

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 ~~(dC)~~ "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 | (aaX) "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 | (ddY) "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 | (hhBB) "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 | (llDD) "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, AND
178 PRECLUDES THE USE OF THE ROOM IN SUBSECTION (2)(A)(V).

179 (V) AN OPERATING ROOM THAT IS OR WILL BE USED EXCLUSIVELY TO PROVIDE SURGICAL
180 SERVICES TO PATIENTS REQUIRING BURN CARE OR TRAUMA CARE, AS THOSE TERMS ARE
181 DEFINED IN THESE STANDARDS. NO MORE THAN 1 BURN CARE AND 1 TRAUMA CARE
182 OPERATING ROOM SHALL BE EXCLUDED PURSUANT TO THIS SUBDIVISION, AND PRECLUDES
183 THE USE OF THE ROOM IN SUBSECTION (2)(A)(IV).

184 (VI) A HYBRID ORCCL SHALL HAVE 0.5 EXCLUDED FOR EACH ROOM MEETING THE
185 REQUIREMENTS OF SECTION 8 OF THESE STANDARDS. A SURGICAL FACILITY WILL NOT BE
186 LIMITED TO THE NUMBER OF HYBRID ORCCLS WITHIN A SINGLE LICENSED FACILITY.

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

189 (c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all
190 operating rooms in which surgery is or will be performed, excluding any operating rooms used exclusively
191 for endoscopy or cystoscopy cases.
192

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

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

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

201 (c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all
202 surgical cases, or hours of use, performed in the operating rooms identified in subsection (2)(c). Cases, or
203 hours of use, performed in any operating room used exclusively for endoscopy or cystoscopy cases, shall
204 be excluded.
205

206 **Section 4. Requirements ~~for approval for applicants proposing~~ to initiate a surgical service**
207

208 Sec. 4. ~~(1) An applicant proposing to~~ To initiate a surgical service means to begin operation of a surgical
209 facility at a site that has not offered surgical services within the 12-month period immediately preceding the
210 date an application is submitted to the Department. The term does not include the relocation of a surgical

211 ~~service of one or more operating rooms.~~ AN APPLICANT PROPOSING TO INITIATE A SURGICAL
212 SERVICE shall demonstrate THE FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT.

213
214 (1) ~~that e~~Each proposed operating room shall perform an average of at least 1,128 surgical cases per
215 year per operating room in the second 12 months of operation, ~~and annually thereafter.~~

216
217 (2) Subsection (1) shall not apply if the proposed project involves the initiation of a surgical service with
218 1 or 2 operating rooms at a licensed hospital site located in a rural or micropolitan statistical area county that
219 does not offer surgical services as of the date an application is submitted to the Department.

220
221 (3) An applicant shall demonstrate that it meets the requirements of Section 140(2) for the number of
222 surgical cases projected under subsection (1).

223 Section 5. Requirements to replace a surgical service

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

234
235 (1) AN APPLICANT PROPOSING TO REPLACE SHALL DEMONSTRATE:

236
237 (a) All existing operating rooms in the existing surgical facility have performed an average of at least:

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

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

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

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

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

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

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

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

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

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

264 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus
265 the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours
266 would equate to $375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00$ OR.), or
267 (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average
268 of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the
269 facility per year per operating room in the second twelve months of operation, and annually thereafter and
270 calculated as follows:
271 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus
272 the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases
273 would equate to $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$ OR.)
274 _____
275 (2) An applicant proposing to replace one or more operating rooms at a licensed hospital and is located
276 in a rural or micropolitan county or the applicant is located in a city, village, or township with a population of
277 not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most
278 recent federal decennial census shall demonstrate each of the following:
279 (a) The applicant has three, four, or five ORs at the licensed hospital.
280 (b) All existing operating rooms have performed an average of at least:
281 (i) 839 surgical cases per year per operating room for which verifiable data is available to the
282 Department, or
283 (ii) 1,200 hours of use per year per operating room for which verifiable data is available to the
284 Department.
285 (c) All operating rooms, existing and replaced, are projected to perform an average of at least:
286 (i) 839 surgical cases per year per operating room in the second twelve months of operation, and
287 annually thereafter, or
288 (ii) 1,200 hours of use per year per operating room in the second twelve months of operation, and
289 annually thereafter.
290 _____
291 (3) Subsections (1) and (2) shall not apply if the proposed project involves replacing one or more
292 operating rooms at the same licensed hospital site, if the surgical facility is located in a rural or micropolitan
293 statistical area county and has one or two operating rooms.
294 _____
295 (4) Subsections (1) and (2) shall not apply to those hospitals licensed under Part 215 of PA 368 of
296 1978, as amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs
297 at the surgical service has not increased as of March 31, 2003, and the location does not change.
298 _____
299 (5) An applicant proposing to designate an OR as a dedicated endoscopy or cystoscopy OR shall
300 submit notification to the Department on a form provided by the Department. An applicant under this
301 subsection shall not be required to comply with subsections (1) and (2).
302 _____
303 (6) An applicant proposing to relocate an existing surgical service or one or more operating rooms shall
304 demonstrate each of the following, as applicable:
305 (a) The proposed new site is within a 10-mile radius of the site at which an existing surgical service is
306 located if an existing surgical service is located in a metropolitan statistical area county, or a 20-mile radius if
307 an existing surgical service is located in a rural or micropolitan statistical area county.
308 (b) All existing operating rooms in the surgical facility from which one or more ORs are proposed to be
309 relocated have performed an average of at least:
310 (i) 1,042 surgical cases per year per operating room for which verifiable data is available to the
311 Department, or
312 (ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room for
313 which verifiable data is available to the Department, or,
314 (iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average
315 of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room for
316 which verifiable data is available to the Department and calculated as follows:

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

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

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

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

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

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

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

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

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

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

344
345 (7) Subsection (6) shall not apply if the proposed project involves relocating one or two operating
346 rooms within a 20-mile radiusthe relocation zone, if the surgical facility is located in a rural or micropolitan
347 statistical area county.

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

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

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

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

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

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

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

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

363
364 (9) An applicant shall demonstrate that it meets the requirements of Section 10(2) for the number of
365 surgical cases, or hours of use, projected under subsection (1), (2), (6), and (8).

366
367 **Section 56. Requirements ~~for approval for surgical services proposing~~ to expand an existing**
368 **surgical service**

370 | Sec. 56. (1) TO expand a surgical service means the addition of one or more operating rooms at an
371 | existing surgical service. This term also includes the change from a dedicated endoscopy or cystoscopy OR
372 | to a non-dedicated OR. An applicant proposing to add one or more operating rooms at an existing surgical
373 | service shall demonstrate each of the following AS APPLICABLE, TO THE PROPOSED PROJECT.
374 |

375 | (a1) AN APPLICANT SHALL DEMONSTRATE THE FOLLOWING:

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

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

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

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

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

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

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

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

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

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

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

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

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

409 | (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus
410 | the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases
411 | would equate to $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$ OR.)
412 |

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

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

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

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

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

- 423 (c) All proposed operating rooms are projected to perform an average of at least:
424 (i) 839 surgical cases per year per operating room in the second twelve months of operation, ~~and~~
425 ~~annually thereafter~~, or
426 (ii) 1,200 hours of use per year per operating room in the second twelve months of operation, ~~and~~
427 ~~annually thereafter~~.

428
429
430 (3) Subsections (1) and (2) shall not apply if the proposed project involves adding a second operating
431 room in a licensed hospital site located in a rural or micropolitan statistical area county that currently has
432 only one operating room.

433
434 (4) An applicant shall demonstrate that it meets the requirements of Section 140(2) for the number of
435 surgical cases, or hours of use, projected under subsections (1) ~~and (2)~~.

436
437 **Section 6. Requirements for approval for facilities proposing to replace a surgical service or one or**
438 **more operating rooms**

439
440 ~~— Sec. 6. (1) An applicant proposing to replace an existing surgical service or one or more operating~~
441 ~~rooms at the same site shall demonstrate each of the following:~~

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

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

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

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

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

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

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

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

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

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

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

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

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

475 ~~—(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus~~
476 ~~the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases~~
477 ~~would equate to $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$ OR.)~~
478 ~~—(2) An applicant proposing to replace one or more operating rooms at a licensed hospital and is located~~
479 ~~in a rural or micropolitan county or the applicant is located in a city, village, or township with a population of~~
480 ~~not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most~~
481 ~~recent federal decennial census shall demonstrate each of the following:~~
482 ~~—(a) The applicant has three, four, or five ORs at the licensed hospital.~~
483 ~~—(b) All existing operating rooms have performed an average of at least:~~
484 ~~—(i) 839 surgical cases per year per operating room for which verifiable data is available to the~~
485 ~~Department, or~~
486 ~~—(ii) 1,200 hours of use per year per operating room for which verifiable data is available to the~~
487 ~~Department.~~
488 ~~—(c) All operating rooms, existing and replaced, are projected to perform an average of at least:~~
489 ~~—(i) 839 surgical cases per year per operating room in the second twelve months of operation, and~~
490 ~~annually thereafter, or~~
491 ~~—(ii) 1,200 hours of use per year per operating room in the second twelve months of operation, and~~
492 ~~annually thereafter.~~
493
494 ~~—(3) Subsections (1) and (2) shall not apply if the proposed project involves replacing one or more~~
495 ~~operating rooms at the same licensed hospital site, if the surgical facility is located in a rural or micropolitan~~
496 ~~statistical area county and has one or two operating rooms.~~
497
498 ~~—(4) Subsections (1) and (2) shall not apply to those hospitals licensed under Part 215 of PA 368 of~~
499 ~~1978, as amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs~~
500 ~~at the surgical service has not increased as of March 31, 2003, and the location does not change.~~
501
502 ~~—(5) An applicant proposing to designate an OR as a dedicated endoscopy or cystoscopy OR shall~~
503 ~~submit notification to the Department on a form provided by the Department. An applicant under this~~
504 ~~subsection shall not be required to comply with subsections (1) and (2).~~
505

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

508
509 ~~—Sec. 7. An applicant proposing to relocate an existing surgical service or one or more operating rooms~~
510 ~~shall demonstrate each of the following, as applicable:~~
511
512 ~~—(1) The proposed relocation will not result in an increase in the total number of operating rooms~~
513 ~~operated by an applicant at the existing and proposed sites unless an applicant can demonstrate~~
514 ~~compliance with the applicable requirements of Section 5.~~
515
516 ~~—(2) The proposed new site is located within the relocation zone.~~
517
518 ~~—(3) All existing operating rooms in the surgical facility from which one or more ORs are proposed to be~~
519 ~~relocated have performed an average of at least:~~
520 ~~—(a) 1,042 surgical cases per year per operating room for which verifiable data is available to the~~
521 ~~Department, or~~
522 ~~—(b) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room for~~
523 ~~which verifiable data is available to the Department, or,~~
524 ~~—(c) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average~~
525 ~~of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room for~~
526 ~~which verifiable data is available to the Department and calculated as follows:~~

527 ~~—(i) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus~~
528 ~~the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours~~
529 ~~would equate to $375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00$ OR.), or~~
530 ~~—(d) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average~~
531 ~~of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the~~
532 ~~facility per year per operating room for which verifiable data is available to the Department and calculated as~~
533 ~~follows:~~
534 ~~—(i) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus~~
535 ~~the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases~~
536 ~~would equate to $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$ OR.)~~
537
538 ~~—(4) All operating rooms, existing and relocated, are projected to perform an average of at least:~~
539 ~~—(a) 1,042 surgical cases per year per operating room in the second twelve months of operation, and~~
540 ~~annually thereafter, or~~
541 ~~—(b) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room in~~
542 ~~the second twelve months of operation, and annually thereafter, or~~
543 ~~—(c) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average~~
544 ~~of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room in~~
545 ~~the second twelve months of operation, and annually thereafter and calculated as follows:~~
546 ~~—(i) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus~~
547 ~~the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours~~
548 ~~would equate to $375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00$ OR.) or~~
549 ~~—(d) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average~~
550 ~~of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the~~
551 ~~facility per year per operating room in the second twelve months of operation, and annually thereafter and~~
552 ~~calculated as follows:~~
553 ~~—(i) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus~~
554 ~~the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases~~
555 ~~would equate to $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$ OR.)~~
556
557 ~~—(5) Subsections (3) and (4) shall not apply if the proposed project involves relocating one or two~~
558 ~~operating rooms within the relocation zone, if the surgical facility is located in a rural or micropolitan~~
559 ~~statistical area county.~~
560
561 ~~—(6) An applicant proposing to relocate one or more operating rooms from one licensed hospital site to~~
562 ~~another licensed hospital site and is located in a rural or micropolitan county or the applicant is located in a~~
563 ~~city, village, or township with a population of not more than 12,000 and in a county with a population of not~~
564 ~~more than 110,000 as defined by the most recent federal decennial census shall demonstrate each of the~~
565 ~~following:~~
566 ~~—(a) The applicant has three, four, or five ORs at the licensed hospital.~~
567 ~~—(b) All existing operating rooms have performed an average of at least:~~
568 ~~—(i) 839 surgical cases per year per operating room for which verifiable data is available to the~~
569 ~~Department, or~~
570 ~~—(ii) 1,200 hours of use per year per operating room for which verifiable data is available to the~~
571 ~~Department.~~
572 ~~—(c) All operating rooms, existing and relocated, are projected to perform an average of at least:~~
573 ~~—(i) 839 surgical cases per year per operating room in the second twelve months of operation, and~~
574 ~~annually thereafter, or~~
575 ~~—(ii) 1,200 hours of use per year per operating room in the second twelve months of operation, and~~
576 ~~annually thereafter.~~
577
578 ~~—(7) An applicant shall demonstrate that it meets the requirements of Section 11(2) for the number of~~
579 ~~surgical cases, or hours of use, projected under subsection (4) and (6).~~

580
581 **Section 87. Requirements ~~for approval for applicants proposing~~ to acquire an existing surgical**
582 **service**
583

584 Sec. 87. Acquisition of a surgical service means a project involving the issuance of a new license for a
585 hospital or a freestanding surgical outpatient facility or a new certification as an ambulatory surgical center
586 as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an
587 existing surgical service. An applicant proposing to acquire an existing surgical service shall demonstrate
588 each of the following, as applicable TO THE PROPOSED PROJECT.
589

590 ~~(1) The acquisition will not result in an increase in the number of operating rooms at the surgical service to~~
591 ~~be acquired unless an applicant can demonstrate compliance with the applicable requirements of Section 5.~~
592

593 ~~— (2) The location of the surgical service does not change as a result of the acquisition unless an~~
594 ~~applicant can demonstrate compliance with the applicable requirements of Section 7.~~
595

596 (31) An applicant agrees and assures to comply with all applicable project delivery requirements.
597

598 (42) For the first application ~~for proposed proposing TO acquisition of~~ ACQUIRE an existing surgical
599 service, for which a final decision has not been issued, on or after January 27, 1996, ~~an THE~~ existing
600 surgical service ~~to be acquired~~ shall not be required to be in compliance with the APPLICABLE volume
601 requirements ~~applicable to the seller/lessor on the date the acquisition occurs~~ SET FORTH IN THESE
602 STANDARDS. The surgical service shall be operating at the applicable volume requirements in the second
603 12 months after the effective date of the acquisition, ~~and annually thereafter.~~
604

605 (53) For any application ~~for proposed acquisition of~~ PROPOSING TO ACQUIRE an existing surgical
606 service except the first application, for which a final decision has not been issued, on or after January 27,
607 1996, THE EXISTING SURGICAL SERVICE ~~an applicant~~ shall be required to ~~document~~ BE IN compliance
608 with the APPLICABLE volume requirements ~~applicable to the existing surgical service~~ on the date ~~an THE~~
609 application is submitted to the Department.
610

611 (64) Subsection (53) shall not apply to those hospitals licensed under Part 215 of PA 368 of 1978, as
612 amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs at the
613 surgical service has not increased as of March 31, 2003, and the location does not change.
614

615 **SECTION 8. REQUIREMENTS FOR A HYBRID OPERATING ROOM/CARDIAC CATHETERIZATION**
616 **LABORATORY (OR/CCL)**
617

618 SEC. 8. A HYBRID OR/CCL MEANS AN OPERATING ROOM LOCATED ON A STERILE CORRIDOR
619 AND EQUIPPED WITH AN ANGIOGRAPHY SYSTEM PERMITTING MINIMALLY INVASIVE
620 PROCEDURES OF THE HEART AND BLOOD VESSELS WITH FULL ANESTHESIA CAPABILITIES. AN
621 APPLICANT PROPOSING TO ADD ONE OR MORE HYBRID OR/CCLS AT AN EXISTING SURGICAL
622 SERVICE SHALL DEMONSTRATE EACH OF THE FOLLOWING:
623

624 (1) THE APPLICANT OPERATES AN OPEN HEART SURGERY SERVICE WHICH IS IN FULL
625 COMPLIANCE WITH THE CURRENT CON REVIEW STANDARDS FOR OPEN HEART SURGERY
626 SERVICES.
627

628 (2) IF THE HYBRID OR/CCL(S) REPRESENTS AN INCREASE IN THE NUMBER OF LICENSED
629 OPERATING ROOMS AT THE FACILITY, THE APPLICANT IS IN COMPLIANCE WITH SECTION 6 OF
630 THESE STANDARDS.
631

632 (3) IF THE HYBRID OR/CCL(S) REPRESENTS CONVERSION OF AN EXISTING OPERATING
633 ROOM(S), THE APPLICANT IS IN COMPLIANCE WITH THE PROVISIONS OF SECTION 5, IF
634 APPLICABLE.

635
636 (4) THE APPLICANT MEETS THE APPLICABLE REQUIREMENTS OF THE CON REVIEW
637 STANDARDS FOR CARDIAC CATHETERIZATION SERVICES.

638
639 (5) EACH CASE PERFORMED IN A HYBRID OR/CCL SHALL BE INCLUDED EITHER IN THE
640 SURGICAL VOLUME OR THE THERAPEUTIC CARDIAC CATHETERIZATION VOLUME OF THE
641 FACILITY. NO CASE SHALL BE COUNTED MORE THAN ONCE.

642
643 **Section 989. Requirements for approval -- all applicants** MEDICAID PARTICIPATION

644
645 Sec. 989. An applicant shall provide VERIFICATION evidence-OF MEDICAID PARTICIPATION.of
646 participation in Medicaid or in Medicaid managed care products or attestation that the applicant has been
647 unable to contract at current Medicaid rates at the time the application is submitted to the Department.
648 By providing a signed affidavit, an applicant that is an ASC or FSO of shall demonstrate a willingness to
649 participate when accepted by Medicaid. An applicant that is initiating a new service or is a new provider
650 not currently enrolled in Medicaid shall provide CERTIFY a signed affidavit stating that proof of Medicaid
651 participation will be provided to the Department within six (6) months from the offering of services if a
652 CON is approved. If the required documentation is not submitted with the application on the designated
653 application date, the application will be deemed filed on the first applicable designated application date
654 after all required documentation is received by the Department.

655
656 **Section 10910. Project delivery requirements -- terms of approval for all applicants**

657
658 Sec. 10910. ~~(1)~~ An applicant shall agree that, if approved, the project SURGICAL SERVICES shall be
659 delivered in compliance with the following terms of CON approval:

660
661 (a1) Compliance with these standards.

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

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

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

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

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

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

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

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

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

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

685 (vii) An applicant shall have a process for credentialing individuals authorized to perform surgery or
686 provide anesthesia services at a surgical facility. An applicant's credentialing process shall insure that the
687 selection and appointment of individuals to the staff of a surgical facility does not discriminate on the basis of
688 licensure, registration, or professional education as doctors of medicine, osteopathic medicine and surgery,
689 podiatric medicine and surgery, or dentistry.
690 (viii) An applicant shall provide laboratory, diagnostic imaging, pathology and pharmacy (including
691 biologicals) services, either on-site or through contractual arrangements.
692 (ix) An applicant shall have written policies and procedures for advising patients of their rights.
693 (x) An applicant shall develop and maintain a system for the collection, storage, and use of patient
694 records.
695 (xi) Surgical facilities shall have separate patient recovery and non-patient waiting areas.
696 (xii) Surgical facilities shall provide a functionally safe and sanitary environment for patients, personnel,
697 and the public. Each facility shall incorporate a safety management program to maintain a physical
698 environment free of hazards and to reduce the risk of human injury.
699 (B) For purposes of evaluating subsection (A), the Department shall consider it prima facie evidence as
700 to compliance with the applicable requirements if an applicant surgical facility is accredited by the Joint
701 Commission on the Accreditation of Healthcare Organizations, the American Osteopathic Hospital
702 Association, or the Accreditation Association for Ambulatory Health Care, or certified by Medicare as an
703 ambulatory surgical center.
704 (C) The operation of and referral of patients to the surgical facility shall be in conformance with 1978 PA
705 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).
706
707 (3) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:
708 (iii) AnTHE applicant, to assure appropriate utilization by all segments of the Michigan population, shall:
709 (Ab) not deny surgical services to any individual based on ability to pay or source of payment;
710 (Bc) provide surgical services to any individual based on the clinical indications of need for the service.
711 (Cd) maintain information by payer and non-paying sources to indicate the volume of care from each
712 source provided annually.
713 Compliance with selective contracting requirements shall not be construed as a violation of this term.
714 (e) An applicant shall participate in Medicaid or in Medicaid managed care products at least 12
715 consecutive months within the first two years of operation and continue to participate annually thereafter
716 or attest that the applicant has been unable to contract with Medicaid managed care products at current
717 Medicaid rates.
718
719 (4) COMPLIANCE WITH THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:
720 (iva) EXISTING OPERATING ROOMS SHALL PERFORM AN AVERAGE OF AT LEAST:
721 (i) 1,042 SURGICAL CASES PER YEAR PER OPERATING ROOM VERIFIABLE BY THE
722 DEPARTMENT, OR
723 (ii) 1,125 HOURS OF USE IN A FACILITY THAT PERFORMS ONLY OUTPATIENT SURGERY PER
724 YEAR PER OPERATING ROOM VERIFIABLE BY THE DEPARTMENT, OR
725 (iii) BE IN COMPLIANCE USING THE APPLICABLE WEIGHTED AVERAGES UNDER SECTION 5.
726 (b) EXISTING OPERATING ROOMS, LOCATED IN A RURAL OR MICROPOLITAN COUNTY, OR
727 WITHIN A CITY, VILLAGE, OR TOWNSHIP WITH A POPULATION OF NOT MORE THAN 12,000 AND IN
728 A COUNTY WITH A POPULATION OF NOT MORE THAN 110,000 AS DEFINED BY THE MOST
729 RECENT FEDERAL DECENNIAL CENSUS IN A SURGICAL SERVICE THAT HAS THREE, FOUR, OR
730 FIVE OR'S SHALL PERFORM AN AVERAGE OF AT LEAST:
731 (i) 839 SURGICAL CASES PER YEAR PER OPERATING ROOM VERIFIABLE BY THE
732 DEPARTMENT OR
733 (ii) 1,200 HOURS OF USE PER YEAR PER OPERATING ROOM VERIFIABLE BY THE
734 DEPARTMENT.
735 (C) AnTHE applicant shall participate in a data collection network-SYSTEM established and
736 administered by the Department. The data may include, but is not limited to, hours of use of operating
737 rooms, annual budget and cost information, operating schedules, and demographic, diagnostic, morbidity

738 and mortality information, as well as the volume of care provided to patients from all payer sources. An
739 applicant shall provide the required data on a separate basis for each licensed or certified site, in a format
740 established by the department, and in a mutually agreed upon media. The Department may elect to verify
741 the data through on-site review of appropriate records.

742 ~~(vD) The applicant SURGICAL SERVICE shall provide the Department with a TIMELY notice stating OF
743 the first date on which the service became operational, and such notice shall be submitted to the
744 Department PROPOSED PROJECT IMPLEMENTATION consistent with applicable statute and promulgated
745 rules.~~

746 ~~—(d) Compliance with the following quality assurance standards, as applicable:~~

747 ~~—(i) Surgical facilities shall have established policies for the selection of patients and delineate
748 procedures which may be performed in that particular facility.~~

749 ~~—(ii) Surgical facilities shall have provisions for handling all types of in-house emergencies, including
750 cardiopulmonary resuscitation.~~

751 ~~—(iii) Surgical facilities performing outpatient surgery shall have policies which allow for hospitalization of
752 patients when necessary. All surgeons who perform surgery within the facility shall have evidence of
753 admitting privileges or of written arrangements with other physicians for patient admissions at a local
754 hospital. The surgical facility shall have an established procedure, including a transfer agreement, that
755 provides for the immediate transfer of a patient requiring emergency care beyond the capabilities of the
756 surgical facility to a hospital that is capable of providing the necessary inpatient services and is located
757 within 30 minutes of the surgical facility. If no hospital is located within 30 minutes of the surgical facility, an
758 applicant shall have a transfer agreement with the nearest hospital having such capability.~~

759 ~~—(iv) An applicant shall have written policies and procedures regarding the administration of a surgical
760 facility.~~

761 ~~—(v) An applicant shall have written position descriptions which include minimum education, licensing, or
762 certification requirements for all personnel employed at the surgical facility.~~

763 ~~—(vi) An applicant shall have a process for credentialing individuals authorized to perform surgery or
764 provide anesthesia services at a surgical facility. An applicant's credentialing process shall insure that the
765 selection and appointment of individuals to the staff of a surgical facility does not discriminate on the basis of
766 licensure, registration, or professional education as doctors of medicine, osteopathic medicine and surgery,
767 podiatric medicine and surgery, or dentistry.~~

768 ~~—(vii) An applicant shall provide laboratory, diagnostic imaging, pathology and pharmacy (including
769 biologicals) services, either on-site or through contractual arrangements.~~

770 ~~—(viii) An applicant shall have written policies and procedures for advising patients of their rights.~~

771 ~~—(ix) An applicant shall develop and maintain a system for the collection, storage, and use of patient
772 records.~~

773 ~~—(x) Surgical facilities shall have separate patient recovery and non-patient waiting areas.~~

774 ~~—(xi) Surgical facilities shall provide a functionally safe and sanitary environment for patients, personnel,
775 and the public. Each facility shall incorporate a safety management program to maintain a physical
776 environment free of hazards and to reduce the risk of human injury.~~

777 ~~—(e) For purposes of evaluating subsection (d), the Department shall consider it prima facie evidence as
778 to compliance with the applicable requirements if an applicant surgical facility is accredited by the Joint
779 Commission on the Accreditation of Healthcare Organizations, the American Osteopathic Hospital
780 Association, or the Accreditation Association for Ambulatory Health Care, or certified by Medicare as an
781 ambulatory surgical center.~~

782 ~~—(f) An applicant shall participate in Medicaid or in Medicaid managed care products at least 12
783 consecutive months within the first two years of operation and continue to participate annually thereafter
784 or attest that the applicant has been unable to contract with Medicaid managed care products at current
785 Medicaid rates.~~

786 ~~—(2) The operation of and referral of patients to the surgical facility shall be in conformance with 1978 PA
787 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).~~

790

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

793 |
794 | **Section 44101. Documentation of projections**
795 |

796 | Sec. 44101. (1) An applicant required to project volumes of service shall specify how the volume
797 | projections were developed and shall include only those surgical cases performed in an OR.
798 |

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

802 | (b) The Department shall subtract any previous commitment, pursuant to subsection 2(d).
803 |

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

811 | (a) The name of each physician that performed surgical cases to be transferred to the applicant
812 | surgical facility.

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

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

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

821 | (e) The number of surgical cases performed, at the existing surgical facility from which surgical cases
822 | will be transferred, during the most recent 12-month period prior to the date an application is submitted to
823 | the Department for which verifiable annual survey data is available.
824 |

825 | (3) An applicant, other than an applicant proposing to initiate a surgical service, may utilize hours of
826 | use in documenting compliance with the applicable sections of these standards, if an applicant provides
827 | documentation, satisfactory to the Department, from the surgical facility from which the hours of use are
828 | being transferred.
829 |

830 | **Section 12. Effect on prior CON review standards; comparative reviews**
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832 | Sec. 12. ~~(1) PROPOSED projects reviewed under these standards shall not be subject to comparative~~
833 | ~~review.~~ These CON review standards supercede and replace the CON Review Standards for Surgical
834 | Facilities approved by the CON Commission on ~~March 21, 2006~~APRIL 30, 2008 and effective on June ~~520,~~
835 | ~~2006~~2008.
836 |

837 | ~~—(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