

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. (1) These standards are requirements for the approval and OF THE INITIATION,~~
13 ~~EXPANSION, REPLACEMENT, RELOCATION, OR ACQUISITION OF CT SERVICES AND THE~~
14 ~~delivery of services for all projects approved and certificates of need issued under Part 222 of the Code~~
15 ~~which involve CT scanners.~~

16
17 ~~(2) CT scanner is a covered clinical service for purposes of PURSUANT TO Part 222 of the Code,~~
18 ~~CT IS A COVERED CLINICAL SERVICE.~~

19
20 ~~(3) The Department shall use sections 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 21, and 22,~~
21 ~~as applicable, THESE STANDARDS in applying Section 22225(1) of the Code, being Section~~
22 ~~333.22225(1) of the Michigan Compiled Laws.~~

23
24 ~~The Department shall use sections 19 and 20, as applicable, in applying AND Section 22225(2)(c) of the~~
25 ~~Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.~~

26 (4)
27

28 **Section 2. Definitions**
29

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

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

35 (b) "Billable procedure" means a CT procedure or set of procedures commonly billed as a single unit,
36 and performed in Michigan.

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

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

41 (e) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to
42 Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

43 (f) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et
44 seq. of the Michigan Compiled Laws.

45 (g) "Computed tomography" or "CT" means the use of radiographic and computer techniques to
46 produce cross-sectional images of the head or body.

47 (h) "CT equivalents" means the resulting number of units produced when the number of billable
48 procedures for each category is multiplied by its respective conversion factor tabled in Section 21.

49 (i) "CT scanner" means x-ray CT scanning systems capable of performing CT scans of the head,
50 other body parts, or full body patient procedures including Positron Emission Tomography (PET)/CT
51 scanner hybrids if used for CT only procedures. The term does not include emission-computed
52 tomographic systems utilizing internally administered single-photon gamma ray emitters, positron
53 annihilation CT systems, magnetic resonance, ultrasound computed tomographic systems, CT simulators

54 used solely for treatment planning purposes in conjunction with an MRT unit, and non-diagnostic, intra-
55 operative guidance tomographic units.

56 (j) "CT scanner services" means the con-approved utilization of a CT scanner(s) at one site in the
57 case of a fixed CT scanner service or at each host site in the case of a mobile CT scanner service.

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

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

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

64 (n) "Department" means the Michigan Department of Community Health (MDCH).

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

68 (p) "EXCESS CT EQUIVALENTS" MEANS THE NUMBER OF CT EQUIVALENTS PERFORMED
69 BY AN EXISTING CT SCANNER SERVICE IN EXCESS OF 10,000 PER FIXED CT SCANNER AND
70 4,500 PER MOBILE CT SCANNER OR EITHER AN EXISTING FIXED OR MOBILE CT SCANNER
71 SERVICE, THE NUMBER OF CT SCANNERS USED TO COMPUTE EXCESS CT EQUIVALENTS
72 SHALL INCLUDE BOTH EXISTING AND APPROVED BUT NOT YET OPERATIONAL CT SCANNERS.
73 IN THE CASE OF A CT SCANNER SERVICE THAT OPERATES OR HAS A VALID CON TO OPERATE
74 THAT HAS MORE THAN ONE FIXED CT SCANNER AT THE SAME SITE, THE TERM MEANS
75 NUMBER OF CT EQUIVALENTS IN EXCESS OF 10,000 MULTIPLIED BY THE NUMBER OF FIXED CT
76 SCANNERS AT THE SAME SITE. FOR EXAMPLE, IF A CT SCANNER SERVICE OPERATES, OR HAS
77 A VALID CON TO OPERATE, TWO FIXED CT SCANNERS AT THE SAME SITE, THE EXCESS CT
78 EQUIVALENTS IS THE NUMBER THAT IS IN EXCESS OF 20,000 (10,000 X 2) CT EQUIVALENTS. IN
79 THE CASE OF AN EXISTING MOBILE CT SCANNER SERVICE, THE TERM MEANS THE SUM OF
80 ALL CT EQUIVALENTS PERFORMED BY THE SAME MOBILE CT SCANNER SERVICE AT ALL OF
81 THE HOST SITES COMBINED THAT IS IN EXCESS OF 4,500. FOR EXAMPLE, IF A MOBILE CT
82 SCANNER SERVICE SERVES FIVE HOST SITES WITH 1 MOBILE CT SCANNER, THE TERM MEANS
83 THE SUM OF CT EQUIVALENTS FOR ALL FIVE HOST SITES COMBINED THAT IS IN EXCESS OF
84 4,500 CT EQUIVALENTS.

85 (Q) "Existing CT scanner service" means the utilization of a CON-approved and operational CT
86 scanner(s) at one site in the case of a fixed CT scanner service or at each host site in the case of a
87 mobile CT scanner service.

88 (qR) "Existing CT scanner" means a CON-approved and operational CT scanner used to provide CT
89 scanner services.

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

92 (sT) "Expand an existing CT scanner service" means the addition of one or more CT scanners at an
93 existing CT scanner service.

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

96 (V) "HEALTH SERVICE AREA" OR "HSA" MEANS THE GROUPS OF COUNTIES LISTED IN
97 SECTION 24.

98 (wW) "HIPAA" means the Health Insurance Portability and Accountability Act of 1996.

99 (xX) "Hospital-based portable CT scanner OR PORTABLE CT SCANNER" means a CT scanner
100 capable of being transported into patient care areas (i.e., ICU rooms, operating rooms, etc.) to provide
101 high-quality imaging of critically ill patients.

102 (wY) "Host site" means the site at which a mobile CT scanner is authorized to provide CT scanner
103 services.

104 (xZ) "Initiate a CT scanner service" means to begin operation of a CT scanner, whether fixed or
105 mobile, at a site that does not perform CT scans as of the date an application is submitted to the

106 Department. The term does not include the acquisition or relocation of an existing CT scanner service or
107 the renewal of a lease.

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

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

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

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

120 (eeEE) "Mobile CT scanner network" means the route (all host facilities) the mobile CT scanner is
121 authorized to serve.

122 (ddFF) "Pediatric patient" means any patient less than 18 years of age.

123 (eeGG) "Relocate a fixed CT scanner" means a change in the location of a fixed CT scanner from the
124 existing site to a different site within the relocation zone.

125 (ffHH) "Relocate an existing CT scanner service" means a change in the geographic location of an
126 existing fixed CT scanner service from an existing site to a different site.

127 (ggII) "Relocation zone," means a site that is within a 10-mile radius of a site at which an existing fixed
128 CT scanner service is located if an existing fixed CT scanner service is located in a metropolitan
129 statistical area county, or a 20-mile radius if an existing fixed CT scanner service is located in a rural or
130 micropolitan statistical area county.

131 (hhJJ) "Replace an existing CT scanner" means an equipment change of an existing CT scanner, that
132 requires a change in the radiation safety certificate, proposed by an applicant which results in that
133 applicant operating the same number of CT scanners before and after project completion, at the same
134 geographic location.

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

140 (jjLL) "Sedated patient" means a patient that meets all of the following:

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

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

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

153
154 (2) The definitions in Part 222 shall apply to these standards.

155
156 **Section 3. Requirements for approval for applicants proposing to initiate a CT scanner service**
157 **other than a dental CT scanner service or hospital-based portable CT scanner service**
158

159 Sec. 3. An applicant proposing to initiate a CT scanner service shall demonstrate each of the
160 following, as applicable:

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

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

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

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

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

174
175 **Section 4. Requirements for approval for applicants proposing to initiate a dental CT scanner**
176 **service**

177
178 Sec. 4. An applicant proposing to initiate a dental CT scanner service shall demonstrate each of the
179 following, as applicable:

180
181 (1) An applicant is proposing a fixed CT scanner service for the sole purpose of performing dental
182 CT examinations.

183
184 (2) The CT scanner generates a peak power of 5 kilowatts or less as certified by the manufacturer.

185
186 (3) An applicant proposing to initiate a dental CT scanner service, OTHER THAN AN APPLICANT
187 THAT IS PROPOSING A DENTAL CT SCANNER SERVICE IN HSA 8, shall project an operating level of
188 at least 200 dental CT examinations per year for the second 12-month period after beginning operation of
189 the dental CT scanner.

190
191 (4) The applicant has demonstrated to the satisfaction of the Department that the person(s) (e.g.,
192 technician, dentist) operating the dental CT scanner has been appropriately trained and/or certified by
193 one of the following groups, as recognized by the Department: a dental radiology program in a certified
194 dental school, an appropriate professional society, or a dental continuing education program accredited
195 by the American Dental Association.

196
197 (5) The applicant has demonstrated to the satisfaction of the Department that the dental CT
198 examinations generated by the proposed dental CT scanner will be interpreted by a licensed dentist(s)
199 trained and/or certified by one of the following groups, as recognized by the Department: a dental
200 radiology program in a certified dental school, an appropriate professional society, or a dental continuing
201 education program accredited by the American Dental Association.

202
203 **Section 5. Requirements for approval for applicants proposing to expand an existing CT scanner**
204 **service other than a dental CT scanner service or hospital-based portable CT scanner service**

205
206 Sec. 5. (1) An applicant proposing to expand an existing fixed CT scanner service shall demonstrate
207 that all of the applicant's fixed CT scanners, excluding CT scanners approved pursuant to sections 13
208 and 17, have performed an average of at least 10,000 CT equivalents per fixed CT scanner for the most
209 recent continuous 12-month period preceding the applicant's request. In computing this average, the
210 Department will divide the total number of CT equivalents performed by the applicant's total number of
211 fixed CT scanners, including both operational and approved but not operational fixed CT scanners.

212
213 (2) An applicant proposing to expand an existing fixed CT scanner service approved pursuant to
214 Section 17 shall demonstrate that all of the applicant's dedicated pediatric CT scanners have performed
215 an average of at least 3,000 CT equivalents per dedicated pediatric CT scanner for the most recent
216 continuous 12-month period preceding the applicant's request. In computing this average, the
217 Department will divide the total number of CT equivalents performed by the applicant's total number of
218 dedicated pediatric CT scanners, including both operational and approved but not operational dedicated
219 pediatric CT scanners.

220
221 (3) If an applicant proposes to expand an existing mobile CT scanner service, the applicant shall
222 demonstrate that all of the applicant's mobile CT scanners have performed an average of at least 5,500
223 CT equivalents per mobile CT scanner for the most recent continuous 12-month period preceding the
224 applicant's request. In computing this average, the Department will divide the total number of CT
225 equivalents performed by the applicant's total number of mobile CT scanners, including both operational
226 and approved but not operational mobile CT scanners.

227
228 **Section 6. Requirements for approval for applicants proposing to expand an existing dental CT**
229 **scanner service**

230
231 Sec. 6. An applicant proposing to expand an existing fixed dental CT scanner service shall
232 demonstrate that all of the applicant's dental CT scanners have performed an average of at least 300
233 dental CT examinations per fixed dental CT scanner for the most recent continuous 12-month period
234 preceding the applicant's request. In computing this average, the Department will divide the total number
235 of dental CT examinations performed by the applicant's total number of fixed dental CT scanners,
236 including both operational and approved but not operational fixed dental CT scanners.

237
238 **Section 7. Requirements for approval for applicants proposing to replace an existing CT scanner**
239 **other than a dental CT scanner or hospital-based portable CT scanner**

240
241 Sec. 7. An applicant proposing to replace an existing CT scanner shall demonstrate each of the
242 following, as applicable:

243
244 (1) An applicant, other than an applicant meeting all of the applicable requirements of subsection (a),
245 (b) or (c) below, proposing to replace an existing fixed CT scanner shall demonstrate that the fixed CT
246 scanner(s) performed at least an average of 7,500 CT equivalents per fixed CT scanner in the most
247 recent 12-month period for which the Department has verifiable data.

248 (a) A hospital proposing to replace an existing CT scanner which is the only fixed CT scanner
249 operated at that site by the hospital shall demonstrate each of the following:

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

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

253 (iii) The replacement CT scanner will be located at the same site as the CT scanner to be replaced.

254 (b) An applicant proposing to replace an existing fixed CT scanner shall be exempt once from the
255 volume requirements if the existing CT scanner demonstrates that it meets all of the following:

256 (i) The existing CT scanner has performed at least 5,000 CT equivalents in the most recent 12-
257 month period for which the Department has verifiable data.

258 (ii) The existing CT scanner is fully depreciated according to generally accepted accounting
259 principles.

260 (iii) The existing CT scanner has at one time met its minimum volume requirements.

261 (c) An applicant proposing to replace an existing fixed CT scanner on an academic medical center
262 campus, at the same site, shall be exempt once, as of the effective date of the standards MAY 5, 2008,
263 from the minimum volume requirements for replacement if the existing CT scanner is fully depreciated
264 according to generally accepted accounting principles.

265 (D) AN APPLICANT PROPOSING TO REPLACE AN EXISTING FIXED CT SCANNER HAVING A
266 CONFIGURATION OF LESS THAN 16 MULTIDETECTOR ROWS SHALL BE EXEMPT ONCE, AS OF
267 THE EFFECTIVE DATE OF THE STANDARDS, FROM THE MINIMUM VOLUME REQUIREMENTS
268 FOR REPLACEMENT IF IT MEETS BOTH OF THE FOLLOWING:

269 (I) THE PROPOSED CT SCANNER TO BE OBTAINED WILL HAVE A CONFIGURATION OF
270 SIXTEEN (16) OR MORE MULTIDETECTOR ROWS, AND

271 (ii) THE EXISTING CT SCANNER IS FULLY DEPRECIATED ACCORDING TO GENERALLY
272 ACCEPTED ACCOUNTING PRINCIPLES.

273
274 (2) An applicant proposing to replace an existing mobile CT scanner(s) shall demonstrate that the
275 mobile CT scanner(s) performed at least 3,500 CT equivalents if the applicant operates only one mobile
276 CT scanner or an average of 5,500 CT equivalents for each CT scanner if the applicant operates more
277 than one mobile CT scanner for the same mobile CT scanner network, in the most recent 12-month
278 period for which the department has verifiable data.

279
280 (3) An applicant proposing to replace an existing dedicated pediatric CT scanner(s) shall
281 demonstrate that the dedicated pediatric CT scanner(s) performed at least an average of 2,500 CT
282 equivalents per dedicated pediatric CT scanner in the most recent 12-month period for which the
283 Department has verifiable data.

284
285 (4) An applicant under this section shall demonstrate that the existing CT scanner(s) proposed to be
286 replaced is fully depreciated according to generally accepted accounting principles, or, that the existing
287 equipment clearly poses a threat to the safety of the public, or, that the proposed replacement CT
288 scanner offers technological improvements which enhance quality of care, increase efficiency, and/or
289 reduce operating costs and patient charges.

291 **Section 8. Requirements for approval for applicants proposing to replace an existing dental CT** 292 **scanner**

293
294 Sec. 8. An applicant proposing to replace an existing dental CT scanner shall demonstrate each of the
295 following:

296 (1) An applicant proposing to replace an existing fixed dental CT scanner shall demonstrate that the
297 fixed dental CT scanner(s) performed at least an average of 200 dental CT examinations per fixed dental
298 CT scanner in the most recent 12-month period for which the Department has verifiable data.

299
300 (2) An applicant under this section shall demonstrate that the existing dental CT scanner(s)
301 proposed to be replaced is fully depreciated according to generally accepted accounting principles, or,
302 that the existing equipment clearly poses a threat to the safety of the public, or that the proposed
303 replacement dental CT scanner offers technological improvements which enhance quality of care,
304 increase efficiency, and/or reduce operating costs and patient charges.

305 306 **Section 9. Requirements for approval for applicants proposing to relocate an existing CT scanner** 307 **service and/or CT scanner(s) other than an existing dental CT scanner service and/or dental CT** 308 **scanner(s) or hospital-based portable CT scanner(s)**

309
310 Sec. 9. (1) An applicant proposing to relocate an existing fixed CT scanner service shall demonstrate
311 that the proposed project meets all of the following:

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

314 (b) The proposed new site is in the relocation zone.

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

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

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

320
321 (2) An applicant proposing to relocate a fixed CT scanner(s) of an existing CT scanner service shall
322 demonstrate that the proposed project meets all of the following:

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

325 (b) The proposed new site is in the relocation zone.

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

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

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

332
333 **Section 10. Requirements for approval for applicants proposing to relocate an existing dental CT**
334 **scanner service and/or dental CT scanner(s)**

335
336 Sec. 10. (1) An applicant proposing to relocate an existing fixed dental CT scanner service shall
337 demonstrate that the proposed project meets all of the following:

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

340 (b) The proposed new site is in the relocation zone.

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

342 (d) The dental CT scanner service to be relocated performed at least an average of 200 dental CT
343 examinations per fixed dental CT scanner in the most recent 12-month period for which the Department
344 has verifiable data.

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

347
348 (2) An applicant proposing to relocate a fixed dental CT scanner(s) of an existing dental CT scanner
349 service shall demonstrate that the proposed project meets all of the following:

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

352 (b) The proposed new site is in the relocation zone.

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

354 (d) Each existing dental CT scanner at the service from which a scanner is to be relocated
355 performed at least an average of 200 dental CT examinations per fixed dental CT scanner in the most
356 recent 12-month period for which the Department has verifiable data.

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

359
360 **Section 11. Requirements for approval for applicants proposing to acquire an existing CT**
361 **scanner service or an existing CT scanner(s) other than an existing dental CT scanner service**
362 **and/or an existing dental CT scanner(s) or hospital-based portable CT scanner(s)**

363
364 Sec. 11. (1) An applicant proposing to acquire an existing fixed or mobile CT scanner service shall
365 demonstrate that a proposed project meets all of the following:

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

367 (b) For an application for the proposed first acquisition of an existing fixed or mobile CT scanner
368 service, for which a final decision has not been issued after June 4, 2004, an existing CT scanner service
369 to be acquired shall not be required to be in compliance with the volume requirement applicable to the
370 seller/lessor on the date the acquisition occurs. The CT scanner service shall be operating at the

371 applicable volume requirements set forth in Section 19 of these standards in the second 12 months after
372 the date the service is acquired, and annually thereafter.

373 (c) For any application for proposed acquisition of an existing fixed or mobile CT scanner service, an
374 applicant shall be required to demonstrate that the CT scanner service to be acquired performed at least
375 7,500 CT equivalents in the most recent 12-month period for which the Department has verifiable data.
376

377 (2) An applicant proposing to acquire an existing fixed or mobile CT scanner(s) of an existing fixed or
378 mobile CT scanner service shall demonstrate that the proposed project meets all of the following:

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

380 (b) For any application for proposed acquisition of an existing fixed or mobile CT scanner(s) of an
381 existing fixed or mobile CT scanner service, an applicant shall be required to demonstrate that the fixed
382 or mobile CT scanner(s) to be acquired performed at least 7,500 CT equivalents in the most recent 12-
383 month period for which the Department has verifiable data.
384

385 **Section 12. Requirements for approval for applicants proposing to acquire an existing dental CT** 386 **scanner service or an existing dental CT scanner(s)** 387

388 Sec. 12. (1) An applicant proposing to acquire an existing fixed dental CT scanner service shall
389 demonstrate that a proposed project meets all of the following:

390 (a) The requirements of sections 6, 8, or 10, as applicable, have been met.

391 (b) For an application for the proposed first acquisition of an existing fixed dental CT scanner
392 service, for which a final decision has not been issued after the effective date of these standards, an
393 existing dental CT scanner service to be acquired shall not be required to be in compliance with the
394 volume requirement applicable to the seller/lessor on the date the acquisition occurs. The dental CT
395 scanner service shall be operating at the applicable volume requirements set forth in Section 19 of these
396 standards in the second 12 months after the date the service is acquired, and annually thereafter.

397 (c) For any application for proposed acquisition of an existing fixed dental CT scanner service, an
398 applicant shall be required to demonstrate that the CT scanner service to be acquired performed at least
399 200 dental CT examinations in the most recent 12-month period, for which the Department has verifiable
400 data.

401 (2) An applicant proposing to acquire an existing fixed dental CT scanner(s) of an existing fixed
402 dental CT scanner service shall demonstrate that the proposed project meets all of the following:

403 (a) The requirements of sections 6, 8, or 10, as applicable, have been met.

404 (b) For any application for proposed acquisition of an existing fixed dental CT scanner(s) of an
405 existing fixed dental CT scanner service, an applicant shall be required to demonstrate that the fixed
406 dental CT scanner(s) to be acquired performed at least 200 dental CT examinations in the most recent
407 12-month period for which the Department has verifiable data.
408

409 **Section 13. Pilot program requirements for approval of a hospital-based portable CT scanner for** 410 **initiation, expansion, replacement, and acquisition** 411

412 Sec. 13. As a pilot program, an applicant proposing to initiate, expand, replace, or acquire a hospital-
413 based portable CT scanner shall demonstrate that it meets all of the following:
414

415 (1) An applicant is limited to the initiation, expansion, replacement, or acquisition of no more than two
416 hospital-based portable CT scanners.
417

418 (2) The proposed site is a hospital licensed under Part 215 of the Code.
419

420 (3) The hospital has been certified as a level I or level II trauma facility by the American College of
421 Surgeons, OR HAS PERFORMED >100 CRANIOTOMIES IN THE MOST RECENT 12- MONTH
422 PERIOD VERIFIABLE BY THE DEPARTMENT.
423

424 (4) The applicant agrees to operate the hospital-based portable CT scanner in accordance with all
425 applicable project delivery requirements set forth in Section 19 of these standards.

426
427 (5) The approved hospital-based portable CT scanner will not be subject to CT volume requirements.
428

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

431
432 (7) THE COMMISSION MAY DECIDE TO HAVE THE REQUIREMENTS OF THE PILOT
433 PROGRAM DESCRIBED IN THIS SECTION BECOME A PERMANENT PART OF THE CT SCANNER
434 SERVICES STANDARDS. IF THE COMMISSION DOES NOT TAKE ACTION TO MAKE THE PILOT
435 PROGRAM A PERMANENT PART OF THE STANDARDS, The-~~THE~~ provisions of Section 13, ~~are a~~S
436 part of a pilot program, ~~approved by the CON Commission and shall WILL~~ expire ON DECEMBER 31,
437 2016 and be of no further force and effect AFTER DECEMBER 31, 2016. ANY APPLICANT SEEKING
438 TO BE PART OF THE PILOT PROGRAM DESCRIBED IN THIS SECTION MUST SUBMIT ITS
439 APPLICATION ON OR BEFORE DECEMBER 1, 2013, ~~and THESE PROVISIONS~~ shall not be
440 applicable to any application which has not been submitted by ~~October~~ DECEMBER 1, 20082013.

441 442 **Section 14. Requirements for approval of a PET/CT hybrid for initiation, expansion, replacement,** 443 **and acquisition**

444
445 Sec. 14. An applicant proposing to initiate, expand, replace, or acquire a PET/CT hybrid shall
446 demonstrate that it meets all of the following:

447
448 (1) There is an approved PET CON for the PET/CT hybrid, and the PET/CT hybrid is in compliance
449 with all applicable project delivery requirements as set forth in the CON review standards for PET.

450
451 (2) The applicant agrees to operate the PET/CT hybrid in accordance with all applicable project
452 delivery requirements set forth in Section 19 of these standards.

453
454 (3) The approved PET/CT hybrid will not be subject to CT volume requirements.
455

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

459 460 **Section 15. Additional requirements for approval of a mobile CT scanner service**

461
462 Sec. 15. (1) An applicant proposing to initiate a mobile CT scanner service in Michigan shall
463 demonstrate that it meets all of the following:

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

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

469 (c) The requirements of sections 3, 5, or 7, as applicable, have been met.
470

471 (2) An applicant proposing to become a host facility on an existing mobile CT scanner network shall
472 demonstrate that it meets all of the following:

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

475 (b) A separate CON application has been filed for each host facility.
476

477 (3) An applicant proposing to replace a central service coordinator on an existing mobile CT scanner
478 network shall demonstrate that approval of the application will not replace the CT scanner and
479 transporting equipment unless the applicable requirements of Section 7 have been met.
480

481 **Section 16. Requirements for approval of an applicant proposing a CT scanner used for the sole**
482 **purpose of performing dental CT examinations exclusively for research**
483

484 Sec. 16. (1) An applicant proposing a CT scanner used for the sole purpose of performing dental CT
485 examinations exclusively for research shall demonstrate each of the following:

486 (a) The applicant operates a dental radiology program in a certified dental school.
487 (b) The research dental CT scanner shall operate under a protocol approved by the applicant's
488 institutional review board.

489 (c) The applicant agrees to operate the research dental CT scanner in accordance with the terms of
490 approval in Section 19(4).
491

492 (2) An applicant meeting the requirements of subsection (1) shall also demonstrate compliance with
493 the requirements of sections 4(2), 4(4) and 4(5).
494

495 **Section 17. Requirements for approval of an applicant proposing to establish dedicated pediatric**
496 **CT**
497

498 Sec. 17. (1) An applicant proposing to establish dedicated pediatric CT shall demonstrate all of the
499 following:

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

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

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

- 507 (i) pediatric radiology (at least two)
- 508 (ii) pediatric anesthesiology
- 509 (iii) pediatric cardiology
- 510 (iv) pediatric critical care
- 511 (v) pediatric gastroenterology
- 512 (vi) pediatric hematology/oncology
- 513 (vii) pediatric neurology
- 514 (viii) pediatric neurosurgery
- 515 (ix) pediatric orthopedic surgery
- 516 (x) pediatric pathology
- 517 (xi) pediatric pulmonology
- 518 (xii) pediatric surgery
- 519 (xiii) neonatology

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

- 522 (i) pediatric bone marrow transplant program
 - 523 (ii) established pediatric sedation program
 - 524 (iii) pediatric open heart program
- 525

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

528 **Section 18. Requirements for approval -- all applicants**
529

530 Sec. 18. An applicant shall provide verification of Medicaid participation. An applicant that is a new
531 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided
532 to the Department within six (6) months from the offering of services, if a CON is approved.
533

534 **Section 19. Project delivery requirements -- terms of approval for all applicants**
535

536 Sec. 19. (1) An applicant shall agree that, if approved, the services provided by the CT scanner(s)
537 shall be delivered in compliance with the following terms of CON approval:

538 (a) Compliance with these standards

539 (b) Compliance with applicable safety and operating standards

540 (c) Compliance with the following quality assurance standards:

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

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

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

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

550 For purposes of evaluating (ii)(A), the Department shall consider it prima facie evidence of a
551 satisfactory assurance mechanism as to screening and interpretation if the applicant requires the
552 screening of requests for and interpretations of CT procedures to be performed by physicians who are
553 board certified or eligible in radiology or are neurologists or other specialists trained in cross-sectional
554 imaging of a specific organ system. For purposes of evaluating (ii)(B) the Department shall consider it
555 prima facie evidence of a satisfactory assurance mechanism as to the operation of a CT scanner if the
556 applicant requires the CT scanner to be operated by a physician or by a technologist registered by the
557 American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical
558 Radiography Technologists (ARCRT). However, the applicant may submit and the Department may
559 accept other evidence that the applicant has established a mechanism to assure that the CT scanner
560 facility is appropriately and adequately staffed as to screening, interpretation, and/or operation of a CT
561 scanner.

562 (iii) The applicant shall employ or contract with a radiation physicist to review the quality and safety of
563 the operation of the CT scanner.

564 (iv) The applicant shall assure that at least one of the physicians responsible for the screening and
565 interpretation as defined in subsection (ii)(A) will be in the CT facility or available on a 24-hour basis
566 (either on-site or through telecommunication capabilities) to make the final interpretation.

567 (v) In the case of an urgent or emergency CT scan, the applicant shall assure that a physician so
568 authorized by the applicant to interpret initial scans will be on-site or available through telecommunication
569 capabilities within 1 hour following completion of the scanning procedure to render an initial interpretation
570 of the scan. A final interpretation shall be rendered by a physician so authorized under subsection (ii)(A)
571 within 24 hours.

572 (vi) The applicant shall have, within the CT scanner facility, equipment and supplies to handle clinical
573 emergencies that might occur within the CT unit, with CT facility staff trained in CPR and other
574 appropriate emergency interventions, and a physician on site in or immediately available to the CT
575 scanner at all times when patients are undergoing scans.

576 (vii) Fixed CT scanner services at each facility shall be made available 24 hours a day for emergency
577 patients.

578 (viii) The applicant shall accept referrals for CT scanner services from all appropriately licensed
579 practitioners.

580 (ix) The applicant shall establish and maintain: (a) a standing medical staff and governing body (or its
581 equivalent) requirement that provides for the medical and administrative control of the ordering and
582 utilization of CT patient procedures, and (b) a formal program of utilization review and quality assurance.
583 These responsibilities may be assigned to an existing body of the applicant, as appropriate.

584 (x) An applicant approved under Section 17 must be able to prove that all radiologists, technologists
585 and nursing staff working with CT patients have continuing education or in-service training on pediatric
586 low-dose CT. The site must also be able to provide evidence of defined low-dose pediatric CT protocols.

587 (xi) The applicant, to assure that the CT scanner will be utilized by all segments of the Michigan
588 population, shall:

589 (A) not deny CT scanner services to any individual based on ability to pay or source of payment;

590 (B) provide CT scanning services to any individual based on the clinical indications of need for the
591 service; and

592 (C) maintain information by payor and non-paying sources to indicate the volume of care from each
593 source provided annually.

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

595 (xii) The applicant shall participate in a data collection network established and administered by the
596 Department or its designee. The data may include, but is not limited to, annual budget and cost
597 information, operating schedules, through-put schedules, demographic and diagnostic information, the
598 volume of care provided to patients from all payor sources, and other data requested by the Department,
599 and approved by the Commission. The applicant shall provide the required data on a separate basis for
600 each separate and distinct site as required by the Department; in a format established by the Department;
601 and in a mutually agreed upon media. The Department may elect to verify the data through on-site
602 review of appropriate records.

603 (xiii) Equipment to be replaced shall be removed from service.

604 (xiv) The applicant shall provide the Department with a notice stating the date the approved CT
605 scanner service is placed in operation and such notice shall be submitted to the Department consistent
606 with applicable statute and promulgated rules.

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

609 (d) An applicant approved under Section 4 shall not be required to be in compliance with subsection
610 (c) but shall be in compliance with the following quality assurance standards:

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

613 (ii) The CT scanner will be used for the sole purpose of dental CT examinations.

614 (iii) The applicant shall demonstrate to the satisfaction of the Department that the person(s) (e.g.,
615 technician, dentist) operating the dental CT scanner has been appropriately trained and/or certified by
616 one of the following groups, as recognized by the Department: a dental radiology program in a certified
617 dental school, an appropriate professional society, or a dental continuing education program accredited
618 by the American Dental Association.

619 (iv) The applicant shall demonstrate to the satisfaction of the Department that the dental CT
620 examinations generated by the dental CT scanner will be interpreted by a licensed dentist(s) trained
621 and/or certified by one of the following groups, as recognized by the Department: a dental radiology
622 program in a certified dental school, an appropriate professional society, or a dental continuing education
623 program accredited by the American Dental Association.

624 (v) The applicant shall demonstrate to the satisfaction of the Department that the dentists using the
625 dental CT examinations for performing dental procedures has had the appropriate training and/or
626 experience certified by one of the following groups, as recognized by the Department: a dental radiology
627 program in a certified dental school, an appropriate professional society, or a dental continuing education
628 program accredited by the American Dental Association.

629 (vi) The applicant, to assure that the dental CT scanner will be utilized by all segments of the
630 Michigan population, shall:

631 (A) not deny dental CT scanner services to any individual based on ability to pay or source of
632 payment;

633 (B) provide dental CT scanning services to any individual based on the clinical indications of need for
634 the service; and

635 (C) maintain information by payor and non-paying sources to indicate the volume of care from each
636 source provided annually. Compliance with selective contracting requirements shall not be construed as
637 a violation of this term.

638 (vii) The applicant shall participate in a data collection network established and administered by the
639 Department or its designee. The data may include, but is not limited to, annual budget and cost
640 information, operating schedules, through-put schedules, demographic and diagnostic information, the
641 volume of care provided to patients from all payor sources, and other data requested by the Department,
642 and approved by the Commission. The applicant shall provide the required data on a separate basis for
643 each separate and distinct site as required by the Department; in a format established by the Department;
644 and in a mutually agreed upon media. The Department may elect to verify the data through on-site
645 review of appropriate records.

646 (viii) Equipment to be replaced shall be removed from service.

647 (ix) The applicant shall provide the Department with a notice stating the date the approved dental CT
648 scanner service is placed in operation and such notice shall be submitted to the Department consistent
649 with applicable statute and promulgated rules.

650 (x) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years
651 of operation and continue to participate annually thereafter.

652

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

655

656 (3) The operation of and referral of patients to the CT scanner shall be in conformance with 1978 PA
657 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

658

659 (4) An applicant for a CT scanner used for dental research under Section 16(1) shall agree that the
660 services provided by the CT scanner approved pursuant to Section 16(1) shall be delivered in compliance
661 with the following terms of CON approval:

662 (a) The capital and operating costs relating to the CT scanner used for dental research pursuant to
663 Section 16(1) shall be charged only to a specific research account(s) and not to any patient or third-party
664 payor.

665 (b) The CT scanner used for dental research approved pursuant to Section 16(1) shall not be used
666 for any purposes other than as approved by the institutional review board unless the applicant has
667 obtained CON approval for the CT scanner pursuant to part 222 and these standards, other than Section
668 16.

669

670 (5) An applicant approved under Section 13 shall be in compliance with the following:

671 (A) PORTABLE CT SCANNER CAN ONLY BE USED BY A QUALIFYING PILOT PROGRAM FOR
672 THE FOLLOWING PURPOSES:

673 (I) BRAIN SCANNING OF PATIENTS BEING TREATED IN AN ADULT OR PEDIATRIC
674 INTENSIVE CARE UNIT (ICU).

675 (II) NON-DIAGNOSTIC, INTRAOPERATIVE GUIDANCE IN AN OPERATING ROOM.

676 (a) The APPROVED applicant agrees to MUST provide quarterly ANNUAL reports to the Department
677 within one month following the end of each calendar quarter, starting with the quarter the applicant
678 initiates use of the hospital-based portable CT scanner BY JANUARY 31ST OF EACH YEAR FOR THE
679 PRECEDING CALENDAR YEAR;-. THIS REQUIREMENT APPLIES TO ALL APPLICANTS APPROVED
680 UNDER SECTION 13 AND BEGINS WITH 2010 DATA WHICH IS TO BE REPORTED IN 2011.

681 (C) THE FOLLOWING DATA MUST BE REPORTED TO THE DEPARTMENT:

682 (b) The Department will develop a questionnaire to be used by the applicant for the quarterly report.
683 This questionnaire, at a minimum, will include information regarding the utilization, cost, and benefit for
684 patient care as compared to the use of full-body CT scanners. NUMBER OF ADULT STUDIES
685 (AGE >= 18)

- 686 (II) NUMBER OF PEDIATRIC STUDIES (AGE<18)
687 (III) NUMBER OF STUDIES PERFORMED USING A PORTABLE CT ON THE SAME PATIENT
688 WHILE THAT PATIENT IS IN AN ICU
689 (IV) NUMBER OF PATIENTS SCANNED ON A PORTABLE CT THAT UNDERWENT SUBSEQUENT
690 SCANNING ON A FIXED CT WITHIN 12 HOURS OF THE PORTABLE CT SCAN
691 (c) The Department will summarize the information from the quarterly reports and provide an
692 assessment to the Commission prior to the March 2010 Commission meeting. The Commission may
693 request updates on the status of the pilot program at its discretion.

694
695 **Section 20. Project delivery requirements -- additional terms of approval for applicants involving**
696 **mobile CT scanners**

697
698 Sec. 20. (1) In addition to the provisions of Section 19, an applicant for a mobile CT scanner shall
699 agree that the services provided by the mobile CT scanner(s) shall be delivered in compliance with the
700 following terms of CON approval:

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

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

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

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

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

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

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

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

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

729 (j) The volume of utilization at each host facility shall be reported to the Department by the central
730 service coordinator under the terms of Section 19(1)(c)(xi).

731
732 (2) The agreements and assurances required by this section shall be in the form of a certification
733 agreed to by the applicant or its authorized agent.

734
735 **Section 21. Determination of CT Equivalents**

736
737 Sec. 21. CT equivalents shall be calculated as follows:

- 738 (a) Each billable procedure for the time period specified in the applicable section(s) of these
 739 standards shall be assigned to a category set forth in Table 1.
 740 (b) The number of billable procedures for each category in the time period specified in the applicable
 741 section(s) of these standards shall be multiplied by the corresponding conversion factor in Table 1 to
 742 determine the number of CT equivalents for that category for that time period.
 743 (c) The number of CT equivalents for each category shall be summed to determine the total CT
 744 equivalents for the time period specified in the applicable section(s) of these standards.
 745 (d) The conversion factor for pediatric/special needs patients does not apply to procedures
 746 performed on a dedicated pediatric CT scanner.

747

748 Table 1

749 Category	Number of 750 Billable CT Procedures		Conversion 751 Factor	=	CT 752 Equivalents
753 Head Scans w/o Contrast (includes dental CT examinations)	_____	X	1.00	=	_____
754 Head Scans with Contrast	_____	X	1.25	=	_____
755 Head Scans w/o & w Contrast	_____	X	1.75	=	_____
756 Body Scans w/o Contrast	_____	X	1.50	=	_____
757 Body Scans with Contrast	_____	X	1.75	=	_____
758 Body Scans w/o & w Contrast	_____	X	2.75	=	_____
759					
760 Pediatric/Special Needs Patient					
761 Head scans w/o Contrast (includes dental CT examinations)	_____	x	1.25	=	_____
762 Pediatric/Special Needs Patient					
763 Head Scans with Contrast	_____	x	1.50	=	_____
764 Pediatric/Special Needs Patient					
765 Head Scans w/o & with Contrast	_____	x	2.00	=	_____
766 Pediatric/Special Needs Patient					
767 Body Scans w/o Contrast	_____	x	1.75	=	_____
768 Pediatric/Special Needs Patient					
769 Body Scans with Contrast	_____	x	2.00	=	_____
770 Pediatric/Special Needs Patient					
771 Body Scans w/o & with Contrast	_____	x	3.00	=	_____
772					
773					
774 TOTAL CT EQUIVALENTS					_____

775

776 **Section 22. Documentation of projections**

777

778 Sec. 22. An applicant required to project volumes under sections 3, 4 and 5 shall demonstrate the
 779 following, as applicable:

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

785

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

- 789 (a) the number of dental procedures performed by the applicant, and

790 (b) the number of committed dental procedures performed by referring licensed dentists. Further,
791 the applicant and the referring licensed dentists shall substantiate the numbers through the submission of
792 HIPAA compliant billing records.
793

794 (3) An applicant required to project under Section 5 shall demonstrate that the projection is based on
795 historical utilization at the applicant's site for the most recent 12-month period immediately preceding the
796 date of the application.
797

798 (4) An applicant shall demonstrate that the projected number of referrals to be performed at the
799 proposed site under subsections (1) and (2) are from an existing CT scanner service that is in compliance
800 with the volume requirements applicable to that service, and will continue to be in compliance with the
801 volume requirements applicable to that service subsequent to the initiation of the proposed CT scanner
802 service by an applicant. ONLY EXCESS CT EQUIVALENTS EQUAL TO OR GREATER THAN WHAT IS
803 BEING COMMITTED PURSUANT TO THIS SUBSECTION MAY BE USED TO DOCUMENT
804 PROJECTIONS UNDER SUBSECTION (1). In demonstrating compliance with this subsection, an
805 applicant shall provide each of the following:

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

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

814 (c) The projected referrals are from an existing CT scanner service within a 75-mile radius for rural
815 and micropolitan statistical area counties or 20-mile radius for metropolitan statistical area counties.
816

817 **Section 23. Effect on prior CON review standards; comparative reviews**

818
819 Sec. 23. (1) These CON review standards supersede and replace the CON Review Standards for
820 Computed Tomography Scanner Services approved by the CON Commission on ~~March 11~~APRIL 30,
821 2008 and effective ~~May 5~~JUNE 20, 2008.
822

823 (2) Projects reviewed under these standards shall not be subject to comparative review.
824

825 SECTION 24. HEALTH SERVICE AREAS

826
827 SEC. 24. COUNTIES ASSIGNED TO EACH OF THE HEALTH SERVICE AREAS ARE AS
828 FOLLOWS:

<u>HSA</u>	<u>COUNTIES</u>		
<u>1 - SOUTHEAST</u>	<u>LIVINGSTON</u>	<u>MONROE</u>	<u>ST. CLAIR</u>
	<u>MACOMB</u>	<u>OAKLAND</u>	<u>WASHTENAW</u>
	<u>WAYNE</u>		
<u>2 - MID-SOUTHERN</u>	<u>CLINTON</u>	<u>HILLSDALE</u>	<u>JACKSON</u>
	<u>EATON</u>	<u>INGHAM</u>	<u>LENAWEE</u>
<u>3 - SOUTHWEST</u>	<u>BARRY</u>	<u>CALHOUN</u>	<u>ST. JOSEPH</u>
	<u>BERRIEN</u>	<u>CASS</u>	<u>VAN BUREN</u>
	<u>BRANCH</u>	<u>KALAMAZOO</u>	
<u>4 - WEST</u>	<u>ALLEGAN</u>	<u>MASON</u>	<u>NEWAYGO</u>

843	IONIA	MECOSTA	OCEANA
844	KENT	MONTCALM	OSCEOLA
845	LAKE	MUSKEGON	OTTAWA
846			

847	5 - GLS	GENESEE	LAPEER	SHIAWASSEE
848				
849	6 - EAST	ARENAC	HURON	ROSCOMMON
850		BAY	IOSCO	SAGINAW
851		CLARE	ISABELLA	SANILAC
852		GLADWIN	MIDLAND	TUSCOLA
853		GRATIOT	OGEMAW	
854				
855	7 - NORTHERN LOWER	ALCONA	CRAWFORD	MISSAUKEE
856		ALPENA	EMMET	MONTMORENCY
857		ANTRIM	GD TRAVERSE	OSCODA
858		BENZIE	KALKASKA	OTSEGO
859		CHARLEVOIX	LEELANAU	PRESQUE ISLE
860		CHEBOYGAN	MANISTEE	WEXFORD
861				
862	8 - UPPER PENINSULA	ALGER	GOGEBIC	MACKINAC
863		BARAGA	HOUGHTON	MARQUETTE
864		CHIPPEWA	IRON	MENOMINEE
865		DELTA	KEWEENAW	ONTONAGON
866		DICKINSON	LUCE	SCHOOLCRAFT

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**CON REVIEW STANDARDS
FOR CT SCANNER 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