approval for all applicants**

620
621 Sec. 409. ~~(1)~~ An applicant shall agree that, if approved, the project SURGICAL SERVICES shall be
622 delivered in compliance with the following terms of CON approval:

623
624 (a1) Compliance with these standards.

625 ~~(b) Compliance with applicable operating standards.~~

626 (2) COMPLIANCE WITH THE FOLLOWING QUALITY ASSURANCE STANDARDS:

627 ~~(c) Compliance with the following terms of approval, as applicable:~~

628 ~~(i) The approved services and/or operating rooms shall be operating at the applicable required~~
629 ~~volumes within the time periods specified in these standards, and annually thereafter.~~

630 (iii) The designation of ORs as defined by the standards shall not be changed without prior notification
631 to the Department.

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

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

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

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

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

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

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

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

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

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

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

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

667 (C) The operation of and referral of patients to the surgical facility shall be in conformance with 1978 PA
668 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

670 (3) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:

671 (iii)a) ~~AN~~THE applicant, to assure appropriate utilization by all segments of the Michigan population, shall:

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

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

674 (Cd) maintain information by payer and non-paying sources to indicate the volume of care from each
675 source provided annually.

676 Compliance with selective contracting requirements shall not be construed as a violation of this term.

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

681 (4) COMPLIANCE WITH THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:

683 _(iva) EXISTING OPERATING ROOMS SHALL PERFORM AN AVERAGE OF AT LEAST:
684 (i) 1,042 SURGICAL CASES PER YEAR PER OPERATING ROOM VERIFIABLE BY THE
685 DEPARTMENT, OR
686 (ii) 1,125 HOURS OF USE IN A FACILITY THAT PERFORMS ONLY OUTPATIENT SURGERY PER
687 YEAR PER OPERATING ROOM VERIFIABLE BY THE DEPARTMENT, OR
688 (iii) BE IN COMPLIANCE USING THE APPLICABLE WEIGHTED AVERAGES UNDER SECTION 5.
689 (b) EXISTING OPERATING ROOMS, LOCATED IN A RURAL OR MICROPOLITAN COUNTY, OR
690 WITHIN A CITY, VILLAGE, OR TOWNSHIP WITH A POPULATION OF NOT MORE THAN 12,000 AND IN
691 A COUNTY WITH A POPULATION OF NOT MORE THAN 110,000 AS DEFINED BY THE MOST
692 RECENT FEDERAL DECENNIAL CENSUS IN A SURGICAL SERVICE THAT HAS THREE, FOUR, OR
693 FIVE OR'S SHALL PERFORM AN AVERAGE OF AT LEAST:
694 (i) 839 SURGICAL CASES PER YEAR PER OPERATING ROOM VERIFIABLE BY THE
695 DEPARTMENT OR
696 (ii) 1,200 HOURS OF USE PER YEAR PER OPERATING ROOM VERIFIABLE BY THE
697 DEPARTMENT.
698 (C) ~~An~~THE applicant shall participate in a data collection ~~network~~SYSTEM established and
699 administered by the Department. The data may include, but is not limited to, hours of use of operating
700 rooms, annual budget and cost information, operating schedules, and demographic, diagnostic, morbidity
701 and mortality information, as well as the volume of care provided to patients from all payer sources. An
702 applicant shall provide the required data on a separate basis for each licensed or certified site, in a format
703 established by the department, and in a mutually agreed upon media. The Department may elect to verify
704 the data through on-site review of appropriate records.
705 (vD) The ~~applicant~~SURGICAL SERVICE shall provide the Department with a-TIMELY notice ~~stating-OF~~
706 the ~~first date on which the service became operational, and such notice shall be submitted to the~~
707 DepartmentPROPOSED PROJECT IMPLEMENTATION consistent with applicable statute and promulgated
708 rules.
709
710 —(d) ~~Compliance with the following quality assurance standards, as applicable:~~
711 —(i) ~~Surgical facilities shall have established policies for the selection of patients and delineate~~
712 ~~procedures which may be performed in that particular facility.~~
713 —(ii) ~~Surgical facilities shall have provisions for handling all types of in-house emergencies, including~~
714 ~~cardiopulmonary resuscitation.~~
715 —(iii) ~~Surgical facilities performing outpatient surgery shall have policies which allow for hospitalization of~~
716 ~~patients when necessary. All surgeons who perform surgery within the facility shall have evidence of~~
717 ~~admitting privileges or of written arrangements with other physicians for patient admissions at a local~~
718 ~~hospital. The surgical facility shall have an established procedure, including a transfer agreement, that~~
719 ~~provides for the immediate transfer of a patient requiring emergency care beyond the capabilities of the~~
720 ~~surgical facility to a hospital that is capable of providing the necessary inpatient services and is located~~
721 ~~within 30 minutes of the surgical facility. If no hospital is located within 30 minutes of the surgical facility, an~~
722 ~~applicant shall have a transfer agreement with the nearest hospital having such capability.~~
723 —(iv) ~~An applicant shall have written policies and procedures regarding the administration of a surgical~~
724 ~~facility.~~
725 —(v) ~~An applicant shall have written position descriptions which include minimum education, licensing, or~~
726 ~~certification requirements for all personnel employed at the surgical facility.~~
727 —(vi) ~~An applicant shall have a process for credentialing individuals authorized to perform surgery or~~
728 ~~provide anesthesia services at a surgical facility. An applicant's credentialing process shall insure that the~~
729 ~~selection and appointment of individuals to the staff of a surgical facility does not discriminate on the basis of~~
730 ~~licensure, registration, or professional education as doctors of medicine, osteopathic medicine and surgery,~~
731 ~~podiatric medicine and surgery, or dentistry.~~
732 —(vii) ~~An applicant shall provide laboratory, diagnostic imaging, pathology and pharmacy (including~~
733 ~~biologicals) services, either on-site or through contractual arrangements.~~
734 —(viii) ~~An applicant shall have written policies and procedures for advising patients of their rights.~~

735 ~~—(ix) An applicant shall develop and maintain a system for the collection, storage, and use of patient~~
736 ~~records.~~
737 ~~—(x) Surgical facilities shall have separate patient recovery and non-patient waiting areas.~~
738 ~~—(xi) Surgical facilities shall provide a functionally safe and sanitary environment for patients, personnel,~~
739 ~~and the public. Each facility shall incorporate a safety management program to maintain a physical~~
740 ~~environment free of hazards and to reduce the risk of human injury.~~
741 ~~—(e) For purposes of evaluating subsection (d), the Department shall consider it prima facie evidence as~~
742 ~~to compliance with the applicable requirements if an applicant surgical facility is accredited by the Joint~~
743 ~~Commission on the Accreditation of Healthcare Organizations, the American Osteopathic Hospital~~
744 ~~Association, or the Accreditation Association for Ambulatory Health Care, or certified by Medicare as an~~
745 ~~ambulatory surgical center.~~
746 ~~—(f) An applicant shall participate in Medicaid or in Medicaid managed care products at least 12~~
747 ~~consecutive months within the first two years of operation and continue to participate annually thereafter~~
748 ~~or attest that the applicant has been unable to contract with Medicaid managed care products at current~~
749 ~~Medicaid rates.~~
750
751 ~~—(2) The operation of and referral of patients to the surgical facility shall be in conformance with 1978 PA~~
752 ~~368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).~~
753

754 (35) The agreements and assurances required by this section shall be in the form of a ~~certification~~
755 ~~agreed~~certification agreed to by the applicant or its authorized agent.
756

757 **Section 4410. Documentation of projections**

758

759 Sec. 4410. (1) An applicant required to project volumes of service shall specify how the volume
760 projections were developed and shall include only those surgical cases performed in an OR.

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

764 (b) The Department shall subtract any previous commitment, pursuant to subsection 2(d).
765

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

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

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

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

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

783 (e) The number of surgical cases performed, at the existing surgical facility from which surgical cases
784 will be transferred, during the most recent 12-month period prior to the date an application is submitted to
785 the Department for which verifiable annual survey data is available.
786

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

791

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

793

794 Sec. 12. ~~(1) PROPOSED projects reviewed under these standards shall not be subject to comparative~~
795 ~~review.~~ These CON review standards supercede and replace the CON Review Standards for Surgical
796 Facilities approved by the CON Commission on ~~March 21, 2006~~ APRIL 30, 2008 and effective on June ~~520,~~
797 ~~2006~~ 2008.

798

799 ~~—(2) Projects reviewed under these standards shall not be subject to comparative review.~~

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**CON REVIEW STANDARDS
FOR SURGICAL SERVICES**

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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