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MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR SURGICAL SERVICES

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

Section 1. Applicability

Sec. 1. These standards are requirements for THE approval of OF THE INITIATION, REPLACEMENT, EXPANSION, OR ACQUISITION OF A SURGICAL SERVICE PROVIDED IN A SURGICAL FACILITY AND THE DELIVERY OF THESE SERVICES under Part 222 of the Code . Surgical services provided in a freestanding surgical outpatient facility, an ambulatory surgery center certified under title XVIII, or a surgical department of a hospital licensed under Part 215 of the Code and offering inpatient or outpatient surgical services are covered clinical services . The Department shall use THESE STANDARDS in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws AND Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

Sec. 2. For purposes of these standards:

- (a) "Ambulatory surgical center" or "ASC" means any distinct entity certified by Medicare as an ASC under the provisions of Title 42, Part 416, that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization.
- (b) "Burn care" means surgical services provided to burn patients in a licensed hospital site that has been verified as meeting the "Guidelines for Development and Operation of Burn Centers" issued by the American Burn Association in March 1988, or equivalent standards for a burn center.
- (c) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.
- (d) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.
- (e) "Cystoscopy" means direct visual examination of the urinary tract with a cystoscope.
- (f) "Cystoscopy case" means a single visit to an operating room during which one or more cystoscopic procedures are performed.
- (g) "Dedicated endoscopy or cystoscopy operating room" means a room used exclusively for endoscopy or cystoscopy cases.
- (h) "Department" means the Michigan Department of Community Health (MDCH).
- (i) "Emergency Room" means a designated area in a licensed hospital and recognized by the Department as having met the staffing and equipment requirements for the treatment of emergency patients.
- (j) "Endoscopy" means visual inspection of any portion of the body by means of an endoscope.
- (k) "Endoscopy case" means a single visit to an operating room during which one or more endoscopic procedures are performed.
- (l) "Existing surgical service" means a surgical facility that, on the date an application is submitted to the Department, is part of a licensed hospital site, a licensed freestanding surgical outpatient facility, or a certified ASC.
- (m) "Freestanding surgical outpatient facility" or "FSOF" means a health facility licensed under Part 208 of the Code. It does not include a surgical outpatient facility owned and operated as a part of a licensed hospital site. A freestanding surgical outpatient facility is a health facility for purposes of Part 222 of the Code.
- (n) "Hospital" means a health facility licensed under Part 215 of the Code.

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

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

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

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

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

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

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

73 (t) "Offer" means to perform surgical services.

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

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

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

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

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

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

90 (ii) does not involve new construction;

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

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

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

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

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

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

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

(ii) "Surgical facility" means either:

(i) a licensed FSOF;

(ii) a certified ASC; or

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

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

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

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

(2) The definitions in Part 222 shall apply to these standards.

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

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

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

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

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

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

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

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

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

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

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

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

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

159 (c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all
160 surgical cases, or hours of use, performed in the operating rooms identified in subsection (2)(c). Cases, or
161 hours of use, performed in any operating room used exclusively for endoscopy or cystoscopy cases, shall
162 be excluded.
163

164 **Section 4. Requirements to initiate a surgical service** 165

166 Sec. 4. To initiate a surgical service means to begin operation of a surgical facility at a site that has not
167 offered surgical services within the 12-month period immediately preceding the date an application is
168 submitted to the Department. AN APPLICANT PROPOSING TO INITIATE A SURGICAL SERVICE shall
169 demonstrate THE FOLLOWING, AS APPICABLE TO THE PROPOSED PROJECT.
170

171 (1) Each proposed operating room shall perform an average of at least 1,128 surgical cases per year
172 per operating room in the second 12 months of operation.
173

174 (2) Subsection (1) shall not apply if the proposed project involves the initiation of a surgical service with
175 1 or 2 operating rooms at a licensed hospital site located in a rural or micropolitan statistical area county that
176 does not offer surgical services as of the date an application is submitted to the Department.
177

178 (3) An applicant shall demonstrate that it meets the requirements of Section 10(2) for the number of
179 surgical cases projected under subsection (1).
180

181 **Section 5. Requirements to replace a surgical service** 182

183 Sec. 5. TO replace a surgical service or one or more operating rooms, means the development of new
184 space (whether through new construction, purchase, lease or similar arrangement) to house one or more
185 operating rooms operated by an applicant at the same site as the operating room(s) to be replaced. This
186 also includes designating an OR as a dedicated endoscopy or cystoscopy OR. The term also includes
187 relocating an existing surgical facility or one or more operating rooms to a NEW GEOGRAPHIC location of
188 an existing surgical facility or one or more operating rooms to a different location currently offering surgical
189 services. The term does not include the renovation of an existing surgical service or one or more operating
190 rooms. AN APPLICANT REQUESTING TO REPLACE AN EXISTING SURGICAL SERVICE SHALL
191 DEMONSTRATE EACH OF THE FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT.
192

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

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

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

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

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

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

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

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

212 (b) All operating rooms, existing and replaced, are projected to perform an average of at least:
213 (i) 1,042 surgical cases per year per operating room in the second twelve months of operation, and
214 annually thereafter, or
215 (ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room in
216 the second twelve months of operation, and annually thereafter, or
217 (iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average
218 of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room in
219 the second twelve months of operation, and annually thereafter and calculated as follows:
220 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus
221 the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours
222 would equate to $375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00$ OR.), or
223 (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average
224 of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the
225 facility per year per operating room in the second twelve months of operation, and annually thereafter and
226 calculated as follows:
227 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus
228 the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases
229 would equate to $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$ OR.)
230
231 (2) An applicant proposing to replace one or more operating rooms at a licensed hospital and is located
232 in a rural or micropolitan county or the applicant is located in a city, village, or township with a population of
233 not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most
234 recent federal decennial census shall demonstrate each of the following:
235 (a) The applicant has three, four, or five ORs at the licensed hospital.
236 (b) All existing operating rooms have performed an average of at least:
237 (i) 839 surgical cases per year per operating room for which verifiable data is available to the
238 Department, or
239 (ii) 1,200 hours of use per year per operating room for which verifiable data is available to the
240 Department.
241 (c) All operating rooms, existing and replaced, are projected to perform an average of at least:
242 (i) 839 surgical cases per year per operating room in the second twelve months of operation, and
243 annually thereafter, or
244 (ii) 1,200 hours of use per year per operating room in the second twelve months of operation, and
245 annually thereafter.
246
247 (3) Subsections (1) and (2) shall not apply if the proposed project involves replacing one or more
248 operating rooms at the same licensed hospital site if the surgical facility is located in a rural or micropolitan
249 statistical area county and has one or two operating rooms.
250
251 (4) Subsections (1) and (2) shall not apply to those hospitals licensed under Part 215 of PA 368 of
252 1978, as amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs
253 at the surgical service has not increased as of March 31, 2003, and the location does not change.
254
255 (5) An applicant proposing to designate an OR as a dedicated endoscopy or cystoscopy OR shall
256 submit notification to the Department on a form provided by the Department. An applicant under this
257 subsection shall not be required to comply with subsections (1) and (2).
258
259 (6) An applicant proposing to relocate an existing surgical service or one or more operating rooms shall
260 demonstrate each of the following, as applicable:
261 (a) The proposed new site is within a 10-mile radius of the site at which an existing surgical service is
262 located if an existing surgical service is located in a metropolitan statistical area county, or a 20-mile radius if
263 an existing surgical service is located in a rural or micropolitan statistical area county.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

300
301 (7) Subsection (6) shall not apply if the proposed project involves relocating one or two operating
302 rooms within a 20-mile radius if the surgical facility is located in a rural or micropolitan statistical area county.
303

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

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

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

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

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

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

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

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

318
319 (9) An applicant shall demonstrate that it meets the requirements of Section 10(2) for the number of
320 surgical cases, or hours of use, projected under subsection (1), (2), (6), and (8).

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

323
324 Sec. 6. TO expand a surgical service means the addition of one or more operating rooms at an existing
325 surgical service. This term also includes the change from a dedicated endoscopy or cystoscopy OR to a
326 non-dedicated OR. An applicant proposing to add one or more operating rooms at an existing surgical
327 service shall demonstrate each of the following AS APPLICABLE, TO THE PROPOSED PROJECT.

328
329 (1) AN APPLICANT SHALL DEMONSTRATE THE FOLLOWING:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- 370 (b) All existing operating rooms have performed an average of at least:
 371 (i) 979 surgical cases per year per operating room for which verifiable data is available to the
 372 Department, or
 373 (ii) 1,400 hours of use per year per operating room for which verifiable data is available to the
 374 Department.
 375 (c) All proposed operating rooms are projected to perform an average of at least:
 376 (i) 839 surgical cases per year per operating room in the second twelve months of operation,, or
 377 (ii) 1,200 hours of use per year per operating room in the second twelve months of operation .
 378
 379 (3) Subsections (1) and (2) shall not apply if the proposed project involves adding a second operating
 380 room in a licensed hospital site located in a rural or micropolitan statistical area county that currently has
 381 only one operating room.
 382
 383 (4) An applicant shall demonstrate that it meets the requirements of Section 10(2) for the number of
 384 surgical cases, or hours of use, projected under subsections (1) and (2).
 385

386 **Section 7. Requirements to acquire an existing surgical service**
 387

388 Sec. 7. Acquisition of a surgical service means a project involving the issuance of a new license for a
 389 hospital or a freestanding surgical outpatient facility or a new certification as an ambulatory surgical center
 390 as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an
 391 existing surgical service. An applicant proposing to acquire an existing surgical service shall demonstrate
 392 each of the following, as applicable TO THE PROPOSED PROJECT.
 393

394 (1) An applicant agrees and assures to comply with all applicable project delivery requirements.
 395

396 (2) For the first application proposing TO ACQUIRE an existing surgical service, for which a final
 397 decision has not been issued, on or after January 27, 1996, THE existing surgical service shall not be
 398 required to be in compliance with the APPLICABLE volume requirements SET FORTH IN THESE
 399 STANDARDS. The surgical service shall be operating at the applicable volume requirements in the second
 400 12 months after the effective date of the acquisition.
 401

402 (3) For any application PROPOSING TO ACQUIRE an existing surgical service except the first
 403 application, for which a final decision has not been issued, on or after January 27, 1996, THE EXISTING
 404 SURGICAL SERVICE shall be required to BE IN compliance with the APPLICABLE volume requirements
 405 on the date THE application is submitted to the Department.
 406

407 (4) Subsection (3) shall not apply to those hospitals licensed under Part 215 of PA 368 of 1978, as
 408 amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs at the
 409 surgical service has not increased as of March 31, 2003, and the location does not change.
 410

411 **Section 8. Requirements for MEDICAID PARTICIPATION**
 412

413 Sec. 8. An applicant shall provide VERIFICATION OF MEDICAID PARTICIPATION. An applicant
 414 that is a new provider not currently enrolled in Medicaid shall CERTIFY that proof of Medicaid
 415 participation will be provided to the Department within six (6) months from the offering of services if a
 416 CON is approved.
 417

418 **Section 9. Project delivery requirements terms of approval for all applicants**
 419

420 Sec. 9. An applicant shall agree that, if approved, the SURGICAL SERVICES shall be delivered in
 421 compliance with the following terms of approval:
 422

- 423 (1) Compliance with these standards.
424
- 425 (2) COMPLIANCE WITH THE FOLLOWING QUALITY ASSURANCE STANDARDS:
426 (i) The designation of ORs as defined by the standards shall not be changed without prior notification
427 to the Department.
428 (ii) Surgical facilities shall have established policies for the selection of patients and delineate
429 procedures which may be performed in that particular facility.
430 (iii) Surgical facilities shall have provisions for handling all types of in-house emergencies, including
431 cardiopulmonary resuscitation.
432 (iv) Surgical facilities performing outpatient surgery shall have policies which allow for hospitalization of
433 patients when necessary. All surgeons who perform surgery within the facility shall have evidence of
434 admitting privileges or of written arrangements with other physicians for patient admissions at a local
435 hospital. The surgical facility shall have an established procedure, including a transfer agreement, that
436 provides for the immediate transfer of a patient requiring emergency care beyond the capabilities of the
437 surgical facility to a hospital that is capable of providing the necessary inpatient services and is located
438 within 30 minutes of the surgical facility. If no hospital is located within 30 minutes of the surgical facility, an
439 applicant shall have a transfer agreement with the nearest hospital having such capability.
440 (v) An applicant shall have written policies and procedures regarding the administration of a surgical
441 facility.
442 (vi) An applicant shall have written position descriptions which include minimum education, licensing, or
443 certification requirements for all personnel employed at the surgical facility.
444 (vii) An applicant shall have a process for credentialing individuals authorized to perform surgery or
445 provide anesthesia services at a surgical facility. An applicant's credentialing process shall insure that the
446 selection and appointment of individuals to the staff of a surgical facility does not discriminate on the basis of
447 licensure, registration, or professional education as doctors of medicine, osteopathic medicine and surgery,
448 podiatric medicine and surgery, or dentistry.
449 (viii) An applicant shall provide laboratory, diagnostic imaging, pathology and pharmacy (including
450 biologicals) services, either on-site or through contractual arrangements.
451 (ix) An applicant shall have written policies and procedures for advising patients of their rights.
452 (x) An applicant shall develop and maintain a system for the collection, storage, and use of patient
453 records.
454 (xi) Surgical facilities shall have separate patient recovery and non-patient waiting areas.
455 (xii) Surgical facilities shall provide a functionally safe and sanitary environment for patients, personnel,
456 and the public. Each facility shall incorporate a safety management program to maintain a physical
457 environment free of hazards and to reduce the risk of human injury.
458 (B) For purposes of evaluating subsection (A), the Department shall consider it prima facie evidence as
459 to compliance with the applicable requirements if an applicant surgical facility is accredited by the Joint
460 Commission on the Accreditation of Healthcare Organizations, the American Osteopathic Hospital
461 Association, or the Accreditation Association for Ambulatory Health Care, or certified by Medicare as an
462 ambulatory surgical center.
463 (C) The operation of and referral of patients to the surgical facility shall be in conformance with 1978 PA
464 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).
465
- 466 (3) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:
467 (a) THE applicant, to assure appropriate utilization by all segments of the Michigan population, shall:
468 (b) not deny surgical services to any individual based on ability to pay or source of payment;
469 (c) provide surgical services to any individual based on the clinical indications of need for the service.
470 (d) maintain information by payer and non-paying sources to indicate the volume of care from each
471 source provided annually. Compliance with selective contracting requirements shall not be construed as a
472 violation of this term.
473 (e) An applicant shall participate in Medicaid or in Medicaid managed care products at least 12
474 consecutive months within the first two years of operation and continue to participate annually thereafter

475 or attest that the applicant has been unable to contract with Medicaid managed care products at current
476 Medicaid rates.

477
478 (4) COMPLIANCE WITH THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:

479 (a) EXISTING OPERATING ROOMS SHALL PERFORM AN AVERAGE OF AT LEAST:

480 (i) 1,042 SURGICAL CASES PER YEAR PER OPERATING ROOM VERIFIABLE BY THE
481 DEPARTMENT, OR

482 (ii) 1,125 HOURS OF USE IN A FACILITY THAT PERFORMS ONLY OUTPATIENT SURGERY PER
483 YEAR PER OPERATING ROOM VERIFIABLE BY THE DEPARTMENT, OR

484 (iii) BE IN COMPLIANCE USING THE APPLICABLE WEIGHTED AVERAGES UNDER SECTION 5.

485 (b) EXISTING OPERATING ROOMS, LOCATED IN A RURAL OR MICROPOLITAN COUNTY, OR
486 WITHIN A CITY, VILLAGE, OR TOWNSHIP WITH A POPULATION OF NOT MORE THAN 12,000 AND IN
487 A COUNTY WITH A POPULATION OF NOT MORE THAN 110,000 AS DEFINED BY THE MOST
488 RECENT FEDERAL DECENNIAL CENSUS IN A SURGICAL SERVICE THAT HAS THREE, FOUR, OR
489 FIVE OR'S SHALL PERFORM AN AVERAGE OF AT LEAST:

490 (i) 839 SURGICAL CASES PER YEAR PER OPERATING ROOM VERIFIABLE BY THE
491 DEPARTMENT OR

492 (ii) 1,200 HOURS OF USE PER YEAR PER OPERATING ROOM VERIFIABLE BY THE
493 DEPARTMENT.

494 (C) THE applicant shall participate in a data collection SYSTEM established and administered by the
495 Department. The data may include, but is not limited to, hours of use of operating rooms, annual budget
496 and cost information, operating schedules, and demographic, diagnostic, morbidity and mortality
497 information, as well as the volume of care provided to patients from all payer sources. An applicant shall
498 provide the required data on a separate basis for each licensed or certified site, in a format established by
499 the department, and in a mutually agreed upon media. The Department may elect to verify the data through
500 on-site review of appropriate records.

501 (D) The SURGICAL SERVICE shall provide the Department with TIMELY notice OF the PROPOSED
502 PROJECT IMPLEMENTATION consistent with applicable statute and promulgated rules.

503
504 (5) The agreements and assurances required by this section shall be in the form of a certification
505 agreed to by the applicant or its authorized agent.

506
507 **Section 10. Documentation of projections**

508
509 Sec. 10. (1) An applicant required to project volumes of service shall specify how the volume
510 projections were developed and shall include only those surgical cases performed in an OR. (a) The applicant shall

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

512
513 (2) If a projected number of surgical cases, or hours of use, under subsection (1) includes surgical
514 cases, or hours of use, performed at another existing surgical facility(s), an applicant shall demonstrate, with
515 documentation satisfactory to the Department, that the utilization of the existing surgical facility(s) is in
516 compliance with the volume requirements applicable to that facility, and will continue to be in compliance
517 with the volume requirements (cases and/or hours) applicable to that facility subsequent to the initiation,
518 expansion, or REPLACEMENT of the surgical services proposed by an applicant. In demonstrating
519 compliance with this subsection, an applicant shall provide each of the following:

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

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

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

526 (d) A written commitment from each physician, identified in subdivision (a), that he or she will perform
527 at least the volume of surgical cases to be transferred to the applicant surgical facility for no less than 3

528 years subsequent to the initiation, expansion, or REPLACEMENT of the surgical service proposed by an
529 applicant.

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

533
534 (3) An applicant, other than an applicant proposing to initiate a surgical service, may utilize hours of
535 use in documenting compliance with the applicable sections of these standards, if an applicant provides
536 documentation, satisfactory to the Department, from the surgical facility from which the hours of use are
537 being transferred.

538

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

540

541 Sec. 12. PROPOSED projects reviewed under these standards shall not be subject to comparative
542 review. These CON review standards supercede and replace the CON Review Standards for Surgical
543 Facilities approved by the CON Commission on APRIL 30, 2008 and effective on June 20, 2008.

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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