

1 MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
2
3 CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR
4 COMPUTED TOMOGRAPHY (CT) SCANNER SERVICES
5

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

10 **Section 1. Applicability**
11

12 Sec. 1. These standards are requirements for the approval of the initiation, expansion, replacement,
13 ~~relocation,~~ or acquisition of CT services and the delivery of services under Part 222 of the Code. Pursuant
14 to Part 222 of the Code, CT is a covered clinical service. The Department shall use these standards in
15 applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and
16 Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.
17

18 **Section 2. Definitions**
19

20 Sec. 2. (1) For purposes of these standards:

21 (a) "Acquisition of an existing CT scanner service" means obtaining possession or control of an
22 existing fixed or mobile CT scanner service or existing CT scanner(s) by contract, ownership, or other
23 comparable arrangement. For proposed projects involving mobile CT scanners, this applies to the central
24 service coordinator and/or host facility.

25 (b) "Billable procedure" means a CT procedure billed as a single unit ~~under procedure codes in effect~~
26 ~~on December 31, 2010,~~ and performed in Michigan.

27 (c) "Body scans" include all spinal CT scans and any CT scan of an anatomical site below and
28 including the neck.

29 (d) "BUNDLED BODY SCAN" MEANS TWO OR MORE BODY SCANS BILLED AS ONE CT
30 PROCEDURE.

31 ~~(de)~~ "Central service coordinator" means the organizational unit which has operational responsibility for
32 a mobile CT scanner and which is a legal entity authorized to do business in the state of Michigan.

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

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

37 ~~(gh)~~ "Computed tomography" or "CT" means the use of radiographic and computer techniques to
38 produce cross-sectional images of the head or body.

39 (i) "CT-ANGIO HYBRID UNIT" MEANS AN INTEGRATED SYSTEM COMPRISED OF BOTH CT
40 AND ANGIOGRAPHY EQUIPMENT SITED IN THE SAME ROOM THAT IS DESIGNED SPECIFICALLY
41 FOR INTERVENTIONAL RADIOLOGY OR CARDIAC PROCEDURES. THE CT UNIT IS A GUIDANCE
42 MECHANISM AND IS INTENDED TO BE USED AS AN ADJUNCT TO THE PROCEDURE. THE CT
43 UNIT SHALL NOT BE USED FOR DIAGNOSTIC STUDIES UNLESS THE PATIENT IS CURRENTLY
44 UNDERGOING A CT-ANGIO HYBRID PROCEDURE AND IS IN NEED OF A SECONDARY
45 DIAGNOSTIC STUDY.

46 (hj) "CT equivalents" means the resulting number of units produced when the number of billable
47 procedures for each category is multiplied by its respective conversion factor tabled in Section ~~2422~~.

48 ~~(ik)~~ "CT scanner" means x-ray CT scanning systems capable of performing CT scans of the head,
49 other body parts, or full body patient procedures including Positron Emission Tomography (PET)/CT
50 scanner hybrids if used for CT only procedures. The term does not include emission-computed
51 tomographic systems utilizing internally administered single-photon gamma ray emitters, positron
52 annihilation CT systems, magnetic resonance, ultrasound computed tomographic systems, CT simulators
53 used solely for treatment planning purposes in conjunction with an MRT unit, and non-diagnostic, intra-
54 operative guidance tomographic units.

55 | (jl) "CT scanner services" means the CON-approved utilization of a CT scanner(s) at one site in the
56 | case of a fixed CT scanner service or at each host site in the case of a mobile CT scanner service.

57 | (km) "Dedicated pediatric CT" means a fixed CT scanner on which at least 70% of the CT procedures
58 | are performed on patients under 18 years of age.

59 | (ln) "Dental CT examinations" means use of a CT scanner specially designed to generate CT images
60 | to facilitate dental procedures.

61 | (mo) "Dental procedures" means dental implants, wisdom teeth surgical procedures, mandibular or
62 | maxillary surgical procedures, or temporal mandibular joint evaluations.

63 | (np) "Department" means the Michigan Department of Community Health (MDCH).

64 | (oq) "Emergency room" means a designated area physically part of a licensed hospital and recognized
65 | by the Department as having met the staffing and equipment requirements for the treatment of emergency
66 | patients.

67 | (pr) "Excess CT Equivalents" means the number of CT equivalents performed by an existing CT
68 | scanner service in excess of 10,000 per fixed CT scanner and 4,500 per mobile CT scanner or either an
69 | existing fixed or mobile CT scanner service, the number of CT scanners used to compute excess CT
70 | equivalents shall include both existing and approved but not yet operational CT scanners. In the case of a
71 | CT scanner service that operates or has a valid CON to operate that has more than one fixed CT scanner
72 | at the same site, the term means number of CT equivalents in excess of 10,000 multiplied by the number
73 | of fixed CT scanners at the same site. For example, if a CT scanner service operates, or has a valid CON
74 | to operate, two fixed CT scanners at the same site, the excess CT equivalents is the number that is in
75 | excess of 20,000 (10,000 x 2) CT equivalents. In the case of an existing mobile CT scanner service, the
76 | term means the sum of all CT equivalents performed by the same mobile CT scanner service at all of the
77 | host sites combined that is in excess of 4,500. For example, if a mobile CT scanner service serves five
78 | host sites with 1 mobile CT scanner, the term means the sum of CT equivalents for all five host sites
79 | combined that is in excess of 4,500 CT equivalents.

80 | (qs) "Existing CT scanner service" means the utilization of a CON-approved and operational CT
81 | scanner(s) at one site in the case of a fixed CT scanner service or at each host site in the case of a
82 | mobile CT scanner service.

83 | (rt) "Existing CT scanner" means a CON-approved and operational CT scanner used to provide CT
84 | scanner services.

85 | (su) "Existing mobile CT scanner service" means a CON-approved and operational CT scanner and
86 | transporting equipment operated by a central service coordinator serving two or more host sites.

87 | (vt) "Expand an existing CT scanner service" means the addition of one or more CT scanners at an
88 | existing CT scanner service.

89 | (uw) "Head scans" include head or brain CT scans; including the maxillofacial area; the orbit, sella, or
90 | posterior fossa; or the outer, middle, or inner ear; or any other CT scan occurring above the neck.

91 | (vx) "Health Service Area" or "HSA" means the groups of counties listed in [Section 24 APPENDIX A.](#)

92 | (wy) "HIPAA" means the Health Insurance Portability and Accountability Act of 1996.

93 | (xz) "Hospital-based portable CT scanner or portable CT scanner" means a CT scanner capable of
94 | being transported into patient care areas (i.e., ICU rooms, operating rooms, etc.) to provide high-quality
95 | imaging of critically ill patients.

96 | (yaa) "Host site" means the site at which a mobile CT scanner is authorized to provide CT scanner
97 | services.

98 | (zbb) "Initiate a CT scanner service" means to begin operation of a CT scanner, whether fixed or
99 | mobile, at a site that does not perform CT scans as of the date an application is submitted to the
100 | Department. The term does not include the acquisition or ~~relocation-REPLACEMENT~~ of an existing CT
101 | scanner service AT THE EXISTING SITE OR TO A DIFFERENT SITE or the renewal of a lease.

102 | (aacc) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and 1396r-
103 | 8 to 1396v1396w-5.

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

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

112 (dd) "Mobile CT scanner service" means a CT scanner and transporting equipment operated by a
113 central service coordinator and which must serve two or more host facilities.

114 (ee) "Mobile CT scanner network" means the route (all host facilities) the mobile CT scanner is
115 authorized to serve.

116 ~~—(ff) "Pediatric patient" means any patient less than 18 years of age.~~

117 ~~—(gg) "Relocate a fixed CT scanner" means a change in the location of a fixed CT scanner from the~~
118 ~~existing site to a different site within the relocation zone.~~

119 ~~(hh) "Relocate an existing CT scanner service" means a change in the geographic location of an~~
120 ~~existing fixed CT scanner service from an existing site to a different site.~~

121 ~~(ii) "Relocation zone," means a site that is within a 10-mile radius of a site at which an existing fixed~~
122 ~~CT scanner service is located if an existing fixed CT scanner service is located in a metropolitan statistical~~
123 ~~area county, or a 20-mile radius if an existing fixed CT scanner service is located in a rural or micropolitan~~
124 ~~statistical area county.~~

125 ~~(jgg) "Replace an existing CT scanner" means an equipment change of an existing CT scanner, that~~
126 ~~requires a change in the radiation safety certificate, proposed by an applicant which results in that~~
127 ~~applicant operating the same number of CT scanners before and after project completion, at the same~~
128 ~~geographic location. THE TERM ALSO INCLUDES RELOCATING an existing CT scanner OR CT~~
129 ~~SCANNER service from an existing site to a different site.~~

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

136 ~~(#hh)~~ "Sedated patient" means a patient that meets all of the following:

137 (i) Patient undergoes procedural sedation and whose level of consciousness is either moderate
138 sedation or a higher level of sedation, as defined by the American Association of Anesthesiologists, the
139 American Academy of Pediatrics, the Joint Commission on the Accreditation of Health Care
140 Organizations, or an equivalent definition.

141 (ii) Who requires observation by personnel, other than technical employees routinely assigned to the
142 CT unit, who are trained in cardiopulmonary resuscitation (CPR) and pediatric advanced life support
143 (PALS).

144 ~~(mmj)~~ "Special needs patient" means a non-sedated patient, either pediatric or adult, with any of the
145 following conditions: down syndrome, autism, attention deficit hyperactivity disorder (ADHD),
146 developmental delay, malformation syndromes, hunter's syndrome, multi-system disorders, psychiatric
147 disorders, and other conditions that make the patient unable to comply with the positional requirements of
148 the exam.

149
150 (2) Terms defined in the Code have the same meanings when used in these standards.

151
152 **Section 3. Requirements for approval for applicants proposing to initiate a CT scanner service**
153 **~~other than a dental CT scanner service or hospital-based portable CT scanner service~~**

154
155 Sec. 3. An applicant proposing to initiate a CT scanner service, OTHER THAN A DENTAL CT
156 SCANNER SERVICE OR A HOSPITAL-BASED PORTABLE CT SCANNER SERVICE, shall demonstrate
157 ~~each of~~ the following, as applicable:

158
159 (1) A hospital proposing to initiate its first fixed CT scanner service shall demonstrate each of the
160 following:

161 (a) The proposed site is a hospital licensed under Part 215 of the Code.

162 (b) The hospital operates an emergency room that provides 24-hour emergency care services as
163 authorized by the local medical control authority to receive ambulance runs.

164
165 (2) An applicant, other than an applicant meeting all of the applicable requirements of subsection (1),
166 proposing to initiate a fixed CT scanner service shall project an operating level of at least 7,500 CT
167 equivalents per year for the second 12-month period after beginning operation of the CT scanner.

168
169 (3) An applicant proposing to initiate a mobile CT scanner service shall project an operating level of at
170 least 3,500 CT equivalents per year for the second 12-month period after beginning operation of the CT
171 scanner.

172
173 (4) AN APPLICANT PROPOSING TO INITIATE CT SCANNER SERVICES AS AN EXISTING HOST
174 SITE ON A DIFFERENT MOBILE CT SCANNER SERVICE SHALL DEMONSTRATE THE FOLLOWING:

175 (a) THE APPLICANT PROVIDES A PROPOSED ROUTE SCHEDULE.

176 (b) THE APPLICANT PROVIDES A DRAFT CONTRACT FOR SERVICES BETWEEN THE
177 PROPOSED HOST SITE AND CENTRAL SERVICE COORDINATOR.

178
179 **Section 4. Requirements for approval for applicants proposing to initiate a dental CT scanner**
180 **service**

181
182 | Sec. 4. An applicant proposing to initiate a FIXED OR MOBILE dental CT scanner service shall
183 demonstrate each of the following, as applicable:

184
185 | (1) An applicant is proposing a DENTALfixed CT scanner service for the sole purpose of performing
186 dental CT examinations.

187
188 (2) The CT scanner generates a peak power of 5 kilowatts or less as certified by the manufacturer.

189
190 (3) An applicant proposing to initiate a dental CT scanner service, other than an applicant that is
191 proposing a dental CT scanner service in HSA 8, shall project an operating level of at least 200 dental CT
192 examinations per year for the second 12-month period after beginning operation of the dental CT scanner.

193
194 (4) The applicant has demonstrated to the satisfaction of the Department that the person(s) (e.g.,
195 technician, dentist) operating the dental CT scanner has been appropriately trained and/or certified by one
196 of the following groups, as recognized by the Department: a dental radiology program in a certified dental
197 school, an appropriate professional society, or a dental continuing education program accredited by the
198 American Dental Association.

199
200 (5) The applicant has demonstrated to the satisfaction of the Department that the dental CT
201 examinations generated by the proposed dental CT scanner will be interpreted by a licensed dentist(s)
202 trained and/or certified by one of the following groups, as recognized by the Department: a dental
203 radiology program in a certified dental school, an appropriate professional society, or a dental continuing
204 education program accredited by the American Dental Association.

205
206 (6) AN APPLICANT PROPOSING TO INITIATE MOBILE DENTAL CT SCANNER SERVICES AS AN
207 EXISTING HOST SITE ON A DIFFERENT MOBILE DENTAL CT SCANNER SERVICE SHALL
208 DEMONSTRATE THE FOLLOWING:

209 (a) THE APPLICANT PROVIDES A PROPOSED ROUTE SCHEDULE.

210 (b) THE APPLICANT PROVIDES A DRAFT CONTRACT FOR SERVICES BETWEEN THE
211 PROPOSED HOST SITE AND CENTRAL SERVICE COORDINATOR.

212
213 **Section 5. Requirements for approval for applicants proposing to expand an existing CT scanner**
214 **service ~~other than a dental CT scanner service or hospital-based portable CT scanner service~~**

216 | Sec. 5. AN APPLICANT PROPOSING TO EXPAND AN EXISTING CT SCANNER SERVICE, OTHER
217 | THAN A DENTAL CT SCANNER SERVICE OR A HOSPITAL-BASED PORTABLE CT SCANNER
218 | SERVICE, SHALL DEMONSTRATE THE FOLLOWING, AS APPLICABLE:
219 |

220 | ___(1) An applicant proposing to expand an existing fixed CT scanner service shall demonstrate that all of
221 | the applicant's fixed CT scanners, excluding CT scanners approved pursuant to sections 6, 13, 14, and
222 | 17-18, have performed an average of at least 10,000 CT equivalents per fixed CT scanner for the most
223 | recent continuous 12-month period preceding the applicant's request. In computing this average, the
224 | Department will divide the total number of CT equivalents performed by the applicant's total number of
225 | fixed CT scanners, including both operational and approved but not operational fixed CT scanners.
226 |

227 | (2) An applicant proposing to expand an existing fixed CT scanner service approved pursuant to
228 | Section 17-18 shall demonstrate that all of the applicant's dedicated pediatric CT scanners have
229 | performed an average of at least 3,000 CT equivalents per dedicated pediatric CT scanner for the most
230 | recent continuous 12-month period preceding the applicant's request. In computing this average, the
231 | Department will divide the total number of CT equivalents performed by the applicant's total number of
232 | dedicated pediatric CT scanners, including both operational and approved but not operational dedicated
233 | pediatric CT scanners.
234 |

235 | (3) If an applicant proposes to expand an existing mobile CT scanner service, the applicant shall
236 | demonstrate that all of the applicant's mobile CT scanners have performed an average of at least 5,500
237 | CT equivalents per mobile CT scanner for the most recent continuous 12-month period preceding the
238 | applicant's request. In computing this average, the Department will divide the total number of CT
239 | equivalents performed by the applicant's total number of mobile CT scanners, including both operational
240 | and approved but not operational mobile CT scanners.
241 |

242 | **Section 6. Requirements for approval for applicants proposing to expand an existing dental CT**
243 | **scanner service**
244 |

245 | Sec. 6. An applicant proposing to expand an existing fixed OR MOBILE dental CT scanner service
246 | shall demonstrate that all of the applicant's dental CT scanners have performed an average of at least 300
247 | dental CT examinations per fixed OR MOBILE dental CT scanner for the most recent continuous 12-
248 | month period preceding the applicant's request. In computing this average, the Department will divide the
249 | total number of dental CT examinations performed by the applicant's total number of fixed OR MOBILE
250 | dental CT scanners, including both operational and approved but not operational fixed OR MOBILE dental
251 | CT scanners.
252 |

253 | **Section 7. Requirements for approval for applicants proposing to replace an existing CT scanner**
254 | **~~other than a dental CT scanner or hospital-based portable CT scanner~~**
255 |

256 | Sec. 7. An applicant proposing to replace an existing CT scanner OR SERVICE, EXCEPT FOR AN
257 | APPLICANT APPROVED UNDER SECTION 3(1), OTHER THAN A DENTAL CT SCANNER SERVICE
258 | OR A HOSPITAL-BASED PORTABLE CT SCANNER SERVICE, shall demonstrate ~~each of~~ the following,
259 | as applicable:
260 |

261 | (1) An applicant, ~~other than an applicant meeting all of the applicable requirements of subsection (a),~~
262 | ~~(b) or (c) below,~~ proposing to replace an existing fixed, MOBILE, OR DEDICATED PEDIATRIC CT
263 | scanner shall demonstrate ~~that the fixed CT scanner(s) performed at least an average of 7,500 CT~~
264 | ~~equivalents per fixed CT scanner in the most recent 12-month period for which the Department has~~
265 | ~~verifiable data.~~

266 | ~~—(a) A hospital proposing to replace an existing CT scanner which is the only fixed CT scanner~~
267 | ~~operated at that site by the hospital shall demonstrate each~~ALL of the following:
268 |

268 | ~~—(i) The proposed site is a hospital licensed under Part 215 of the Code.~~

269 ~~— (ii) The hospital operates an emergency room that provides 24-hour emergency care services as~~
270 ~~authorized by the local medical control authority to receive ambulance runs.~~
271 (iii) The replacement CT scanner will be located at the same site as the CT scanner to be replaced.
272 ~~— (b) An applicant proposing to replace an existing fixed CT scanner shall be exempt once from the~~
273 ~~volume requirements if the existing CT scanner demonstrates that it meets all of the following:~~
274 ~~— (i) The existing CT scanner has performed at least 5,000 CT equivalents in the most recent 12-~~
275 ~~month period for which the Department has verifiable data.~~
276 ~~— (ii) The existing CT scanner is fully depreciated according to generally accepted accounting~~
277 ~~principles.~~
278 ~~— (iii) The existing CT scanner has at one time met its minimum volume requirements.~~
279 ~~— (c) An applicant proposing to replace an existing fixed CT scanner on an academic medical center~~
280 ~~campus, at the same site, shall be exempt once, as of May 5, 2008, from the minimum volume~~
281 ~~requirements for replacement if the existing CT scanner is fully depreciated according to generally~~
282 ~~accepted accounting principles.~~
283 ~~— (d) An applicant proposing to replace an existing fixed CT scanner having a configuration of less than~~
284 ~~16 multi-detector rows shall be exempt once, as of the effective date of the standards, from the minimum~~
285 ~~volume requirements for replacement if it meets both of the following:~~
286 ~~— (i) The proposed CT scanner to be obtained will have a configuration of sixteen (16) or more multi-~~
287 ~~detector rows, and~~
288 ~~— (ii) The existing CT scanner is fully depreciated according to generally accepted accounting~~
289 ~~principles.~~
290
291 ~~— (2) An applicant proposing to replace an existing mobile CT scanner(s) shall demonstrate that the~~
292 ~~mobile CT scanner(s) performed at least 3,500 CT equivalents if the applicant operates only one mobile~~
293 ~~CT scanner or an average of 5,500 CT equivalents for each CT scanner if the applicant operates more~~
294 ~~than one mobile CT scanner for the same mobile CT scanner network, in the most recent 12-month~~
295 ~~period for which the department has verifiable data.~~
296 ~~— (3) An applicant proposing to replace an existing dedicated pediatric CT scanner(s) shall demonstrate~~
297 ~~that the dedicated pediatric CT scanner(s) performed at least an average of 2,500 CT equivalents per~~
298 ~~dedicated pediatric CT scanner in the most recent 12-month period for which the Department has~~
299 ~~verifiable data.~~
300
301
302 ~~— (4b) An applicant under this section shall demonstrate that t~~The existing CT scanner(s) proposed to be
303 replaced is fully depreciated according to generally accepted accounting principles, or, that the existing
304 equipment clearly poses a threat to the safety of the public, or, that the proposed replacement CT scanner
305 offers technological improvements which enhance quality of care, increase efficiency, and/or reduce
306 operating costs and patient charges.
307
308 ~~— (2) An applicant proposing to relocate~~REPLACE an existing fixed CT scanner service TO A
309 DIFFERENT SITE shall demonstrate that the proposed project meets all of the following:
310 — (a) The existing fixed CT scanner service to be relocatedREPLACED has been in operation for at
311 least 36 months as of the date an application is submitted to the Department.
312 — (b) The proposed new site is in the relocation zone is within a 10-mile radius of a site at which an
313 existing fixed CT scanner service is located if an existing fixed CT scanner service is located in a
314 metropolitan statistical area county, or a 20-mile radius if an existing fixed CT scanner service is located in
315 a rural or micropolitan statistical area county.-
316 ~~— (c) The requirements of sections 5 or 7, as applicable, have been met.~~
317 — (dc) The CT scanner service to be relocateREPLACEDd performed at least an average of 7,500 CT
318 equivalents per fixed scanner in the most recent 12-month period for which the Department has verifiable
319 data.- EXCEPT FOR AN APPLICANT THAT MEETS ALL OF THE REQUIREMENTS OF SECTION 3(1).
320 — (ed) The applicant agrees to operate the CT scanner service in accordance with all applicable project
321 delivery requirements set forth in Section 4920 of these standards.
322

323 (3) An applicant proposing to ~~relocate~~REPLACE a fixed CT scanner(s) of an existing CT scanner
324 service TO A DIFFERENT SITE shall demonstrate that the proposed project meets all of the following:
325 (a) The existing CT scanner service from which the CT scanner(s) is to be ~~relocated~~REPLACED has
326 been in operation for at least 36 months as of the date an application is submitted to the Department.
327 (b) The proposed new site ~~is in the relocation zone~~ is within a 10-mile radius of a site at which an
328 existing fixed CT scanner service is located if an existing fixed CT scanner service is located in a
329 metropolitan statistical area county, or a 20-mile radius if an existing fixed CT scanner service is located in
330 a rural or micropolitan statistical area county..
331 ~~(c) The requirements of sections 5 or 7, as applicable, have been met.~~
332 (dc) Each existing CT scanner at the service from which a scanner is to be ~~relocated~~REPLACED
333 performed at least an average of 7,500 CT equivalents per fixed scanner in the most recent 12-month
334 period for which the Department has verifiable data.
335 (ed) The applicant agrees to operate the CT scanner(s) at the proposed site in accordance with all
336 applicable project delivery requirements set forth in Section 4920 of these standards.
337 (fe) FOR VOLUME PURPOSES, THE NEW SITE SHALL REMAIN ASSOCIATED WITH THE
338 EXISTING CT SERVICE FOR A MINIMUM OF THREE YEARS.

339
340 **Section 8. Requirements for approval for applicants proposing to replace an existing dental CT**
341 **scanner**

342
343 Sec. 8. An applicant proposing to replace an existing dental CT scanner OR SERVICE shall
344 demonstrate ~~each of~~ the following, AS APPLICABLE:

345
346 (1) An applicant proposing to replace an existing fixed OR MOBILE dental CT scanner shall
347 demonstrate ~~that the fixed OR MOBILE dental CT scanner(s) performed at least an average of 200 dental~~
348 ~~CT examinations per fixed OR MOBILE dental CT scanner in the most recent 12-month period for which~~
349 ~~the Department has verifiable data.~~ ALL OF THE FOLLOWING:

350 (a) THE REPLACEMENT DENTAL CT SCANNER WILL BE LOCATED AT THE SAME SITE AS
351 THE DENTAL CT SCANNER TO BE REPLACED.

352
353 (2b) An applicant under this section shall demonstrate that t~~he~~ existing dental CT scanner(s)
354 proposed to be replaced is fully depreciated according to generally accepted accounting principles, or, that
355 the existing equipment clearly poses a threat to the safety of the public, or that the proposed replacement
356 dental CT scanner offers technological improvements which enhance quality of care, increase efficiency,
357 and/or reduce operating costs and patient charges.

358
359 (2) An applicant proposing to ~~relocate~~REPLACE an existing fixed dental CT scanner service TO A
360 DIFFERENT SITE shall demonstrate that the proposed project meets all of the following:

361 (a) The existing fixed dental CT scanner service to be ~~relocated~~REPLACED has been in operation for
362 at least 36 month as of the date an application is submitted to the Department.

363
364 (b) The proposed new site is ~~in the relocation ZONE~~WITHIN A 10-MILE RADIUS OF A SITE AT
365 WHICH AN EXISTING FIXED DENTAL CT SCANNER SERVICE IS LOCATED IF AN EXISTING FIXED
366 DENTAL CT SCANNER SERVICE IS LOCATED IN A METROPOLITAN STATISTICAL AREA COUNTY,
367 OR A 20-MILE RADIUS IF AN EXISTING FIXED DENTAL CT SCANNER SERVICE IS LOCATED IN A
368 RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY.

369 ~~(c) The requirements of sections 6 or 8, as applicable, have been met.~~

370 (dc) The dental CT scanner service to be REPLACED ~~relocated~~performed at least an average of 200
371 dental CT examinations per fixed dental CT scanner in the most recent 12-month period for which the
372 Department has verifiable data.

373 (ed) The applicant agrees to operate the dental CT scanner service in accordance with all applicable
374 project delivery requirements set forth in Section 4920 of these standards.

376 (3) An applicant proposing to ~~relocate~~REPLACE a fixed dental CT scanner(s) of an existing dental
377 CT scanner service TO A DIFFERENT SITE shall demonstrate that the proposed project meets all of the
378 following:

379 (a) The existing dental CT scanner service from which the dental CT scanner(s) is to be
380 ~~relocated~~REPLACED has been in operation for at least 36 months as of the date an application is
381 submitted to the Department.

382 (b) FOR VOLUME PURPOSES, THE NEW SITE SHALL REMAIN ASSOCIATED WITH THE
383 EXISTING CT SERVICE FOR A MINIMUM OF THREE YEARS.

384 (c) The proposed new site is ~~in the relocation zone~~WITHIN A 10-MILE RADIUS OF A SITE AT
385 WHICH AN EXISTING FIXED DENTAL CT SCANNER SERVICE IS LOCATED IF AN EXISTING FIXED
386 DENTAL CT SCANNER SERVICE IS LOCATED IN A METROPOLITAN STATISTICAL AREA COUNTY,
387 OR A 20-MILE RADIUS IF AN EXISTING FIXED DENTAL CT SCANNER SERVICE IS LOCATED IN A
388 RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY.

389 ~~—(d) The requirements of sections 6 or 8, as applicable have been met.~~

390 (e) Each existing dental CT scanner at the service from which a scanner is to be ~~relocated~~
391 REPLACED performed at least an average of 200 dental CT examinations per fixed dental CT scanner in
392 the most recent 12-month period for which the Department has verifiable data.

393 (f) The applicant agrees to operate the dental CT scanner(s) at the proposed site in accordance with
394 all applicable project delivery requirements set forth in Section 4920 of these standards.

395
396 **Section 9. ~~Requirements for approval for applicants proposing to relocate an existing CT scanner~~**
397 **~~service and/or CT scanner(s) other than an existing dental CT scanner service and/or dental CT~~**
398 **~~scanner(s) or hospital-based portable CT scanner(s)~~**
399

400 ~~Sec. 9. (1) An applicant proposing to relocate an existing fixed CT scanner service shall demonstrate~~
401 ~~that the proposed project meets all of the following:~~

402 ~~—(a) The existing fixed CT scanner service to be relocated has been in operation for at least 36 months~~
403 ~~as of the date an application is submitted to the Department.~~

404 ~~—(b) The proposed new site is in the relocation zone.~~

405 ~~—(c) The requirements of sections 5 or 7, as applicable, have been met.~~

406 ~~—(d) The CT scanner service to be relocated performed at least an average of 7,500 CT equivalents~~
407 ~~per fixed scanner in the most recent 12-month period for which the Department has verifiable data.~~

408 ~~—(e) The applicant agrees to operate the CT scanner service in accordance with all applicable project~~
409 ~~delivery requirements set forth in Section 19 of these standards.~~

410
411 ~~—(2) An applicant proposing to relocate a fixed CT scanner(s) of an existing CT scanner service shall~~
412 ~~demonstrate that the proposed project meets all of the following:~~

413 ~~—(a) The existing CT scanner service from which the CT scanner(s) is to be relocated has been in~~
414 ~~operation for at least 36 months as of the date an application is submitted to the Department.~~

415 ~~—(b) The proposed new site is in the relocation zone.~~

416 ~~—(c) The requirements of sections 5 or 7, as applicable, have been met.~~

417 ~~—(d) Each existing CT scanner at the service from which a scanner is to be relocated performed at~~
418 ~~least an average of 7,500 CT equivalents per fixed scanner in the most recent 12-month period for which~~
419 ~~the Department has verifiable data.~~

420 ~~—(e) The applicant agrees to operate the CT scanner(s) at the proposed site in accordance with all~~
421 ~~applicable project delivery requirements set forth in Section 19 of these standards.~~

422
423
424 **Section 10. ~~Requirements for approval for applicants proposing to relocate an existing dental CT~~**
425 **~~scanner service and/or dental CT scanner(s)~~**
426

427 ~~—Sec. 10. (1) An applicant proposing to relocate an existing fixed dental CT scanner service shall~~
428 ~~demonstrate that the proposed project meets all of the following:~~

- 429 ~~—(a) The existing fixed dental CT scanner service to be relocated has been in operation for at least 36~~
- 430 ~~month as of the date an application is submitted to the Department.~~
- 431 ~~—(b) The proposed new site is in the relocation zone.~~
- 432 ~~—(c) The requirements of sections 6 or 8, as applicable, have been met.~~
- 433 ~~—(d) The dental CT scanner service to be relocated performed at least an average of 200 dental CT~~
- 434 ~~examinations per fixed dental CT scanner in the most recent 12-month period for which the Department~~
- 435 ~~has verifiable data.~~
- 436 ~~—(e) The applicant agrees to operate the dental CT scanner service in accordance with all applicable~~
- 437 ~~project delivery requirements set forth in Section 19 of these standards.~~
- 438
- 439 ~~—(2) An applicant proposing to relocate a fixed dental CT scanner(s) of an existing dental CT scanner~~
- 440 ~~service shall demonstrate that the proposed project meets all of the following:~~
- 441 ~~—(a) The existing dental CT scanner service from which the dental CT scanner(s) is to be relocated~~
- 442 ~~has been in operation for at least 36 months as of the date an application is submitted to the Department.~~
- 443 ~~—(b) The proposed new site is in the relocation zone.~~
- 444 ~~—(c) The requirements of sections 6 or 8, as applicable have been met.~~
- 445 ~~—(d) Each existing dental CT scanner at the service from which a scanner is to be relocated performed~~
- 446 ~~at least an average of 200 dental CT examinations per fixed dental CT scanner in the most recent 12-~~
- 447 ~~month period for which the Department has verifiable data.~~
- 448 ~~—(e) The applicant agrees to operate the dental CT scanner(s) at the proposed site in accordance with~~
- 449 ~~all applicable project delivery requirements set forth in Section 19 of these standards.~~

450

451 **Section 149. Requirements for approval for applicants proposing to acquire an existing CT**

452 **scanner service or an existing CT scanner(s) ~~other than an existing dental CT scanner service~~**

453 **~~and/or an existing dental CT scanner(s) or hospital-based portable CT scanner(s)~~**

454

455 Sec. 149. An applicant proposing to acquire an existing fixed or mobile CT scanner service, OTHER

456 THAN A DENTAL CT SCANNER SERVICE OR A HOSPITAL-BASED PORTABLE CT SCANNER

457 SERVICE, SHALL DEMONSTRATE THE FOLLOWING, AS APPLICABLE:

458

459 —(1) An applicant proposing to acquire an existing fixed or mobile CT scanner service, EXCEPT FOR

460 AN APPLICANT APPROVED UNDER SECTION 3(1), shall demonstrate that a proposed project meets all

461 of the following:

462 ~~—(a) The requirements of sections 5, 7, or 9, as applicable, have been met.~~

463 (ba) For an application for the proposed first acquisition of an existing fixed or mobile CT scanner

464 service, for which a final decision has not been issued after June 4, 2004, an existing CT scanner service

465 to be acquired shall not be required to be in compliance with the volume requirement applicable to the

466 seller/lessor on the date the acquisition occurs. The CT scanner service shall be operating at the

467 applicable volume requirements set forth in Section 19-20 of these standards in the second 12 months

468 after the date the service is acquired, and annually thereafter.

469 (eb) For any application for proposed acquisition of an existing fixed or mobile CT scanner service, an

470 applicant shall be required to demonstrate THE FOLLOWING, AS APPLICABLE:

471 (i) The fixed CT SCANNER SERVICE TO BE ACQUIRED PERFORMED AT LEAST 7,500 CT

472 EQUIVALENTS PER FIXED CT SCANNER IN THE MOST RECENT 12-MONTH PERIOD FOR WHICH

473 THE DEPARTMENT HAS VERIFIABLE DATA, UNLESS AN APPLICANT MEETS ALL OF THE

474 REQUIREMENTS OF SECTION 3(1).

475 (ii) that the The MOBILE CT scanner service to be acquired performed at least 73,500 CT

476 equivalents PER MOBILE CT SCANNER in the most recent 12-month period for which the Department

477 has verifiable data.

478

479 (2) An applicant proposing to acquire an existing fixed or mobile CT scanner(s) of an existing fixed or

480 mobile CT scanner service shall demonstrate that the proposed project meets ~~all of~~ the following:

481 ~~—(a) The requirements of sections 5, 7 or 9, as applicable, have been met.~~

482 (ba) For any application for proposed acquisition of an existing fixed or mobile CT scanner(s) of an
483 existing fixed or mobile CT scanner service, an applicant shall be required to demonstrate THE
484 FOLLOWING, AS APPLICABLE:
485 (i) that the fixed CT SCANNER(S) TO BE ACQUIRED PERFORMED AT LEAST 7,500 CT
486 EQUIVALENTS PER FIXED CT SCANNER IN THE MOST RECENT 12-MONTH PERIOD FOR WHICH
487 THE DEPARTMENT HAS VERIFIABLE DATA of,
488 (ii) THE mobile CT scanner(s) to be acquired performed at least 73,500 CT equivalents PER
489 MOBILE CT SCANNER in the most recent 12-month period for which the Department has verifiable data.
490

491 **Section 4210. Requirements for approval for applicants proposing to acquire an existing dental**
492 **CT scanner service or an existing dental CT scanner(s)**
493

494 Sec. 4210. (1) An applicant proposing to acquire an existing fixed OR MOBILE dental CT scanner
495 service shall demonstrate that a proposed project meets all of the following:

496 (a) ~~The requirements of sections 6 OR, 8, or 10, as applicable, have been met.~~
497 ~~(b)~~ For an application for the proposed first acquisition of an existing fixed OR MOBILE dental CT
498 scanner service, for which a final decision has not been issued after the effective date of these standards,
499 an existing dental CT scanner service to be acquired shall not be required to be in compliance with the
500 volume requirement applicable to the seller/lessor on the date the acquisition occurs. The dental CT
501 scanner service shall be operating at the applicable volume requirements set forth in Section 19-20 of
502 these standards in the second 12 months after the date the service is acquired, and annually thereafter.

503 (eb) For any application for proposed acquisition of an existing fixed OR MOBILE dental CT scanner
504 service, an applicant shall be required to demonstrate that the CT scanner service to be acquired
505 performed at least 200 dental CT examinations PER DENTAL CT SCANNER in the most recent 12-month
506 period, for which the Department has verifiable data.

507 (2) An applicant proposing to acquire an existing fixed dental CT scanner(s) of an existing fixed OR
508 MOBILE dental CT scanner service shall demonstrate that the proposed project meets ~~all of~~ the following:

509 (a) ~~The requirements of sections 6 OR, 8, or 10, as applicable, have been met.~~
510 ~~(b)~~ For any application for proposed acquisition of an existing fixed OR MOBILE dental CT scanner(s)
511 of an existing fixed OR MOBILE dental CT scanner service, an applicant shall be required to demonstrate
512 that the fixed OR MOBILE dental CT scanner(s) to be acquired performed at least 200 dental CT
513 examinations PER DENTAL CT SCANNER in the most recent 12-month period for which the Department
514 has verifiable data.
515

516 SECTION 11. REQUIREMENTS FOR A DEDICATED RESEARCH FIXED CT SCANNER
517

518 SEC. 11. AN APPLICANT PROPOSING TO ADD A FIXED CT SCANNER TO AN EXISTING CT
519 SCANNER SERVICE FOR EXCLUSIVE RESEARCH USE SHALL DEMONSTRATE THE FOLLOWING:
520

521 (1) THE APPLICANT AGREES THAT THE DEDICATED RESEARCH CT SCANNER WILL BE
522 USED PRIMARILY (70% OR MORE OF THE SCANS) FOR RESEARCH PURPOSES ONLY.
523

524 (2) THE DEDICATED RESEARCH CT SCANNER SHALL OPERATE UNDER A PROTOCOL
525 APPROVED BY THE APPLICANT'S INSTITUTIONAL REVIEW BOARD, AS DEFINED BY PUBLIC LAW
526 93-348 AND REGULATED BY TITLE 45 CFR 46.
527

528 (3) THE PROPOSED SITE CAN HAVE NO MORE THAN THREE DEDICATED RESEARCH FIXED
529 CT SCANNERS APPROVED UNDER THIS SECTION.
530

531 (4) THE DEDICATED RESEARCH SCANNER APPROVED UNDER THIS SECTION MAY NOT
532 UTILIZE CT PROCEDURES PERFORMED ON THE DEDICATED CT SCANNER TO DEMONSTRATE
533 NEED OR TO SATISFY CT CON REVIEW STANDARDS REQUIREMENTS.
534

535 **Section 12. Requirements for approval of an applicant proposing a CT scanner used for the sole**
536 **purpose of performing dental CT examinations exclusively for research**

537
538 Sec. 12. (1) An applicant proposing a CT scanner used for the sole purpose of performing dental CT
539 examinations exclusively for research shall demonstrate each of the following:

540 (a) The applicant operates a dental radiology program in a certified dental school.

541 (b) The research dental CT scanner shall operate under a protocol approved by the applicant's
542 institutional review board.

543 (c) The applicant agrees to operate the research dental CT scanner in accordance with the terms of
544 approval in Section 4920(46).

545 (2) An applicant meeting the requirements of subsection (1) shall also demonstrate compliance with
546 the requirements of sections 4(2), 4(4) and 4(5).

547
548 **~~Section 13. Pilot program requirements~~ Requirements for approval of a hospital-based portable**
549 **CT scanner for initiation, expansion, replacement, and acquisition**

550
551 ~~Sec. 13. As a pilot program, a~~ An applicant proposing to initiate, expand, replace, or acquire a hospital-
552 based portable CT scanner shall demonstrate that it meets all of the following:

553
554 (1) An applicant is limited to the initiation, expansion, replacement, or acquisition of no more than two
555 hospital-based portable CT scanners.

556
557 (2) The proposed site is a hospital licensed under Part 215 of the Code.

558
559 (3) The hospital has been certified as a level I or level II trauma facility by the American College of
560 Surgeons, or has performed >100 craniotomies in the most recent 12- month period verifiable by the
561 Department.

562
563 (4) The applicant agrees to operate the hospital-based portable CT scanner in accordance with all
564 applicable project delivery requirements set forth in Section ~~49-20~~ of these standards.

565
566 (5) The approved hospital-based portable CT scanner will not be subject to CT volume requirements.

567
568 (6) The applicant may not utilize CT procedures performed on a hospital-based portable CT scanner
569 to demonstrate need or to satisfy CT CON review standards requirements.

570
571 ~~(7) The Commission may decide to have the requirements of the pilot program described in this~~
572 ~~section become a permanent part of the CT scanner services standards. If the Commission does not take~~
573 ~~action to make the pilot program a permanent part of the standards, the provisions of Section 13, as part~~
574 ~~of a pilot program, will expire on December 31, 2016 and be of no further force and effect after December~~
575 ~~31, 2016. Any applicant seeking to be part of the pilot program described in this section must submit its~~
576 ~~application on or before December 1, 2013. These provisions shall not be applicable to any application~~
577 ~~which has not been submitted by December 1, 2013.~~

578
579 **Section 14. Requirements for approval of a PET/CT hybrid for initiation, expansion, replacement,**
580 **and acquisition**

581
582 Sec. 14. An applicant proposing to initiate, expand, replace, or acquire a PET/CT hybrid shall
583 demonstrate that it meets all of the following:

584
585 (1) There is an approved PET CON for the PET/CT hybrid, and the PET/CT hybrid is in compliance
586 with all applicable project delivery requirements as set forth in the CON review standards for PET.

588 (2) The applicant agrees to operate the PET/CT hybrid in accordance with all applicable project
589 delivery requirements set forth in Section ~~49-20~~ of these standards.

590
591 (3) The approved PET/CT hybrid will not be subject to CT volume requirements.

592
593 (4) A PET/CT scanner hybrid approved under the CON Review Standards for PET Scanner Services
594 and the Review Standards for CT Scanner Services may not utilize CT procedures performed on a hybrid
595 scanner to demonstrate need or to satisfy CT CON review standards requirements.

596
597 **SECTION 15. REQUIREMENTS FOR APPROVAL OF A CT-ANGIO HYBRID UNIT FOR INITIATION,**
598 **REPLACEMENT, AND ACQUISITION**

599
600 SEC. 15. AN APPLICANT PROPOSING TO INITIATE, REPLACE, OR ACQUIRE A HOSPITAL-
601 BASED CT-ANGIO HYBRID UNIT SHALL DEMONSTRATE EACH OF THE FOLLOWING, AS
602 APPLICABLE TO THE PROPOSED PROJECT:

603
604 (1) THE PROPOSED SITE IS A LICENSED HOSPITAL UNDER PART 215 OF THE CODE.

605
606 (2) THE PROPOSED SITE HAS AN EXISTING FIXED CT SCANNER SERVICE THAT HAS BEEN
607 OPERATIONAL FOR THE PREVIOUS 36 CONSECUTIVE MONTHS AND IS MEETING ITS MINIMUM
608 VOLUME REQUIREMENTS.

609
610 (3) THE PROPOSED SITE OFFERS THE FOLLOWING SERVICES:

611 (a) DIAGNOSTIC CARDIAC CATHETERIZATION; OR

612 (b) INTERVENTIONAL RADIOLOGY; OR

613 (c) SURGICAL SERVICES

614
615 (4) THE PROPOSED CT-ANGIO HYBRID UNIT MUST BE LOCATED IN ONE OF THE
616 FOLLOWING ROOMS:

617 (a) CARDIAC CATHETERIZATION LAB; OR

618 (b) INTERVENTIONAL RADIOLOGY SUITE; OR

619 (c) LICENSED OPERATING ROOM

620
621 (5) DIAGNOSTIC CT STUDIES SHALL NOT BE PERFORMED ON A CT-ANGIO HYBRID UNIT
622 APPROVED UNDER THIS SECTION UNLESS THE PATIENT IS CURRENTLY UNDERGOING A CT-
623 ANGIO HYBRID INTERVENTIONAL PROCEDURE AND IS IN NEED OF A SECONDARY DIAGNOSTIC
624 CT STUDY.

625
626 (6) THE APPROVED CT-ANGIO HYBRID SHALL NOT BE SUBJECT TO CT VOLUME
627 REQUIREMENTS.

628
629 (7) THE APPLICANT SHALL NOT UTILIZE THE PROCEDURES PERFORMED ON THE CT-ANGIO
630 HYBRID UNIT TO DEMONSTRATE NEED OR TO SATISFY CT CON REVIEW STANDARDS
631 REQUIREMENTS.

632
633 **Section ~~4516~~. Additional requirements for approval of a mobile CT scanner service**

634
635 Sec. ~~4516~~. (1) An applicant proposing to initiate a mobile CT scanner service in Michigan shall
636 demonstrate that it meets all of the following **ADDITIONAL REQUIREMENTS**:

637 (a) A separate CON application shall be submitted by the central service coordinator and each
638 Michigan host facility.

639 (b) The normal route schedule, the procedures for handling emergency situations, and copies of all
640 potential contracts related to the mobile CT scanner service shall be included in the CON application
641 submitted by the central service coordinator.

642 | ~~—(c) The requirements of sections 3, 5, or 7, as applicable, have been met.~~

643
644 (2) An applicant proposing to become a host facility on an existing mobile CT scanner network shall
645 demonstrate that it meets all of the following **ADDITIONAL REQUIREMENTS**:

646 (a) Approval of the application will not result in an increase in the number of operating mobile CT
647 scanners for the mobile CT scanner network unless the requirements of Section 5 have been met.

648 (b) A separate CON application has been filed for each host facility.

649
650 ~~(3) An applicant proposing to replace a central service coordinator on an existing mobile CT scanner~~
651 ~~network shall demonstrate that approval of the application will not replace the CT scanner and~~
652 ~~transporting equipment unless the applicable requirements of Section 7 have been met.~~

653
654 **SECTION 17. ADDITIONAL REQUIREMENTS FOR APPROVAL OF A MOBILE DENTAL CT**
655 **SCANNER SERVICE**

656
657 SEC. 17. (1) AN APPLICANT PROPOSING TO INITIATE A MOBILE DENTAL CT SCANNER
658 SERVICE IN MICHIGAN SHALL DEMONSTRATE THAT IT MEETS ALL OF THE FOLLOWING
659 ADDITIONAL REQUIREMENTS:

660 (A) A SEPARATE CON APPLICATION SHALL BE SUBMITTED BY THE CENTRAL SERVICE
661 COORDINATOR AND EACH MICHIGAN HOST FACILITY.

662 (B) THE NORMAL ROUTE SCHEDULE, THE PROCEDURES FOR HANDLING EMERGENCY
663 SITUATIONS, AND COPIES OF ALL POTENTIAL CONTRACTS RELATED TO THE MOBILE DENTAL
664 CT SCANNER SERVICE SHALL BE INCLUDED IN THE CON APPLICATION SUBMITTED BY THE
665 CENTRAL SERVICE COORDINATOR.

666
667 (2) AN APPLICANT PROPOSING TO BECOME A HOST FACILITY ON AN EXISTING MOBILE
668 DENTAL CT SCANNER NETWORK SHALL DEMONSTRATE THAT IT MEETS ALL OF THE
669 FOLLOWING ADDITIONAL REQUIREMENTS:

670 (A) APPROVAL OF THE APPLICATION WILL NOT RESULT IN AN INCREASE IN THE NUMBER
671 OF OPERATING MOBILE DENTAL CT SCANNERS FOR THE MOBILE DENTAL CT SCANNER
672 NETWORK UNLESS THE REQUIREMENTS OF SECTION 6 HAVE BEEN MET.

673 (B) A SEPARATE CON APPLICATION HAS BEEN FILED FOR EACH HOST FACILITY.

674
675 **Section 1615. Requirements for approval of an applicant proposing a CT scanner used for the**
676 **sole purpose of performing dental CT examinations exclusively for research**

677
678 ~~—Sec. 1615. (1) An applicant proposing a CT scanner used for the sole purpose of performing dental~~
679 ~~CT examinations exclusively for research shall demonstrate each of the following:~~

680 ~~—(a) The applicant operates a dental radiology program in a certified dental school.~~

681 ~~—(b) The research dental CT scanner shall operate under a protocol approved by the applicant's~~
682 ~~institutional review board.~~

683 ~~—(c) The applicant agrees to operate the research dental CT scanner in accordance with the terms of~~
684 ~~approval in Section 19(4).~~

685 ~~—(2) An applicant meeting the requirements of subsection (1) shall also demonstrate compliance with~~
686 ~~the requirements of sections 4(2), 4(4) and 4(5).~~

687
688 **Section 4718. Requirements for approval of an applicant proposing to establish dedicated**
689 **pediatric CT Scanner**

690
691 Sec. 4718. (1) An applicant proposing to establish dedicated pediatric CT shall demonstrate all of the
692 following:

693 (a) The applicant shall have experienced at least 7,000 pediatric (< 18 years old) discharges
694 (excluding normal newborns) in the most recent year of operation.

695 (b) The applicant shall have performed at least 5,000 pediatric (< 18 years old) surgeries in the most
696 recent year of operation.

697 (c) The applicant shall have an active medical staff, at the time the application is submitted to the
698 Department that includes, but is not limited to, physicians who are fellowship-trained in the following
699 pediatric specialties:

- 700 (i) pediatric radiology (at least two)
- 701 (ii) pediatric anesthesiology
- 702 (iii) pediatric cardiology
- 703 (iv) pediatric critical care
- 704 (v) pediatric gastroenterology
- 705 (vi) pediatric hematology/oncology
- 706 (vii) pediatric neurology
- 707 (viii) pediatric neurosurgery
- 708 (ix) pediatric orthopedic surgery
- 709 (x) pediatric pathology
- 710 (xi) pediatric pulmonology
- 711 (xii) pediatric surgery
- 712 (xiii) neonatology

713 (d) The applicant shall have in operation the following pediatric specialty programs at the time the
714 application is submitted to the Department:

- 715 (i) pediatric bone marrow transplant program
- 716 (ii) established pediatric sedation program
- 717 (iii) pediatric open heart program

718
719 (2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the
720 requirements of Section 3 of these standards.

721

722 | **Section ~~4819~~. Requirements for MEDICAID approval -- all applicants PARTICIPATION**

723

724 | Sec. ~~4819~~. An applicant shall provide verification of Medicaid participation. An applicant that is a new
725 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided
726 to the Department within six (6) months from the offering of services if a CON is approved.

727

728 | **Section ~~4920~~. Project delivery requirements -- AND terms of approval for all applicants**

729

730 | Sec. ~~4920~~. ~~(1)~~ An applicant shall agree that, if approved, the ~~services provided by the~~ CT scanner(s)
731 SERVICES shall be delivered in compliance with the following terms of CON approval:

732 | ~~(a1)~~ Compliance with these standards:

733 | ~~(b) Compliance with applicable safety and operating standards~~

734

735 | ~~(e2)~~ Compliance with the following quality assurance standards:

736 | ~~(i) The approved CT scanners shall be operating at the applicable required volumes within the time~~
737 ~~periods specified in these standards, and annually thereafter.~~

738 | ~~(ii)~~ The applicant shall establish a mechanism to assure that the CT scanner facility is staffed so that:

739 | ~~(A)~~ The screening of requests for CT procedures and interpretation of CT procedures will be
740 performed by physicians with training and experience in the appropriate diagnostic use and interpretation
741 of cross-sectional images of the anatomical region(s) to be examined, and

742 | ~~(B)~~ The CT scanner is operated by physicians and/or is operated by radiological technologists
743 qualified by training and experience to operate the CT scanner safely and effectively.

744 | For purposes of evaluating ~~(ii)~~ ~~(A)~~, the Department shall consider it prima facie evidence of a
745 satisfactory assurance mechanism as to screening and interpretation if the applicant requires the
746 screening of requests for and interpretations of CT procedures to be performed by physicians who are
747 board certified or eligible in radiology or are neurologists or other specialists trained in cross-sectional
748 imaging of a specific organ system. For purposes of evaluating ~~(ii)~~ ~~(B)~~ the Department shall consider it

749 prima facie evidence of a satisfactory assurance mechanism as to the operation of a CT scanner if the
750 applicant requires the CT scanner to be operated by a physician or by a technologist registered by the
751 American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography
752 Technologists (ARCRT). However, the applicant may submit and the Department may accept other
753 evidence that the applicant has established a mechanism to assure that the CT scanner facility is
754 appropriately and adequately staffed as to screening, interpretation, and/or operation of a CT scanner.
755 | (iii**b**) The applicant shall employ or contract with a radiation physicist to review the quality and safety of
756 the operation of the CT scanner.
757 | (iv**c**) The applicant shall assure that at least one of the physicians responsible for the screening and
758 | interpretation as defined in subsection (ii**a**)(A*i*) will be in the CT facility or available on a 24-hour basis
759 | (either on-site or through telecommunication capabilities) to make the final interpretation.
760 | (v**d**) In the case of an urgent or emergency CT scan, the applicant shall assure that a physician so
761 | authorized by the applicant to interpret initial scans will be on-site or available through telecommunication
762 | capabilities within 1 hour following completion of the scanning procedure to render an initial interpretation
763 | of the scan. A final interpretation shall be rendered by a physician so authorized under subsection (ii**a**)(A*i*)
764 | within 24 hours.
765 | (vi**e**) The applicant shall have, within the CT scanner facility, equipment and supplies to handle clinical
766 | emergencies that might occur within the CT unit, with CT facility staff trained in CPR and other appropriate
767 | emergency interventions, and a physician on site in or immediately available to the CT scanner at all times
768 | when patients are undergoing scans.
769 | (vii**f**) Fixed CT scanner services at each facility shall be made available 24 hours a day for emergency
770 | patients.
771 | (viii**g**) The applicant shall accept referrals for CT scanner services from all appropriately licensed
772 | practitioners.
773 | (ix**h**) The applicant shall establish and maintain: (a) a standing medical staff and governing body (or its
774 | equivalent) requirement that provides for the medical and administrative control of the ordering and
775 | utilization of CT patient procedures, and (b) a formal program of utilization review and quality assurance.
776 | These responsibilities may be assigned to an existing body of the applicant, as appropriate.
777 | (x**i**) An applicant approved under Section 47-18 must be able to prove that all radiologists,
778 | technologists and nursing staff working with CT patients have continuing education or in-service training
779 | on pediatric low-dose CT. The site must also be able to provide evidence of defined low-dose pediatric
780 | CT protocols.

781 | _____
782 | (3) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:

- 783 | (xii**a**) The applicant, to assure that the CT scanner will be utilized by all segments of the Michigan
784 | population, shall:
785 | (A*i*) not deny ANY CT scanner services to any individual based on ability to pay or source of payment;
786 | (B*ii*) provide ALL CT scanning services to any individual based on the clinical indications of need for
787 | the service; and
788 | (C*iii*) maintain information by payor and non-paying sources to indicate the volume of care from each
789 | source provided annually.
790 | (b) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years
791 | of operation and continue to participate annually thereafter.
792 | (c) The operation of and referral of patients to the CT scanner shall be in conformance with 1978 PA
793 | 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

794 |
795 | Compliance with selective contracting requirements shall not be construed as a violation of this term.

796 | _____
797 | (4) COMPLIANCE WITH THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:
798 | (i**a**) The approved CT scanners shall be operating at the applicable required volumes AN AVERAGE
799 | within the time periods specified in these standards, OF 7,500 CT EQUIVALENTS SCANNER PER FIXED
800 | SCANNER AND 3,500 CT EQUIVALENTS PER MOBILE SCANNER PER YEAR FOR THE SECOND 12-
801 | MONTH PERIOD AFTER BEGINNING OPERATION OF THE CT SCANNER, and annually thereafter,
802 | EXCEPT FOR THOSE SCANNERS EXEMPT UNDER APPLICABLE SECTIONS.

803 | ~~(xiiib)~~ The applicant shall participate in a data collection network established and administered by the
804 Department or its designee. The data may include, but is not limited to, annual budget and cost
805 information, operating schedules, through-put schedules, demographic and diagnostic information, the
806 volume of care provided to patients from all payor sources, and other data requested by the Department,
807 and approved by the Commission. The applicant shall provide the required data on a separate basis for
808 each separate and distinct site as required by the Department; in a format established by the Department;
809 and in a mutually agreed upon media. The Department may elect to verify the data through on-site review
810 of appropriate records.

811 | ~~(xiiic)~~ Equipment to be replaced shall be removed from service.

812 | ~~(xivd)~~ The applicant shall provide the Department with a TIMELY notice ~~stating the date the approved~~
813 ~~CT scanner service is placed in operation and such notice shall be submitted to the Department OF THE~~
814 PROPOSED PROJECT IMPLEMENTATION consistent with applicable statute and promulgated rules.

815 | ~~(xv)~~ ~~An applicant shall participate in Medicaid at least 12 consecutive months within the first two years~~
816 ~~of operation and continue to participate annually thereafter.~~

817 | ~~(de)~~ An applicant approved under Section 4 shall not be required to be in compliance with subsection
818 ~~(e2), but shall be in compliance with the following quality assurance standards:~~

819 | ~~(i)~~ ~~The CT scanner shall be operating at least 200 CT equivalents per year for the second 12-month~~
820 ~~period after beginning operation of the dental CT scanner and annually thereafter.~~

821

822

823 | (5) COMPLIANCE WITH THE FOLLOWING DENTAL CT SCANNER (FIXED OR MOBILE)
824 REQUIREMENTS, IF APPLICABLE:

825 | ~~(iia)~~ The CT scanner will be used for the sole purpose of dental CT examinations.

826 | ~~(iiib)~~ The applicant shall demonstrate to the satisfaction of the Department that the person(s) (e.g.,
827 technician, dentist) operating the dental CT scanner has been appropriately trained and/or certified by one
828 of the following groups, as recognized by the Department: a dental radiology program in a certified dental
829 school, an appropriate professional society, or a dental continuing education program accredited by the
830 American Dental Association.

831 | ~~(ivc)~~ The applicant shall demonstrate to the satisfaction of the Department that the dental CT
832 examinations generated by the dental CT scanner will be interpreted by a licensed dentist(s) trained
833 and/or certified by one of the following groups, as recognized by the Department: a dental radiology
834 program in a certified dental school, an appropriate professional society, or a dental continuing education
835 program accredited by the American Dental Association.

836 | ~~(vd)~~ The applicant shall demonstrate to the satisfaction of the Department that the dentists using the
837 dental CT examinations for performing dental procedures has had the appropriate training and/or
838 experience certified by one of the following groups, as recognized by the Department: a dental radiology
839 program in a certified dental school, an appropriate professional society, or a dental continuing education
840 program accredited by the American Dental Association.

841 | ~~(vie)~~ The applicant, to assure that the dental CT scanner will be utilized by all segments of the Michigan
842 population, shall:

843 | ~~(Ai)~~ not deny dental CT scanner services to any individual based on ability to pay or source of
844 payment;

845 | ~~(Bji)~~ provide dental CT scanning services to any individual based on the clinical indications of need for
846 the service; and

847 | ~~(Cjii)~~ maintain information by payor and non-paying sources to indicate the volume of care from each
848 source provided annually. Compliance with selective contracting requirements shall not be construed as a
849 violation of this term.

850 | ~~(f)~~ The CT scanner shall be operating at least 200 CT equivalents per year for the second 12-
851 month period after beginning operation of the dental CT scanner and annually thereafter.

852 | ~~(viig)~~ The applicant shall participate in a data collection network established and administered by the
853 Department or its designee. The data may include, but is not limited to, annual budget and cost
854 information, operating schedules, through-put schedules, demographic and diagnostic information, the
855 volume of care provided to patients from all payor sources, and other data requested by the Department,
856 and approved by the Commission. The applicant shall provide the required data on a separate basis for

857 each separate and distinct site as required by the Department; in a format established by the Department;
858 and in a mutually agreed upon media. The Department may elect to verify the data through on-site review
859 of appropriate records.

860 ~~___(viih) ___~~ Equipment to be replaced shall be removed from service.

861 ~~___(ixi) ___~~ The applicant shall provide the Department with a TIMELY notice ~~stating the date the approved~~
862 ~~dental CT scanner service is placed in operation and such notice shall be submitted to the Department OF~~
863 THE PROPOSED PROJECT IMPLEMENTATION consistent with applicable statute and promulgated
864 rules.

865 ~~(xji) ___~~ An applicant shall participate in Medicaid at least 12 consecutive months within the first two
866 years of operation and continue to participate annually thereafter.

867 ~~-(2ei) The agreements and assurances required by this section shall be in the form of a certification~~
868 ~~agreed to by the applicant or its authorized agent.~~

869
870 ~~—(3) The operation of and referral of patients to the CT scanner shall be in conformance with 1978 PA~~
871 ~~368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).~~

872
873 (46) An applicant for a CT scanner used for dental research under Section 4612(1) shall agree that the
874 services provided by the CT scanner approved pursuant to Section 4612(1) shall be delivered in
875 compliance with the following terms of CON approval:

876 (a) The capital and operating costs relating to the CT scanner used for dental research pursuant to
877 Section 4612(1) shall be charged only to a specific research account(s) and not to any patient or third-
878 party payor.

879 (b) The CT scanner used for dental research approved pursuant to Section 4612(1) shall not be used
880 for any purposes other than as approved by the institutional review board unless the applicant has
881 obtained CON approval for the CT scanner pursuant to part 222 and these standards, other than Section
882 4612.

883
884 (57) An applicant approved under Section 13 shall be in compliance with the following:

885 (a) Portable CT scanner can only be used by a qualifying ~~pilot~~ program for the following purposes:

886 (i) Brain scanning of patients being treated in an adult or pediatric Intensive Care Unit (ICU).

887 (ii) Non-diagnostic, intraoperative guidance in an operating room.

888 (b) The approved applicant must provide annual reports to the Department by January 31st of each
889 year for the preceding calendar year. This requirement applies to all applicants approved under Section
890 13 ~~and begins with 2010 data which is to be reported in 2011.~~

891 (c) The following data must be reported to the Department:

892 (i) Number of adult studies (age>=18)

893 (ii) Number of pediatric studies (age<18)

894 (iii) Number of studies performed using a portable CT on the same patient while that patient is in an
895 ICU

896 ~~—(iv) Number of patients scanned on a portable CT that underwent subsequent scanning on a fixed CT~~
897 ~~within 12 hours of the portable CT scan~~

898
899 (8) AN APPLICANT APPROVED UNDER SECTION 15 SHALL BE IN COMPLIANCE WITH THE
900 FOLLOWING:

901 ___(a) THE PROPOSED SITE OFFERS THE FOLLOWING SERVICES:

902 ___(i) DIAGNOSTIC CARDIAC CATHETERIZATION; OR

903 ___(ii) INTERVENTIONAL RADIOLOGY; OR

904 ___(iii) SURGICAL SERVICES

905 ___(b) THE PROPOSED CT-ANGIO HYBRID UNIT MUST BE LOCATED IN ONE OF THE
906 FOLLOWING ROOMS:

907 ___(i) CARDIAC CATHETERIZATION LAB; OR

908 ___(ii) INTERVENTIONAL RADIOLOGY SUITE; OR

909 ___(iii) LICENSED OPERATING ROOM

910

911 | (29) The agreements and assurances required by this section shall be in the form of a certification
912 | agreed to by the applicant or its authorized agent.

913
914 | **Section 2021. Project delivery requirements AND additional terms of approval for applicants**
915 | **involving mobile CT scanners**

916
917 | Sec. 2021. (1) In addition to the provisions of Section 1920, an applicant for a mobile CT scanner
918 | shall agree that the services provided by the mobile CT scanner(s) shall be delivered in compliance with
919 | the following terms of CON approval:

920 | (a) A host facility shall submit only one CON application for a CT scanner for review at any given
921 | time.

922 | (b) A mobile CT scanner with an approved CON shall notify the Michigan Department of Community
923 | Health prior to ending service with an existing host facility.

924 | (c) A CON shall be required to add a host facility.

925 | (d) A CON shall be required to change the central service coordinator.

926 | (e) Each host facility must have at least one board certified or board eligible radiologist on its medical
927 | staff. The radiologist(s) shall be responsible for: (i) establishing patient examination and infusion
928 | protocol, and (ii) providing for the interpretation of scans performed by the mobile CT scanner.

929 | (f) Each mobile CT scanner service must have an Operations Committee with members
930 | representing each host facility, the central service coordinator, and the central service medical director.
931 | This committee shall oversee the effective and efficient use of the CT scanner, establish the normal route
932 | schedule, identify the process by which changes are to be made to the schedule, develop procedures for
933 | handling emergency situations, and review the ongoing operations of the mobile CT scanner on at least a
934 | quarterly basis.

935 | (g) The central service coordinator shall arrange for emergency repair services to be available 24
936 | hours each day for the mobile CT scanner as well as the vehicle transporting the equipment. In addition,
937 | to preserve image quality and minimize CT scanner downtime, calibration checks shall be performed on
938 | the CT scanner at least once each work day and routine maintenance services shall be provided on a
939 | regularly scheduled basis, at least once a week during hours not normally used for patient procedures.

940 | (h) Each host facility must provide a properly prepared parking pad for the mobile CT scanner of
941 | sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for
942 | patients to enter the vehicle without going outside (such as a canopy or enclosed corridor). Each host
943 | facility must also provide the capability for processing the film and maintaining the confidentiality of patient
944 | records. A communication system must be provided between the mobile vehicle and each host facility to
945 | provide for immediate notification of emergency medical situations.

946 | (i) A mobile CT scanner service shall operate under a contractual agreement that includes the
947 | provision of CT scanner services at each host facility on a regularly scheduled basis.

948 | (j) The volume of utilization at each host facility shall be reported to the Department by the central
949 | service coordinator under the terms of Section 1920(42)(ej)(xi).

950
951 | (2) The agreements and assurances required by this section shall be in the form of a certification
952 | agreed to by the applicant or its authorized agent.

953
954 | **Section 2422. Determination of CT Equivalents**

955
956 | Sec. 2422. CT equivalents shall be calculated as follows:

957 | (a) Each billable procedure for the time period specified in the applicable section(s) of these
958 | standards shall be assigned to a category set forth in Table 1.

959 | (b) The number of billable procedures for each category in the time period specified in the applicable
960 | section(s) of these standards shall be multiplied by the corresponding conversion factor in Table 1 to
961 | determine the number of CT equivalents for that category for that time period.

962 | (c) The number of CT equivalents for each category shall be summed to determine the total CT
963 | equivalents for the time period specified in the applicable section(s) of these standards.

964 (d) The conversion factor for pediatric/special needs patients does not apply to procedures performed
 965 on a dedicated pediatric CT scanner.

966

967 Table 1

968 Category	Number of 969 Billable CT Procedures		Conversion 970 Factor	=	CT 971 Equivalent
972 ADULT PATIENT					
973 Head Scans w/o Contrast (includes dental CT examinations)	_____	X	1.00	=	_____
974 Head Scans with Contrast	_____	X	1.25	=	_____
975 Head Scans w/o & w Contrast	_____	X	1.75	=	_____
976 Body Scans w/o Contrast	_____	X	1.50	=	_____
977 Body Scans with Contrast	_____	X	1.75	=	_____
978 Body Scans w/o & w Contrast	_____	X	2.75	=	_____
979 BUNDLED BODY SCAN	_____	X	3.50	=	_____
980					
981 PEDIATRIC/SPECIAL NEEDS PATIENT					
982 Head scans w/o Contrast (includes dental CT examinations)	_____	x	1.25	=	_____
983 Pediatric/Special Needs Patient					
984 Head Scans with Contrast	_____	x	1.50	=	_____
985 Pediatric/Special Needs Patient					
986 Head Scans w/o & with Contrast	_____	x	2.00	=	_____
987 Pediatric/Special Needs Patient					
988 Body Scans w/o Contrast	_____	x	1.75	=	_____
989 Pediatric/Special Needs Patient					
990 Body Scans with Contrast	_____	x	2.00	=	_____
991 Pediatric/Special Needs Patient					
992 Body Scans w/o & with Contrast	_____	x	3.00	=	_____
993 BUNDLED BODY SCAN	_____	X	4.00	=	_____
994					
995					
996 Total CT Equivalents _____					

997

998 **Section 2223. Documentation of projections**

999

1000 Sec. 2223. An applicant required to project volumes under sections 3, ~~AND 4 and 5~~ shall demonstrate
 1001 the following, as applicable:

1002 (1) An applicant required to project under Section 3 shall demonstrate that the projection is based on
 1003 historical physician referrals that resulted in an actual scan for the most recent 12-month period
 1004 immediately preceding the date of the application. Historical physician referrals will be verified with the
 1005 data maintained by the Department through its “Annual Hospital statistical survey” and/or “Annual
 1006 Freestanding Statistical Survey.”

1007

1008 (2) An applicant required to project under Section 4 shall demonstrate that the projection is based on
 1009 a combination of the following for the most recent 12-month period immediately preceding the date of the
 1010 application:

- 1011 (a) the number of dental procedures performed by the applicant, and
 1012 (b) the number of committed dental procedures performed by referring licensed dentists. Further, the
 1013 applicant and the referring licensed dentists shall substantiate the numbers through the submission of
 1014 HIPAA compliant billing records.
- 1015

1016 | ~~—(3) An applicant required to project under Section 5 shall demonstrate that the projection is based on~~
1017 | ~~historical utilization at the applicant's site for the most recent 12-month period immediately preceding the~~
1018 | ~~date of the application.~~

1019 |
1020 | (43) An applicant shall demonstrate that the projected number of referrals to be performed at the
1021 | proposed site under subsections (1) ~~and (2)~~ are from an existing CT scanner service that is in compliance
1022 | with the volume requirements applicable to that service, and will continue to be in compliance with the
1023 | volume requirements applicable to that service subsequent to the initiation of the proposed CT scanner
1024 | service by an applicant. **THIS DOES NOT INCLUDE DENTAL CT SCANNERS.** Only excess CT
1025 | equivalents equal to or greater than what is being committed pursuant to this subsection may be used to
1026 | document projections under subsection (1). In demonstrating compliance with this subsection, an
1027 | applicant shall provide each of the following:

1028 | (a) A written commitment from each referring physician that he or she will refer at least the volume of
1029 | CT scans to be transferred to the proposed CT scanner service for no less than 3 years subsequent to the
1030 | initiation of the CT scanner service proposed by an applicant.

1031 | (b) The number of referrals committed must have resulted in an actual CT scan of the patient at the
1032 | existing CT scanner service from which referral will be transferred. The committing physician must make
1033 | available HIPAA compliant audit material if needed upon Department request to verify referral sources and
1034 | outcomes. Commitments must be verified by the most recent data set maintained by the Department
1035 | through its "Annual Hospital Statistical Survey" and/or "Annual Freestanding Statistical Survey."

1036 | (c) The projected referrals are from an existing CT scanner service within a 75-mile radius for rural
1037 | and micropolitan statistical area counties or 20-mile radius for metropolitan statistical area counties.

1038 |

1039 | **Section ~~2324~~. Effect on prior CON review standards; comparative reviews**

1040 |

1041 | Sec. ~~2324~~. (1) These CON review standards supersede and replace the CON Review Standards
1042 | for Computed Tomography Scanner Services approved by the CON Commission on ~~April 30,~~
1043 | ~~2008~~DECEMBER 15, 2011 and effective on ~~June 20, 2008~~FEBRUARY 27, 2012.

1044 |

1045 | (2) Projects reviewed under these standards shall not be subject to comparative review.

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Section 24. Health Service Areas

~~Sec. 24.~~ Counties assigned to each of the health service areas are as follows:

HEALTH SERVICE AREA

COUNTIES

1—Southeast	Livingston Macomb Wayne	Monroe Oakland	St. Clair Washtenaw
2—Mid-Southern	Eaton	Clinton Ingham	Hillsdale Jackson Lenawee
3—Southwest	Barry Berrien Branch	Calhoun Cass Kalamazoo	St. Joseph Van Buren
4—West	Allegan Ionia Kent Lake	Mason Mecosta Montcalm Muskegon	Newaygo Oceana Osceola Ottawa
5—GLS	Genesee	Lapeer	Shiawassee
6—East	Arenac Bay Clare Gladwin Gratiot	Huron Iosco Isabella Midland Ogemaw	Roscommon Saginaw Sanilac Tuscola
7—Northern Lower	Alcona Alpena Antrim Benzie Charlevoix Cheboygan	Crawford Emmet Gd Traverse Kalkaska Leelanau Manistee	Missaukee Montmorency Oscoda Otsego Presque Isle Wexford
8—Upper Peninsula	Alger Baraga Chippewa Delta Dickinson	Gogebic Houghton Iron Keweenaw Luce	Mackinac Marquette Menominee Ontonagon Schoolcraft

1091 |
 1092
 1093 Rural Michigan counties are as follows:
 1094

1095	Alcona	Hillsdale	Ogemaw
1096	Alger	Huron	Ontonagon
1097	Antrim	Iosco	Osceola
1098	Arenac	Iron	Oscoda
1099	Baraga	Lake	Otsego
1100	Charlevoix	Luce	Presque Isle
1101	Cheboygan	Mackinac	Roscommon
1102	Clare	Manistee	Sanilac
1103	Crawford	Mason	Schoolcraft
1104	Emmet	Montcalm	Tuscola
1105	Gladwin	Montmorency	
1106	Gogebic	Oceana	

1107
 1108 Micropolitan statistical area Michigan counties are as follows:
 1109

1110	Allegan	Gratiot	Mecosta
1111	Alpena	Houghton	Menominee
1112	Benzie	Isabella	Midland
1113	Branch	Kalkaska	Missaukee
1114	Chippewa	Keweenaw	St. Joseph
1115	Delta	Leelanau	Shiawassee
1116	Dickinson	Lenawee	Wexford
1117	Grand Traverse	Marquette	

1118
 1119 Metropolitan statistical area Michigan counties are as follows:
 1120

1121	Barry	Ionia	Newaygo
1122	Bay	Jackson	Oakland
1123	Berrien	Kalamazoo	Ottawa
1124	Calhoun	Kent	Saginaw
1125	Cass	Lapeer	St. Clair
1126	Clinton	Livingston	Van Buren
1127	Eaton	Macomb	Washtenaw
1128	Genesee	Monroe	Wayne
1129	Ingham	Muskegon	

1130
 1131 Source:
 1132 65 F.R., p. 82238 (December 27, 2000)
 1133 Statistical Policy Office
 1134 Office of Information and Regulatory Affairs
 1135 United States Office of Management and Budget