

1 MICHIGAN DEPARTMENT OF ~~COMMUNITY HEALTH~~ AND HUMAN SERVICES

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, or
13 acquisition of CT services and the delivery of services under Part 222 of the Code. Pursuant to Part 222
14 of the Code, CT is a covered clinical service. The Department shall use these standards in applying
15 Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section
16 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 and performed in Michigan.

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

28 (d) "Bundled body scan" means two or more body scans billed as one CT procedure.

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

31 (f) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to
32 Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

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

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

37 (i) "CT-angio hybrid unit" means an integrated system comprised of both CT and angiography
38 equipment sited in the same room that is designed specifically for interventional radiology or cardiac
39 procedures. The CT unit is a guidance mechanism and is intended to be used as an adjunct to the
40 procedure. The CT unit shall not be used for diagnostic studies unless the patient is currently undergoing
41 a CT-angio hybrid procedure and is in need of a secondary diagnostic study.

42 (j) "CT equivalents" means the resulting number of units produced when the number of billable
43 procedures for each category is multiplied by its respective conversion factor tabled in Section 22.

44 (k) "CT scanner" means x-ray CT scanning systems capable of performing CT scans of the head,
45 other body parts, or full body patient procedures including Positron Emission Tomography (PET)/CT
46 scanner hybrids if used for CT only procedures. The term does not include emission-computed
47 tomographic systems utilizing internally administered single-photon gamma ray emitters, positron
48 annihilation CT systems, magnetic resonance, ultrasound computed tomographic systems, CT simulators
49 used solely for treatment planning purposes in conjunction with an MRT unit, ~~and~~ non-diagnostic, intra-
50 operative guidance tomographic units, AND DENTAL CT SCANNERS THAT generate a peak power of 5
51 kilowatts or less as certified by the manufacturer, AND specifically designed to generate CT images to
52 facilitate dental procedures BY A LICENSED DENTIST UNDER THE PRACTICE OF DENTISTRY.

53 (l) "CT scanner services" means the CON-approved utilization of a CT scanner(s) at one site in the
54 case of a fixed CT scanner service or at each host site in the case of a mobile CT scanner service.

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

57 ~~—(n) "Dental CT examinations" means use of a CT scanner specially designed to generate CT images
58 to facilitate dental procedures.~~

59 ~~—(o) "Dental procedures" means dental implants, wisdom teeth surgical procedures, mandibular or
60 maxillary surgical procedures, or temporal mandibular joint evaluations.~~

61 (p) "Department" means the Michigan Department of ~~Community Health~~ AND HUMAN SERVICES
62 (MDCHHS).

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

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

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

82 (t) "Existing CT scanner" means a CON-approved and operational CT scanner used to provide CT
83 scanner services.

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

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

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

90 (x) "Health Service Area" or "HSA" means the groups of counties listed in Appendix A.

91 (y) "HIPAA" means the Health Insurance Portability and Accountability Act of 1996.

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

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

97 (bb) "Initiate a CT scanner service" means to begin operation of a CT scanner, whether fixed or
98 mobile, at a site that does not perform CT scans as of the date an application is submitted to the
99 Department. The term does not include the acquisition or replacement of an existing CT scanner service
100 at the existing site or to a different site or the renewal of a lease.

101 (cc) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396 to 1396w-5.

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

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

- 106 (ff) "Pediatric patient" means any patient less than 18 years of age.
- 107 (gg) "Replace an existing CT scanner" means an equipment change of an existing CT scanner, that
108 requires a change in the radiation safety certificate, proposed by an applicant which results in that
109 applicant operating the same number of CT scanners before and after project completion, at the same
110 geographic location. The term also includes relocating an existing CT scanner or CT scanner service
111 from an existing site to a different site.
- 112 (hh) "Sedated patient" means a patient that meets all of the following:
- 113 (i) Patient undergoes procedural sedation and whose level of consciousness is either moderate
114 sedation or a higher level of sedation, as defined by the American Association of Anesthesiologists, the
115 American Academy of Pediatrics, the Joint Commission on the Accreditation of Health Care
116 Organizations, or an equivalent definition.
- 117 (ii) Who requires observation by personnel, other than technical employees routinely assigned to the
118 CT unit, who are trained in cardiopulmonary resuscitation (CPR) and pediatric advanced life support
119 (PALS).
- 120 (ii) "Special needs patient" means a non-sedated patient, either pediatric or adult, with any of the
121 following conditions: down syndrome, autism, attention deficit hyperactivity disorder (ADHD),
122 developmental delay, malformation syndromes, hunter's syndrome, multi-system disorders, psychiatric
123 disorders, and other conditions that make the patient unable to comply with the positional requirements of
124 the exam.
- 125
- 126 (2) Terms defined in the Code have the same meanings when used in these standards.
- 127

128 **Section 3. Requirements for approval for applicants proposing to initiate a CT scanner service**

129

130 Sec. 3. An applicant proposing to initiate a CT scanner service, other than a ~~dental CT scanner service~~
131 ~~or a~~ hospital-based portable CT scanner service, shall demonstrate the following, as applicable:

132

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

- 135 (a) The proposed site is a hospital licensed under Part 215 of the Code.
- 136 (b) The hospital operates an emergency room that provides 24-hour emergency care services as
137 authorized by the local medical control authority to receive ambulance runs.
- 138

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

142

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

146

147 (4) An applicant proposing to initiate CT scanner services as an existing host site on a different
148 mobile CT scanner service shall demonstrate the following:

- 149 (a) The applicant provides a proposed route schedule.
- 150 (b) The applicant provides a draft contract for services between the proposed host site and central
151 service coordinator.
- 152

153 ~~Section 4. Requirements for approval for applicants proposing to initiate a dental CT scanner~~ 154 ~~service~~

155

156 ~~—Sec. 4. An applicant proposing to initiate a fixed or mobile dental CT scanner service shall demonstrate~~
157 ~~each of the following, as applicable:~~

158

- 159 ~~—(1) An applicant is proposing a dental CT scanner service for the sole purpose of performing dental~~
160 ~~CT examinations.~~
- 161
- 162 ~~—(2) The CT scanner generates a peak power of 5 kilowatts or less as certified by the manufacturer.~~
- 163
- 164 ~~—(3) An applicant proposing to initiate a dental CT scanner service, other than an applicant that is~~
165 ~~proposing a dental CT scanner service in HSA 8, shall project an operating level of at least 200 dental CT~~
166 ~~examinations per year for the second 12-month period after beginning operation of the dental CT scanner.~~
- 167
- 168 ~~—(4) The applicant has demonstrated to the satisfaction of the Department that the person(s) (e.g.,~~
169 ~~technician, dentist) operating the dental CT scanner has been appropriately trained and/or certified by one~~
170 ~~of the following groups, as recognized by the Department: a dental radiology program in a certified dental~~
171 ~~school, an appropriate professional society, or a dental continuing education program accredited by the~~
172 ~~American Dental Association.~~
- 173
- 174 ~~—(5) The applicant has demonstrated to the satisfaction of the Department that the dental CT~~
175 ~~examinations generated by the proposed dental CT scanner will be interpreted by a licensed dentist(s)~~
176 ~~trained and/or certified by one of the following groups, as recognized by the Department: a dental~~
177 ~~radiology program in a certified dental school, an appropriate professional society, or a dental continuing~~
178 ~~education program accredited by the American Dental Association.~~
- 179
- 180 ~~—(6) An applicant proposing to initiate mobile dental CT scanner services as an existing host site on a~~
181 ~~different mobile dental CT scanner service shall demonstrate the following:~~
- 182 ~~—(a) The applicant provides a proposed route schedule.~~
- 183 ~~—(b) The applicant provides a draft contract for services between the proposed host site and central~~
184 ~~service coordinator.~~

185

186 **Section 5. Requirements for approval for applicants proposing to expand an existing CT scanner**
187 **service**

188

189 Sec. 5. An applicant proposing to expand an existing CT scanner service, other than a ~~dental CT~~
190 ~~scanner service or a~~ hospital-based portable CT scanner service, shall demonstrate the following, as
191 applicable:

192

193 (1) An applicant proposing to expand an existing fixed CT scanner service shall demonstrate that all of
194 the applicant's fixed CT scanners, excluding CT scanners approved pursuant to sections 6, 13, 14, and
195 18, have performed an average of at least 10,000 CT equivalents per fixed CT scanner for the most
196 recent continuous 12-month period preceding the applicant's request. In computing this average, the
197 Department will divide the total number of CT equivalents performed by the applicant's total number of
198 fixed CT scanners, including both operational and approved but not operational fixed CT scanners.

199

200 (2) An applicant proposing to expand an existing fixed CT scanner service approved pursuant to
201 Section 18 shall demonstrate that all of the applicant's dedicated pediatric CT scanners have performed
202 an average of at least 3,000 CT equivalents per dedicated pediatric CT scanner for the most recent
203 continuous 12-month period preceding the applicant's request. In computing this average, the
204 Department will divide the total number of CT equivalents performed by the applicant's total number of
205 dedicated pediatric CT scanners, including both operational and approved but not operational dedicated
206 pediatric CT scanners.

207

208 (3) If an applicant proposes to expand an existing mobile CT scanner service, the applicant shall
209 demonstrate that all of the applicant's mobile CT scanners have performed an average of at least 5,500
210 CT equivalents per mobile CT scanner for the most recent continuous 12-month period preceding the
211 applicant's request. In computing this average, the Department will divide the total number of CT

212 equivalents performed by the applicant's total number of mobile CT scanners, including both operational
213 and approved but not operational mobile CT scanners.

214
215 **Section 6. Requirements for approval for applicants proposing to expand an existing dental CT**
216 **scanner service**

217
218 ~~— Sec. 6. An applicant proposing to expand an existing fixed or mobile dental CT scanner service shall~~
219 ~~demonstrate that all of the applicant's dental CT scanners have performed an average of at least 300~~
220 ~~dental CT examinations per fixed or mobile dental CT scanner for the most recent continuous 12-month~~
221 ~~period preceding the applicant's request. In computing this average, the Department will divide the total~~
222 ~~number of dental CT examinations performed by the applicant's total number of fixed or mobile dental CT~~
223 ~~scanners, including both operational and approved but not operational fixed or mobile dental CT scanners.~~
224

225 **Section 7. Requirements for approval for applicants proposing to replace an existing CT scanner**

226
227 Sec. 7. An applicant proposing to replace an existing CT scanner or service, other than a ~~dental CT~~
228 ~~scanner service or a~~ hospital-based portable CT scanner service, shall demonstrate the following, as
229 applicable:

230
231 (1) An applicant proposing to replace an existing fixed, mobile, or dedicated pediatric CT scanner
232 shall demonstrate all of the following:

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

234 (b) The existing CT scanner(s) proposed to be replaced is fully depreciated according to generally
235 accepted accounting principles, or, that the existing equipment clearly poses a threat to the safety of the
236 public, or, that the proposed replacement CT scanner offers technological improvements which enhance
237 quality of care, increase efficiency, and/or reduce operating costs and patient charges.

238
239 (2) An applicant proposing to replace an existing fixed CT scanner service to a different site shall
240 demonstrate that the proposed project meets all of the following:

241 (a) The existing fixed CT scanner service to be replaced has been in operation for at least 36 months
242 as of the date an application is submitted to the Department UNLESS THE APPLICANT MEETS THE
243 REQUIREMENT IN SUBSECTION (c)(ii) OR (iii).

244 (b) The proposed new site is within a 10-mile radius of a site at which an existing fixed CT scanner
245 service is located if an existing fixed CT scanner service is located in a metropolitan statistical area
246 county, or a 20-mile radius if an existing fixed CT scanner service is located in a rural or micropolitan
247 statistical area county.

248 (c) The CT scanner service to be replaced performed at least an average of 7,500 CT equivalents
249 per fixed scanner in the most recent 12-month period for which the Department has verifiable data,
250 UNLESS ONE OF THE FOLLOWING REQUIRMENTS ARE MET:

251 (i) except for a An applicant ~~that~~ meets all of the requirements of Section 3(1).

252 (ii) THE OWNER OF THE BUILDING WHERE THE SITE IS LOCATED HAS INCURRED A FILING
253 FOR BANKRUPTCY UNDER CHAPTER SEVEN (7) WITHIN THE LAST THREE YEARS;

254 (iii) THE OWNERSHIP OF THE BUILDING WHERE THE SITE IS LOCATED HAS CHANGED
255 WITHIN 24 MONTHS OF THE DATE OF THE SERVICE BEING OPERATIONAL; OR

256 (iv) THE CT SERVICE BEING REPLACED IS PART OF THE REPLACEMENT OF AN ENTIRE
257 HOSPITAL TO A NEW GEOGRAPHIC SITE AND HAS ONLY ONE (1) CT UNIT.

258 (d) The applicant agrees to operate the CT scanner service in accordance with all applicable project
259 delivery requirements set forth in Section 20 of these standards.

260
261 (3) An applicant proposing to replace a fixed CT scanner(s) of an existing CT scanner service to a
262 different site shall demonstrate that the proposed project meets all of the following:

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

265 (b) The proposed new site is within a 10-mile radius of a site at which an existing fixed CT scanner
266 service is located if an existing fixed CT scanner service is located in a metropolitan statistical area
267 county, or a 20-mile radius if an existing fixed CT scanner service is located in a rural or micropolitan
268 statistical area county..

269 (c) Each existing CT scanner at the service from which a scanner is to be replaced performed at
270 least an average of 7,500 CT equivalents per fixed scanner in the most recent 12-month period for which
271 the Department has verifiable data.

272 (d) The applicant agrees to operate the CT scanner(s) at the proposed site in accordance with all
273 applicable project delivery requirements set forth in Section 20 of these standards.

274 (e) For volume purposes, the new site shall remain associated with the existing CT service for a
275 minimum of three years.

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

278 ~~—Sec. 8. An applicant proposing to replace an existing dental CT scanner or service shall demonstrate~~
279 ~~the following, as applicable:~~

280 ~~—(1) An applicant proposing to replace an existing fixed or mobile dental CT scanner shall demonstrate~~
281 ~~all of the following:~~

282 ~~—(a) The replacement dental CT scanner will be located at the same site as the dental CT scanner to~~
283 ~~be replaced.~~

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

289 ~~—(2) An applicant proposing to replace an existing fixed dental CT scanner service to a different site~~
290 ~~shall demonstrate that the proposed project meets all of the following:~~

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

293 ~~—(b) The proposed new site is within a 10-mile radius of a site at which an existing fixed dental CT~~
294 ~~scanner service is located if an existing fixed dental CT scanner service is located in a metropolitan~~
295 ~~statistical area county, or a 20-mile radius if an existing fixed dental CT scanner service is located in a~~
296 ~~rural or micropolitan statistical area county.~~

297 ~~—(c) The dental CT scanner service to be replaced performed at least an average of 200 dental CT~~
298 ~~examinations per fixed dental CT scanner in the most recent 12-month period for which the Department~~
299 ~~has verifiable data.~~

300 ~~—(d) The applicant agrees to operate the dental CT scanner service in accordance with all applicable~~
301 ~~project delivery requirements set forth in Section 20 of these standards.~~

302 ~~—(3) An applicant proposing to replace a fixed dental CT scanner(s) of an existing dental CT scanner~~
303 ~~service to a different site shall demonstrate that the proposed project meets all of the following:~~

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

306 ~~—(b) For volume purposes, the new site shall remain associated with the existing CT service for a~~
307 ~~minimum of three years.~~

308 ~~—(c) The proposed new site is within a 10-mile radius of a site at which an existing fixed dental CT~~
309 ~~scanner service is located if an existing fixed dental CT scanner service is located in a metropolitan~~
310 ~~statistical area county, or a 20-mile radius if an existing fixed dental CT scanner service is located in a~~
311 ~~rural or micropolitan statistical area county.~~

317 ~~—(d) Each existing dental CT scanner at the service from which a scanner is to be replaced performed~~
318 ~~at least an average of 200 dental CT examinations per fixed dental CT scanner in the most recent 12-~~
319 ~~month period for which the Department has verifiable data.~~

320 ~~—(e) The applicant agrees to operate the dental CT scanner(s) at the proposed site in accordance with~~
321 ~~all applicable project delivery requirements set forth in Section 20 of these standards.~~

322 **Section 9. Requirements for approval for applicants proposing to acquire an existing CT scanner** 323 **service or an existing CT scanner(s)**

324
325
326 Sec. 9. An applicant proposing to acquire an existing fixed or mobile CT scanner service, other than a
327 ~~dental CT scanner service or a~~ hospital-based portable CT scanner service, shall demonstrate the
328 following, as applicable:
329

330 (1) ~~An THE applicant proposing to acquire an existing fixed or mobile CT scanner service, shall not be~~
331 ~~required to be in compliance with the volume requirement applicable to the seller/lessor on the date the~~
332 ~~acquisition occurs demonstrate that a~~ IF THE proposed project meets ~~all ONE~~ of the following:

333 (a) ~~For an application for the proposed~~ IT IS THE first acquisition of ~~an THE~~ existing fixed or mobile
334 CT scanner service, for which a final decision has not been issued after June 4, 2004, ~~an existing CT~~
335 ~~scanner service to be acquired shall not be required to be in compliance with the volume requirement~~
336 ~~applicable to the seller/lessor on the date the acquisition occurs. The CT scanner service shall be~~
337 ~~operating at the applicable volume requirements set forth in Section 20 of these standards in the second~~
338 ~~12 months after the date the service is acquired, and annually thereafter.~~

339 ~~(b) THE EXISTING FIXED OR MOBILE CT SCANNER SERVICE IS OWNED BY, IS UNDER~~
340 ~~COMMON CONTROL OF, OR HAS A COMMON PARENT AS THE APPLICANT, AND THE CT~~
341 ~~SCANNER SERVICE SHALL REMAIN AT THE SAME SITE.~~

342
343 (b2) For any application for proposed acquisition of an existing fixed or mobile CT scanner service, an
344 applicant shall be required to demonstrate the following, as applicable:

345 (i) The fixed CT scanner service to be acquired performed at least 7,500 CT equivalents per fixed
346 CT scanner in the most recent 12-month period for which the Department has verifiable data, unless an
347 applicant meets all of the requirements of Section 3(1). ~~OR MEETS THE REQUIREMENTS OF SECTION~~
348 ~~9(1)(b).~~

349 (ii) The mobile CT scanner service to be acquired performed at least 3,500 CT equivalents per
350 mobile CT scanner in the most recent 12-month period for which the Department has verifiable data,
351 ~~UNLESS AN APPLICANT MEETS THE REQUIREMENTS OF SECTION 9(1)(b).~~

352
353 (23) An applicant proposing to acquire an existing fixed or mobile CT scanner(s) of an existing fixed or
354 mobile CT scanner service shall demonstrate that the proposed project meets the following:

355 (a) For any application for proposed acquisition of an existing fixed or mobile CT scanner(s) of an
356 existing fixed or mobile CT scanner service, an applicant shall be required to demonstrate the following,
357 as applicable:

358 (i) The fixed CT scanner(s) to be acquired performed at least 7,500 CT equivalents per fixed CT
359 scanner in the most recent 12-month period for which the department has verifiable data.

360 (ii) The mobile CT scanner(s) to be acquired performed at least 3,500 CT equivalents per mobile CT
361 scanner in the most recent 12-month period for which the Department has verifiable data.

362
363 ~~(4) The CT scanner service shall be operating at the applicable volume requirements set forth in~~
364 ~~Section 20 of these standards in the second 12 months after the date the service is acquired, and annually~~
365 ~~thereafter.~~

366 **Section 10. Requirements for approval for applicants proposing to acquire an existing dental CT** 367 **scanner service or an existing dental CT scanner(s)**

370 ~~—Sec. 10. (1) An applicant proposing to acquire an existing fixed or mobile dental CT scanner service~~
371 ~~shall demonstrate that a proposed project meets all of the following:~~

372 ~~—(a) For an application for the proposed first acquisition of an existing fixed or mobile dental CT~~
373 ~~scanner service, for which a final decision has not been issued after the effective date of these standards,~~
374 ~~an existing dental CT scanner service to be acquired shall not be required to be in compliance with the~~
375 ~~volume requirement applicable to the seller/lessor on the date the acquisition occurs. The dental CT~~
376 ~~scanner service shall be operating at the applicable volume requirements set forth in Section 20 of these~~
377 ~~standards in the second 12 months after the date the service is acquired, and annually thereafter.~~

378 ~~—(b) For any application for proposed acquisition of an existing fixed or mobile dental CT scanner~~
379 ~~service, an applicant shall be required to demonstrate that the CT scanner service to be acquired~~
380 ~~performed at least 200 dental CT examinations per dental CT scanner in the most recent 12-month~~
381 ~~period, for which the Department has verifiable data.~~

382 ~~—(2) An applicant proposing to acquire an existing fixed dental CT scanner(s) of an existing fixed or~~
383 ~~mobile dental CT scanner service shall demonstrate that the proposed project meets the following:~~

384 ~~—(a) For any application for proposed acquisition of an existing fixed or mobile dental CT scanner(s) of~~
385 ~~an existing fixed or mobile dental CT scanner service, an applicant shall be required to demonstrate that~~
386 ~~the fixed or mobile dental CT scanner(s) to be acquired performed at least 200 dental CT examinations~~
387 ~~per dental CT scanner in the most recent 12-month period for which the Department has verifiable data.~~
388

389 **Section 11. Requirements for a dedicated research fixed CT scanner**

390
391 Sec. 11. An applicant proposing to add a fixed CT scanner to an existing CT scanner service for
392 exclusive research use shall demonstrate the following:

393
394 (1) The applicant agrees that the dedicated research CT scanner will be used primarily (70% or more
395 of the scans) for research purposes.

396
397 (2) The dedicated research CT scanner shall operate under a protocol approved by the applicant's
398 Institutional Review Board, as defined by Public Law 93-348 and regulated by Title 45 CFR 46.

399
400 (3) The proposed site can have no more than three dedicated research fixed CT scanners approved
401 under this section.

402
403 (4) The dedicated research scanner approved under this section may not utilize CT procedures
404 performed on the dedicated CT scanner to demonstrate need or to satisfy CT CON review standards
405 requirements.

406 407 **Section 12. Requirements for approval of an applicant proposing a CT scanner used for the sole** 408 **purpose of performing dental CT examinations exclusively for research**

409
410 ~~—Sec. 12. (1) An applicant proposing a CT scanner used for the sole purpose of performing dental CT~~
411 ~~examinations exclusively for research shall demonstrate each of the following:~~

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

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

415 ~~—(c) The applicant agrees to operate the research dental CT scanner in accordance with the terms of~~
416 ~~approval in Section 20(6).~~

417
418 ~~—(2) An applicant meeting the requirements of subsection (1) shall also demonstrate compliance with~~
419 ~~the requirements of sections 4(2), 4(4) and 4(5).~~

420 421 **Section 13. Requirements for approval of a hospital-based portable CT scanner for initiation,** 422 **expansion, replacement, and acquisition**

423
424
425
426
427
428
429
430
431
432
433
434
435
436
437
438
439
440
441
442
443
444
445
446
447
448
449
450
451
452
453
454
455
456
457
458
459
460
461
462
463
464
465
466
467
468
469
470
471
472
473
474
475

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 15. Requirements for approval of a CT-angio hybrid unit for initiation, replacement, and acquisition

Sec. 15. An applicant proposing to initiate, replace, or acquire a hospital-based CT-angio hybrid unit shall demonstrate each of the following, as applicable to the proposed project:

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

(2) The proposed site has an existing fixed CT scanner service that has been operational for the previous 36 consecutive months and is meeting its minimum volume requirements.

(3) The proposed site offers the following services:

(a) diagnostic cardiac catheterization; or

(b) interventional radiology; or

- 476 (c) surgical services
477
478 (4) The proposed CT-angio hybrid unit must be located in one of the following rooms:
479 (a) cardiac catheterization lab; or
480 (b) interventional radiology suite; or
481 (c) licensed operating room
482
483 (5) Diagnostic CT studies shall not be performed on a CT-angio hybrid unit approved under this
484 section unless the patient is currently undergoing a CT-angio hybrid interventional procedure and is in
485 need of a secondary diagnostic CT study.
486
487 (6) The approved CT-angio hybrid shall not be subject to CT volume requirements.
488
489 (7) The applicant shall not utilize the procedures performed on the CT-angio hybrid unit to
490 demonstrate need or to satisfy CT CON review standards requirements.
491

492 **Section 16. Additional requirements for approval of a mobile CT scanner service**
493

494 Sec. 16. (1) An applicant proposing to initiate a mobile CT scanner service in Michigan shall
495 demonstrate that it meets all of the following additional requirements:

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

498 (b) The normal route schedule, the procedures for handling emergency situations, and copies of all
499 potential contracts related to the mobile CT scanner service shall be included in the CON application
500 submitted by the central service coordinator.
501

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

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

506 (b) A separate CON application has been filed for each host facility.
507

508 ~~**Section 17. Additional requirements for approval of a mobile dental CT scanner service**~~
509

510 ~~— Sec. 17. (1) An applicant proposing to initiate a mobile dental CT scanner service in Michigan shall~~
511 ~~demonstrate that it meets all of the following additional requirements:~~

512 ~~— (a) A separate CON application shall be submitted by the central service coordinator and each~~
513 ~~Michigan host facility.~~

514 ~~— (b) The normal route schedule, the procedures for handling emergency situations, and copies of all~~
515 ~~potential contracts related to the mobile dental CT scanner service shall be included in the CON~~
516 ~~application submitted by the central service coordinator.~~
517

518 ~~— (2) An applicant proposing to become a host facility on an existing mobile dental CT scanner network~~
519 ~~shall demonstrate that it meets all of the following additional requirements:~~

520 ~~— (a) Approval of the application will not result in an increase in the number of operating mobile dental~~
521 ~~CT scanners for the mobile dental CT scanner network unless the requirements of Section 6 have been~~
522 ~~met.~~

523 ~~— (b) A separate CON application has been filed for each host facility.~~
524

525 **Section 18. Requirements for approval of an applicant proposing to establish dedicated pediatric**
526 **CT Scanner**
527

528 Sec. 18. (1) An applicant proposing to establish dedicated pediatric CT shall demonstrate all of the
529 following:

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

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

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

537 (i) pediatric radiology (at least two)

538 (ii) pediatric anesthesiology

539 (iii) pediatric cardiology

540 (iv) pediatric critical care

541 (v) pediatric gastroenterology

542 (vi) pediatric hematology/oncology

543 (vii) pediatric neurology

544 (viii) pediatric neurosurgery

545 (ix) pediatric orthopedic surgery

546 (x) pediatric pathology

547 (xi) pediatric pulmonology

548 (xii) pediatric surgery

549 (xiii) neonatology

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

552 (i) pediatric bone marrow transplant program

553 (ii) established pediatric sedation program

554 (iii) pediatric open heart program

555

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

558

559 **Section 19. Requirements for Medicaid participation**

560

561 Sec. 19. An applicant shall provide verification of Medicaid participation. An applicant that is a new
562 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided
563 to the Department within six (6) months from the offering of services if a CON is approved.

564

565 **Section 20. Project delivery requirements and terms of approval for all applicants**

566

567 Sec. 20. An applicant shall agree that, if approved, the CT scanner(s) services shall be delivered in
568 compliance with the following terms of approval.

569

570 (1) Compliance with these standards.

571

572 (2) Compliance with the following quality assurance standards:

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

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

577 (ii) The CT scanner is operated by physicians and/or is operated by radiological technologists
578 qualified by training and experience to operate the CT scanner safely and effectively.

579 For purposes of evaluating (a)(i), the Department shall consider it prima facie evidence of a satisfactory
580 assurance mechanism as to screening and interpretation if the applicant requires the screening of

581 requests for and interpretations of CT procedures to be performed by physicians who are board certified
582 or eligible in radiology or are neurologists or other specialists trained in cross-sectional imaging of a
583 specific organ system. For purposes of evaluating (a)(i) the Department shall consider it prima facie
584 evidence of a satisfactory assurance mechanism as to the operation of a CT scanner if the applicant
585 requires the CT scanner to be operated by a physician or by a technologist registered by the American
586 Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography
587 Technologists (ARCRT). However, the applicant may submit and the Department may accept other
588 evidence that the applicant has established a mechanism to assure that the CT scanner facility is
589 appropriately and adequately staffed as to screening, interpretation, and/or operation of a CT scanner.

590 (b) The applicant shall employ or contract with a radiation physicist to review the quality and safety of
591 the operation of the CT scanner.

592 (c) The applicant shall assure that at least one of the physicians responsible for the screening and
593 interpretation as defined in subsection (a)(i) will be in the CT facility or available ~~on a 24-hour basis~~ (either
594 on-site or through telecommunication capabilities) to make the final interpretation.

595 (d) In the case of an urgent or emergency CT scan, the applicant shall assure that a physician so
596 authorized by the applicant to interpret initial scans will be on-site or available through telecommunication
597 capabilities within 1 hour following completion of the scanning procedure to render an initial interpretation
598 of the scan. A final interpretation shall be rendered by a physician so authorized under subsection (a)(i)
599 within 24 hours.

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

604 (f) Fixed CT scanner services ~~at each facility~~ shall be made available 24 hours a day for emergency
605 patients if the facility operates an emergency room that provides 24-hour emergency care services as
606 authorized by the local medical control authority to receive ambulance runs.

607 (g) The applicant shall accept referrals for CT scanner services from all appropriately licensed
608 practitioners.

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

613 (i) An applicant approved under Section 18 must be able to prove that all radiologists, technologists
614 and nursing staff working with CT patients have continuing education or in-service training on pediatric
615 low-dose CT. The site must also be able to provide evidence of defined low-dose pediatric CT protocols.
616

617 (3) Compliance with the following access to care requirements:

618 (a) The applicant, to assure that the CT scanner will be utilized by all segments of the Michigan
619 population, shall:

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

621 (ii) provide all CT scanning services to any individual based on the clinical indications of need for the
622 service; and

623 (iii) maintain information by payor and non-paying sources to indicate the volume of care from each
624 source provided annually.

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

627 (c) The operation of and referral of patients to the CT scanner shall be in conformance with 1978 PA
628 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

629

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

631

632 (4) Compliance with the following monitoring and reporting requirements:

633 (a) The approved CT scanners shall be operating at an average of 7,500 CT equivalents scanner per
634 fixed scanner and 3,500 CT equivalents per mobile scanner per year for the second 12-month period after
635 beginning operation of the CT scanner, and annually thereafter, except for those scanners exempt under
636 applicable sections.

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

645 (c) Equipment to be replaced shall be removed from service.

646 (d) The applicant shall provide the Department with timely notice of the proposed project
647 implementation consistent with applicable statute and promulgated rules.

648 (e) An applicant approved under Section 4 shall not be required to be in compliance with subsection
649 (2).

650
651 ~~—(5) Compliance with the following dental CT scanner (fixed or mobile) requirements, if applicable:~~

652 ~~—(a) The CT scanner will be used for the sole purpose of dental CT examinations.~~

653 ~~—(b) The applicant shall demonstrate to the satisfaction of the Department that the person(s) (e.g.,~~
654 ~~technician, dentist) operating the dental CT scanner has been appropriately trained and/or certified by one~~
655 ~~of the following groups, as recognized by the Department: a dental radiology program in a certified dental~~
656 ~~school, an appropriate professional society, or a dental continuing education program accredited by the~~
657 ~~American Dental Association.~~

658 ~~—(c) The applicant shall demonstrate to the satisfaction of the Department that the dental CT~~
659 ~~examinations generated by the dental CT scanner will be interpreted by a licensed dentist(s) trained~~
660 ~~and/or certified by one of the following groups, as recognized by the Department: a dental radiology~~
661 ~~program in a certified dental school, an appropriate professional society, or a dental continuing education~~
662 ~~program accredited by the American Dental Association.~~

663 ~~—(d) The applicant shall demonstrate to the satisfaction of the Department that the dentists using the~~
664 ~~dental CT examinations for performing dental procedures has had the appropriate training and/or~~
665 ~~experience certified by one of the following groups, as recognized by the Department: a dental radiology~~
666 ~~program in a certified dental school, an appropriate professional society, or a dental continuing education~~
667 ~~program accredited by the American Dental Association.~~

668 ~~—(e) The applicant, to assure that the dental CT scanner will be utilized by all segments of the Michigan~~
669 ~~population, shall:~~

670 ~~—(i) not deny dental CT scanner services to any individual based on ability to pay or source of~~
671 ~~payment;~~

672 ~~—(ii) provide dental CT scanning services to any individual based on the clinical indications of need for~~
673 ~~the service; and~~

674 ~~—(iii) maintain information by payor and non-paying sources to indicate the volume of care from each~~
675 ~~source provided annually. Compliance with selective contracting requirements shall not be construed as a~~
676 ~~violation of this term.~~

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

679 ~~—(g) The applicant shall participate in a data collection network established and administered by the~~
680 ~~Department or its designee. The data may include, but is not limited to, annual budget and cost~~
681 ~~information, operating schedules, through-put schedules, demographic and diagnostic information, the~~
682 ~~volume of care provided to patients from all payor sources, and other data requested by the Department,~~
683 ~~and approved by the Commission. The applicant shall provide the required data on a separate basis for~~
684 ~~each separate and distinct site as required by the Department; in a format established by the Department;~~

685 ~~and in a mutually agreed upon media. The Department may elect to verify the data through on-site review~~
686 ~~of appropriate records.~~

687 ~~—(h) Equipment to be replaced shall be removed from service.~~

688 ~~—(i) The applicant shall provide the Department with timely notice of the proposed project~~
689 ~~implementation consistent with applicable statute and promulgated rules.~~

690 ~~—(j) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years~~
691 ~~of operation and continue to participate annually thereafter.~~

692
693 ~~—(6) An applicant for a CT scanner used for dental research under Section 12(1) shall agree that the~~
694 ~~services provided by the CT scanner approved pursuant to Section 12(1) shall be delivered in compliance~~
695 ~~with the following terms of CON approval:~~

696 ~~—(a) The capital and operating costs relating to the CT scanner used for dental research pursuant to~~
697 ~~Section 12(1) shall be charged only to a specific research account(s) and not to any patient or third-party~~
698 ~~payer.~~

699 ~~—(b) The CT scanner used for dental research approved pursuant to Section 12(1) shall not be used~~
700 ~~for any purposes other than as approved by the institutional review board unless the applicant has~~
701 ~~obtained CON approval for the CT scanner pursuant to part 222 and these standards, other than Section~~
702 ~~12.~~

703
704 (7) An applicant approved under Section 13 shall be in compliance with the following:

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

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

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

708 (b) The approved applicant must provide annual reports to the Department by January 31st of each
709 year for the preceding calendar year. This requirement applies to all applicants approved under Section
710 13.

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

712 (i) Number of adult studies (age \geq 18)

713 (ii) Number of pediatric studies (age $<$ 18)

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

716
717 (8) An applicant approved under Section 15 shall be in compliance with the following:

718 (a) The proposed site offers the following services:

719 (i) diagnostic cardiac catheterization; or

720 (ii) interventional radiology; or

721 (iii) surgical services

722 (b) The proposed CT-Angio hybrid unit must be located in one of the following rooms:

723 (i) cardiac catheterization lab; or

724 (ii) interventional radiology suite; or

725 (iii) licensed operating room

726
727 (9) The agreements and assurances required by this section shall be in the form of a certification
728 agreed to by the applicant or its authorized agent.

729
730 **Section 21. Project delivery requirements and additional terms of approval for applicants**
731 **involving mobile CT scanners**

732
733 Sec. 21. (1) In addition to the provisions of Section 20, an applicant for a mobile CT scanner shall
734 agree that the services provided by the mobile CT scanner(s) shall be delivered in compliance with the
735 following terms of CON approval:

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

- 738 (b) A mobile CT scanner with an approved CON shall notify the Michigan Department of Community
 739 Health prior to ending service with an existing host facility.
- 740 (c) A CON shall be required to add a host facility.
- 741 (d) A CON shall be required to change the central service coordinator.
- 742 (e) Each host facility must have at least one board certified or board eligible radiologist on its medical
 743 staff. The radiologist(s) shall be responsible for: (i) establishing patient examination and infusion
 744 protocol, and (ii) providing for the interpretation of scans performed by the mobile CT scanner.
- 745 (f) Each mobile CT scanner service must have an Operations Committee with members
 746 representing each host facility, the central service coordinator, and the central service medical director.
 747 This committee shall oversee the effective and efficient use of the CT scanner, establish the normal route
 748 schedule, identify the process by which changes are to be made to the schedule, develop procedures for
 749 handling emergency situations, and review the ongoing operations of the mobile CT scanner on at least a
 750 quarterly basis.
- 751 (g) The central service coordinator shall arrange for emergency repair services to be available 24
 752 hours each day for the mobile CT scanner as well as the vehicle transporting the equipment. In addition,
 753 to preserve image quality and minimize CT scanner downtime, calibration checks shall be performed on
 754 the CT scanner at least once each work day and routine maintenance services shall be provided on a
 755 regularly scheduled basis, at least once a week during hours not normally used for patient procedures.
- 756 (h) Each host facility must provide a properly prepared parking pad for the mobile CT scanner of
 757 sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for
 758 patients to enter the vehicle without going outside (such as a canopy or enclosed corridor). Each host
 759 facility must also provide the capability for processing the film and maintaining the confidentiality of patient
 760 records. A communication system must be provided between the mobile vehicle and each host facility to
 761 provide for immediate notification of emergency medical situations.
- 762 (i) A mobile CT scanner service shall operate under a contractual agreement that includes the
 763 provision of CT scanner services at each host facility on a regularly scheduled basis.
- 764 (j) The volume of utilization at each host facility shall be reported to the Department by the central
 765 service coordinator under the terms of Section 20(2)(i).
- 766
- 767 (2) The agreements and assurances required by this section shall be in the form of a certification
 768 agreed to by the applicant or its authorized agent.

769
 770 **Section 22. Determination of CT Equivalents**

771
 772 Sec. 22. CT equivalents shall be calculated as follows:

- 773 (a) Each billable procedure for the time period specified in the applicable section(s) of these
 774 standards shall be assigned to a category set forth in Table 1.
- 775 (b) The number of billable procedures for each category in the time period specified in the applicable
 776 section(s) of these standards shall be multiplied by the corresponding conversion factor in Table 1 to
 777 determine the number of CT equivalents for that category for that time period.
- 778 (c) The number of CT equivalents for each category shall be summed to determine the total CT
 779 equivalents for the time period specified in the applicable section(s) of these standards.
- 780 (d) The conversion factor for pediatric/special needs patients does not apply to procedures performed
 781 on a dedicated pediatric CT scanner.

782

783 Table 1	784 Number of		785 Conversion		786 CT
787 Category	788 Billable CT		789 Factor		790 Equivalents
	Procedures				
787 <u>Adult Patient</u>					
788 Head Scans w/o Contrast	_____	X	1.00	=	_____
789 (includes dental CT examinations)					
790 Head Scans with Contrast	_____	X	1.25	=	_____

791	Head Scans w/o & w Contrast	_____	X	1.75	=	_____
792	Body Scans w/o Contrast	_____	X	1.50	=	_____
793	Body Scans with Contrast	_____	X	1.75	=	_____
794	Body Scans w/o & w Contrast	_____	X	2.75	=	_____
795	Bundled body Scan	_____	X	3.50	=	_____
796						
797	<u>Pediatric/Special Needs Patient</u>					
798	Head scans w/o Contrast	_____	x	1.25	=	_____
799	(includes dental CT examinations)					
800	Head Scans with Contrast	_____	x	1.50	=	_____
801	Head Scans w/o & with Contrast	_____	x	2.00	=	_____
802	Body Scans w/o Contrast	_____	x	1.75	=	_____
803	Body Scans with Contrast	_____	x	2.00	=	_____
804	Body Scans w/o & with Contrast	_____	x	3.00	=	_____
805	Bundled body Scan	_____	X	4.00	=	_____
806						
807	Total CT Equivalents					_____

809 **Section 23. Documentation of projections**

810
811 Sec. 23. An applicant required to project volumes under sections 3 and 4 shall demonstrate the
812 following, as applicable:

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

818
819 ~~—(2) An applicant required to project under Section 4 shall demonstrate that the projection is based on
820 a combination of the following for the most recent 12-month period immediately preceding the date of the
821 application:~~

822 ~~—(a) the number of dental procedures performed by the applicant, and
823 —(b) the number of committed dental procedures performed by referring licensed dentists. Further, the
824 applicant and the referring licensed dentists shall substantiate the numbers through the submission of
825 HIPAA compliant billing records.~~

826 (3) An applicant shall demonstrate that the projected number of referrals to be performed at the
827 proposed site under subsection (1) are from an existing CT scanner service that is in compliance with the
828 volume requirements applicable to that service, and will continue to be in compliance with the volume
829 requirements applicable to that service subsequent to the initiation of the proposed CT scanner service by
830 an applicant. ~~This does not include dental CT scanners.~~ Only excess CT equivalents equal to or greater
831 than what is being committed pursuant to this subsection may be used to document projections under
832 subsection (1). In demonstrating compliance with this subsection, an applicant shall provide each of the
833 following:

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

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

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

844
845
846
847
848
849
850
851
852

Section 24. Effect on prior CON review standards; comparative reviews

Sec. 24. (1) These CON review standards supersede and replace the CON Review Standards for Computed Tomography Scanner Services approved by the CON Commission on ~~March 18~~SEPTEMBER 25, 2014 and effective on ~~June 2~~DECEMBER 22, 2014.

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

APPENDIX A

853
854
855
856
857
858
859
860
861
862
863
864
865
866
867
868
869
870
871
872
873
874
875
876
877
878
879
880
881
882
883
884
885
886
887
888
889
890
891
892
893
894

Counties assigned to each of the health service areas are as follows:

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

895
896
897
898
899
900
901
902
903
904
905
906
907
908
909
910
911
912
913
914
915
916
917
918
919
920
921
922
923
924
925
926
927
928
929
930
931
932
933
934
935
936
937
938
939
940

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

75 F.R., p. 37245 (June 28, 2010)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget