

1 MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

2
3 CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR
4 COMPUTED TOMOGRAPHY (CT) SCANNER SERVICES
5

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

10 Section 1. Applicability

11
12 Sec. 1. These standards are requirements for the approval of the initiation, expansion, replacement,
13 ~~relocation,~~ or acquisition of CT services and the delivery of services under Part 222 of the Code. Pursuant
14 to Part 222 of the Code, CT is a covered clinical service. The Department shall use these standards in
15 applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and
16 Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.
17

18 Section 2. Definitions

19
20 Sec. 2. (1) For purposes of these standards:

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

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

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

29 (d) "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 (e) "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 (f) "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 (g) "Computed tomography" or "CT" means the use of radiographic and computer techniques to
36 produce cross-sectional images of the head or body.

37 (h) "CT-ANGIO HYBRID UNIT" MEANS^[A1]

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

40 (j)^[A2] "CT scanner" means x-ray CT scanning systems capable of performing CT scans of the head,
41 other body parts, or full body patient procedures including Positron Emission Tomography (PET)/CT
42 scanner hybrids if used for CT only procedures. The term does not include emission-computed
43 tomographic systems utilizing internally administered single-photon gamma ray emitters, positron
44 annihilation CT systems, magnetic resonance, ultrasound computed tomographic systems, CT simulators
45 used solely for treatment planning purposes in conjunction with an MRT unit, and non-diagnostic, intra-
46 operative guidance tomographic units.

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

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

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

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

- 55 (n) "Department" means the Michigan Department of Community Health (MDCH).
- 56 (o) "Emergency room" means a designated area physically part of a licensed hospital and recognized
57 by the Department as having met the staffing and equipment requirements for the treatment of emergency
58 patients.
- 59 (p) "Excess CT Equivalents" means the number of CT equivalents performed by an existing CT
60 scanner service in excess of 10,000 per fixed CT scanner and 4,500 per mobile CT scanner or either an
61 existing fixed or mobile CT scanner service, the number of CT scanners used to compute excess CT
62 equivalents shall include both existing and approved but not yet operational CT scanners. In the case of a
63 CT scanner service that operates or has a valid CON to operate that has more than one fixed CT scanner
64 at the same site, the term means number of CT equivalents in excess of 10,000 multiplied by the number
65 of fixed CT scanners at the same site. For example, if a CT scanner service operates, or has a valid CON
66 to operate, two fixed CT scanners at the same site, the excess CT equivalents is the number that is in
67 excess of 20,000 (10,000 x 2) CT equivalents. In the case of an existing mobile CT scanner service, the
68 term means the sum of all CT equivalents performed by the same mobile CT scanner service at all of the
69 host sites combined that is in excess of 4,500. For example, if a mobile CT scanner service serves five
70 host sites with 1 mobile CT scanner, the term means the sum of CT equivalents for all five host sites
71 combined that is in excess of 4,500 CT equivalents.
- 72 (q) "Existing CT scanner service" means the utilization of a CON-approved and operational CT
73 scanner(s) at one site in the case of a fixed CT scanner service or at each host site in the case of a
74 mobile CT scanner service.
- 75 (r) "Existing CT scanner" means a CON-approved and operational CT scanner used to provide CT
76 scanner services.
- 77 (s) "Existing mobile CT scanner service" means a CON-approved and operational CT scanner and
78 transporting equipment operated by a central service coordinator serving two or more host sites.
- 79 (t) "Expand an existing CT scanner service" means the addition of one or more CT scanners at an
80 existing CT scanner service.
- 81 (u) "Head scans" include head or brain CT scans; including the maxillofacial area; the orbit, sella, or
82 posterior fossa; or the outer, middle, or inner ear; or any other CT scan occurring above the neck.
- 83 (v) "Health Service Area" or "HSA" means the groups of counties listed in [Section 24 APPENDIX A](#).
- 84 (w) "HIPAA" means the Health Insurance Portability and Accountability Act of 1996.
- 85 (x) "Hospital-based portable CT scanner or portable CT scanner" means a CT scanner capable of
86 being transported into patient care areas (i.e., ICU rooms, operating rooms, etc.) to provide high-quality
87 imaging of critically ill patients.
- 88 (y) "Host site" means the site at which a mobile CT scanner is authorized to provide CT scanner
89 services.
- 90 (z) "Initiate a CT scanner service" means to begin operation of a CT scanner, whether fixed or
91 mobile, at a site that does not perform CT scans as of the date an application is submitted to the
92 Department. The term does not include the acquisition or ~~relocation~~ REPLACEMENT of an existing CT
93 scanner service TO A DIFFERENT SITE or the renewal of a lease.
- 94 (aa) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396 ~~r-6 and 1396r-~~
95 ~~8 to 1396v1396w-5~~.
- 96 ~~(bb) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as~~
97 ~~that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by~~
98 ~~the statistical policy office of the office of information and regulatory affairs of the United States office of~~
99 ~~management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.~~
- 100 ~~—(cc) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as~~
101 ~~that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by~~
102 ~~the statistical policy office of the office of information and regulatory affairs of the United States office of~~
103 ~~management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.~~
- 104 (dd) "Mobile CT scanner service" means a CT scanner and transporting equipment operated by a
105 central service coordinator and which must serve two or more host facilities.
- 106 (ee) "Mobile CT scanner network" means the route (all host facilities) the mobile CT scanner is
107 authorized to serve.
- 108 (ff) "Pediatric patient" means any patient less than 18 years of age.

109 ~~—(gg) “Relocate a fixed CT scanner” means a change in the location of a fixed CT scanner from the~~
110 ~~existing site to a different site within the relocation zone.~~

111 ~~(hh) “Relocate an existing CT scanner service” means a change in the geographic location of an~~
112 ~~existing fixed CT scanner service from an existing site to a different site.~~

113 ~~(ii) “Relocation zone,” means a site that is within a 10-mile radius of a site at which an existing fixed~~
114 ~~CT scanner service is located if an existing fixed CT scanner service is located in a metropolitan statistical~~
115 ~~area county, or a 20-mile radius if an existing fixed CT scanner service is located in a rural or micropolitan~~
116 ~~statistical area county.~~

117 (jj) “Replace an existing CT scanner” means an equipment change of an existing CT scanner, that
118 requires a change in the radiation safety certificate, proposed by an applicant which results in that
119 applicant operating the same number of CT scanners before and after project completion, at the same
120 geographic location. THE TERM ALSO INCLUDES RELOCATING an existing CT scanner OR CT
121 SCANNER service from an existing site to a different site.
122

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

128 (ll) “Sedated patient” means a patient that meets all of the following:

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

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

136 (mm) “Special needs patient” means a non-sedated patient, either pediatric or adult, with any of the
137 following conditions: down syndrome, autism, attention deficit hyperactivity disorder (ADHD),
138 developmental delay, malformation syndromes, hunter’s syndrome, multi-system disorders, psychiatric
139 disorders, and other conditions that make the patient unable to comply with the positional requirements of
140 the exam.

141
142 (2) Terms defined in the Code have the same meanings when used in these standards.
143

144 **Section 3. Requirements for approval for applicants proposing to initiate a CT scanner service** 145 **other than a dental CT scanner service or hospital-based portable CT scanner service** 146

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

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

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

152 (b) The hospital operates an emergency room that provides 24-hour emergency care services as
153 authorized by the local medical control authority to receive ambulance runs.
154

155 (2) An applicant, other than an applicant meeting all of the applicable requirements of subsection (1),
156 proposing to initiate a fixed CT scanner service shall project an operating level of at least 7,500 CT
157 equivalents per year for the second 12-month period after beginning operation of the CT scanner.
158

159 (3) An applicant proposing to initiate a mobile CT scanner service shall project an operating level of at
160 least 3,500 CT equivalents per year for the second 12-month period after beginning operation of the CT
161 scanner.
162

163 | (4) AN APPLICANT PROPOSING TO INITIATE CT SCANNER SERVICES AS AN EXISTING HOST
164 | SITE ON A DIFFERENT MOBILE CT SCANNER SERVICE SHALL DEMONSTRATE THE FOLLOWING:
165 | (a) THE APPLICANT PROVIDES A PROPOSED ROUTE SCHEDULE.
166 | (b) THE APPLICANT PROVIDES A DRAFT CONTRACT FOR SERVICES BETWEEN THE
167 | PROPOSED HOST SITE AND CENTRAL SERVICE COORDINATOR.^[A3]
168 |

169 | **Section 4. Requirements for approval for applicants proposing to initiate a dental CT scanner**
170 | **service**

171 |
172 | Sec. 4. An applicant proposing to initiate A FIXED OR MOBILE dental CT scanner service shall
173 | demonstrate each of the following, as applicable:
174 |

175 | (1) An applicant is proposing a DENTALfixed^[A4] CT scanner service for the sole purpose of
176 | performing dental CT examinations.
177 |

178 | (2) The CT scanner generates a peak power of 5 kilowatts or less as certified by the
179 | manufacturer.^[A5]
180 |

181 | (3) An applicant proposing to initiate a dental CT scanner service, other than an applicant that is
182 | proposing a dental CT scanner service in HSA 8, shall project an operating level of at least 200 dental CT
183 | examinations per year for the second 12-month period after beginning operation of the dental CT scanner.
184 |

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

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

197 | **Section 5. Requirements for approval for applicants proposing to expand an existing CT scanner**
198 | **service other than a dental CT scanner service or hospital-based portable CT scanner service**
199 |

200 | Sec. 5. (1) An applicant proposing to expand an existing fixed CT scanner service shall demonstrate
201 | that all of the applicant's fixed CT scanners, excluding CT scanners approved pursuant to sections 13 and
202 | 17, have performed an average of at least 10,000 CT equivalents per fixed CT scanner for the most
203 | recent 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 | fixed CT scanners, including both operational and approved but not operational fixed CT scanners.
206 |

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

215 | (3) If an applicant proposes to expand an existing mobile CT scanner service, the applicant shall
216 | demonstrate that all of the applicant's mobile CT scanners have performed an average of at least 5,500

217 CT equivalents per mobile CT scanner for the most recent continuous 12-month period preceding the
218 applicant's request. In computing this average, the Department will divide the total number of CT
219 equivalents performed by the applicant's total number of mobile CT scanners, including both operational
220 and approved but not operational mobile CT scanners.

221

222 **Section 6. Requirements for approval for applicants proposing to expand an existing dental CT**
223 **scanner service**

224

225 | Sec. 6. An applicant proposing to expand an existing fixed OR MOBILE [A6] dental CT scanner service
226 shall demonstrate that all of the applicant's dental CT scanners have performed an average of at least 300
227 | dental CT examinations per fixed OR MOBILE dental CT scanner for the most recent continuous 12-
228 month period preceding the applicant's request. In computing this average, the Department will divide the
229 | total number of dental CT examinations performed by the applicant's total number of fixed OR MOBILE
230 | dental CT scanners, including both operational and approved but not operational fixed OR MOBILE dental
231 CT scanners.

232

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

235

236 | Sec. 7. An applicant proposing to replace an existing CT scanner, EXCEPT FOR AN APPLICANT
237 APPROVED UNDER SECTION 3(1), shall demonstrate each of the following, as applicable:

238

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

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

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

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

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

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

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

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

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

256 (c) An applicant proposing to replace an existing fixed CT scanner on an academic medical center
257 campus, at the same site, shall be exempt once, as of May 5, 2008, from the minimum volume
258 requirements for replacement if the existing CT scanner is fully depreciated according to generally
259 accepted accounting principles.

260 (d) An applicant proposing to replace an existing fixed CT scanner having a configuration of less than
261 | 16 multi-detector rows shall be exempt once, as of ~~the effective date~~ FEBRUARY 27, 2012 ~~of the~~
262 | ~~standards~~, from the minimum volume requirements for replacement if it meets both of the following:

263 (i) The proposed CT scanner to be obtained will have a configuration of sixteen (16) or more multi-
264 detector rows, and

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

267

268 (2) An applicant proposing to replace an existing mobile CT scanner(s) shall demonstrate that the
269 mobile CT scanner(s) performed at least 3,500 CT equivalents if the applicant operates only one mobile
270 CT scanner or an average of 5,500 CT equivalents for each CT scanner if the applicant operates more

271 than one mobile CT scanner for the same mobile CT scanner network, in the most recent 12-month
272 period for which the department has verifiable data.

273
274 (3) An applicant proposing to replace an existing dedicated pediatric CT scanner(s) shall demonstrate
275 that the dedicated pediatric CT scanner(s) performed at least an average of 2,500 CT equivalents per
276 dedicated pediatric CT scanner in the most recent 12-month period for which the Department has
277 verifiable data.

278
279 (4) An applicant under this section shall demonstrate that the existing CT scanner(s) proposed to be
280 replaced is fully depreciated according to generally accepted accounting principles, or, that the existing
281 equipment clearly poses a threat to the safety of the public, or, that the proposed replacement CT scanner
282 offers technological improvements which enhance quality of care, increase efficiency, and/or reduce
283 operating costs and patient charges.

284
285 (5) An applicant proposing to ~~relocate~~REPLACE an existing fixed CT scanner service TO A
286 DIFFERENT SITE shall demonstrate that the proposed project meets all of the following:

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

289 (b) The proposed new site ~~is in the relocation zone~~ is within a 10-mile radius of a site at which an
290 existing fixed CT scanner service is located if an existing fixed CT scanner service is located in a
291 metropolitan statistical area county, or a 20-mile radius if an existing fixed CT scanner service is located in
292 a rural or micropolitan statistical area county.-

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

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

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

298
299 (6) An applicant proposing to ~~relocate~~REPLACE a fixed CT scanner(s) of an existing CT scanner
300 service TO A DIFFERENT SITE shall demonstrate that the proposed project meets all of the following:

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

303 (b) The proposed new site ~~is in the relocation zone~~ is within a 10-mile radius of a site at which an
304 existing fixed CT scanner service is located if an existing fixed CT scanner service is located in a
305 metropolitan statistical area county, or a 20-mile radius if an existing fixed CT scanner service is located in
306 a rural or micropolitan statistical area county..

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

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

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

313

314

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

317

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

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

324

325 (2) An applicant under this section shall demonstrate that the existing dental CT scanner(s) proposed
326 to be replaced is fully depreciated according to generally accepted accounting principles, or, that the
327 existing equipment clearly poses a threat to the safety of the public, or that the proposed replacement
328 dental CT scanner offers technological improvements which enhance quality of care, increase efficiency,
329 and/or reduce operating costs and patient charges.
330

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

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

335 (B) FOR VOLUME PURPOSES, THE NEW SITE SHALL REMAIN ASSOCIATED WITH THE
336 EXISTING CT SERVICE FOR A MINIMUM OF THREE YEARS.
337

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

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

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

347 (f) The applicant agrees to operate the dental CT scanner service in accordance with all applicable
348 project delivery requirements set forth in Section 19 of these standards.
349

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

353 (a) The existing dental CT scanner service from which the dental CT scanner(s) is to be
354 ~~relocated~~REPLACED has been in operation for at least 36 months as of the date an application is
355 submitted to the Department.
356

357 (B) FOR VOLUME PURPOSES, THE NEW SITE SHALL REMAIN ASSOCIATED WITH THE
358 EXISTING CT SERVICE FOR A MINIMUM OF THREE YEARS.

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

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

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

368 (f) The applicant agrees to operate the dental CT scanner(s) at the proposed site in accordance with
369 all applicable project delivery requirements set forth in Section 19 of these standards.
370

371 **~~Section 9. Requirements for approval for applicants proposing to relocate an existing CT scanner~~**
372 **~~service and/or CT scanner(s) other than an existing dental CT scanner service and/or dental CT~~**
373 **~~scanner(s) or hospital-based portable CT scanner(s)~~**
374

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

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

- ~~—(b) The proposed new site is in the relocation zone.~~
- ~~—(c) The requirements of sections 5 or 7, as applicable, have been met.~~
- ~~—(d) The CT scanner service to be relocated performed at least an average of 7,500 CT equivalents per fixed scanner in the most recent 12-month period for which the Department has verifiable data.~~
- ~~—(e) The applicant agrees to operate the CT scanner service in accordance with all applicable project delivery requirements set forth in Section 19 of these standards.~~

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

- ~~—(a) The existing CT scanner service from which the CT scanner(s) is to be relocated has been in operation for at least 36 months as of the date an application is submitted to the Department.~~
- ~~—(b) The proposed new site is in the relocation zone.~~
- ~~—(c) The requirements of sections 5 or 7, as applicable, have been met.~~
- ~~—(d) Each existing CT scanner at the service from which a scanner is to be relocated performed at least an average of 7,500 CT equivalents per fixed scanner in the most recent 12-month period for which the Department has verifiable data.~~
- ~~—(e) The applicant agrees to operate the CT scanner(s) at the proposed site in accordance with all applicable project delivery requirements set forth in Section 19 of these standards.~~

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

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

- ~~—(a) The existing fixed dental CT scanner service to be relocated has been in operation for at least 36 month as of the date an application is submitted to the Department.~~
- ~~—(b) The proposed new site is in the relocation zone.~~
- ~~—(c) The requirements of sections 6 or 8, as applicable, have been met.~~
- ~~—(d) The dental CT scanner service to be relocated performed at least an average of 200 dental CT examinations per fixed dental CT scanner in the most recent 12-month period for which the Department has verifiable data.~~
- ~~—(e) The applicant agrees to operate the dental CT scanner service in accordance with all applicable project delivery requirements set forth in Section 19 of these standards.~~

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

- ~~—(a) The existing dental CT scanner service from which the dental CT scanner(s) is to be relocated has been in operation for at least 36 months as of the date an application is submitted to the Department.~~
- ~~—(b) The proposed new site is in the relocation zone.~~
- ~~—(c) The requirements of sections 6 or 8, as applicable have been met.~~
- ~~—(d) Each existing dental CT scanner at the service from which a scanner is to be relocated performed at least an average of 200 dental CT examinations per fixed dental CT scanner in the most recent 12-month period for which the Department has verifiable data.~~
- ~~—(e) The applicant agrees to operate the dental CT scanner(s) at the proposed site in accordance with all applicable project delivery requirements set forth in Section 19 of these standards.~~

Section 149. Requirements for approval for applicants proposing to acquire an existing CT scanner service or an existing CT scanner(s) other than an existing dental CT scanner service and/or an existing dental CT scanner(s) or hospital-based portable CT scanner(s)

Sec. 149. (1) An applicant proposing to acquire an existing fixed or mobile CT scanner service, EXCEPT FOR AN APPLICANT APPROVED UNDER SECTION 3(1), shall demonstrate that a proposed project meets all of the following:

- 433 (a) The requirements of sections 5, 7, or 9, as applicable, have been met.
434 (b) For an application for the proposed first acquisition of an existing fixed or mobile CT scanner
435 service, for which a final decision has not been issued after June 4, 2004, an existing CT scanner service
436 to be acquired shall not be required to be in compliance with the volume requirement applicable to the
437 seller/lessor on the date the acquisition occurs. The CT scanner service shall be operating at the
438 applicable volume requirements set forth in Section 19 of these standards in the second 12 months after
439 the date the service is acquired, and annually thereafter.
440 (c) For any application for proposed acquisition of an existing fixed or mobile CT scanner service, an
441 applicant shall be required to demonstrate that the CT scanner service to be acquired performed at least
442 7,500 CT equivalents in the most recent 12-month period for which the Department has verifiable data.
443

- 444 (2) An applicant proposing to acquire an existing fixed or mobile CT scanner(s) of an existing fixed or
445 mobile CT scanner service shall demonstrate that the proposed project meets all of the following:
446 (a) The requirements of sections 5, 7 or 9, as applicable, have been met.
447 (b) For any application for proposed acquisition of an existing fixed or mobile CT scanner(s) of an
448 existing fixed or mobile CT scanner service, an applicant shall be required to demonstrate that the fixed or
449 mobile CT scanner(s) to be acquired performed at least 7,500 CT equivalents in the most recent 12-
450 month period for which the Department has verifiable data.
451

452 | **Section 4210. Requirements for approval for applicants proposing to acquire an existing dental**
453 **CT scanner service or an existing dental CT scanner(s)**
454

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

- 457 (a) The requirements of sections 6, 8, or 10, as applicable, have been met.
458 (b) For an application for the proposed first acquisition of an existing fixed OR MOBILE dental CT
459 scanner service, for which a final decision has not been issued after the effective date of these standards,
460 an existing dental CT scanner service to be acquired shall not be required to be in compliance with the
461 volume requirement applicable to the seller/lessor on the date the acquisition occurs. The dental CT
462 scanner service shall be operating at the applicable volume requirements set forth in Section 19 of these
463 standards in the second 12 months after the date the service is acquired, and annually thereafter.
464 (c) For any application for proposed acquisition of an existing fixed OR MOBILE dental CT scanner
465 service, an applicant shall be required to demonstrate that the CT scanner service to be acquired
466 performed at least 200 dental CT examinations in the most recent 12-month period, for which the
467 Department has verifiable data.

- 468 (2) An applicant proposing to acquire an existing fixed dental CT scanner(s) of an existing fixed OR
469 MOBILE dental CT scanner service shall demonstrate that the proposed project meets all of the following:
470 (a) The requirements of sections 6, 8, or 10, as applicable, have been met.
471 (b) For any application for proposed acquisition of an existing fixed OR MOBILE dental CT scanner(s)
472 of an existing fixed OR MOBILE dental CT scanner service, an applicant shall be required to demonstrate
473 that the fixed OR MOBILE dental CT scanner(s) to be acquired performed at least 200 dental CT
474 examinations in the most recent 12-month period for which the Department has verifiable data.
475

476 | SECTION 11. REQUIREMENTS FOR A DEDICATED RESEARCH FIXED CT SCANNER
477

478 | SEC. 11. AN APPLICANT PROPOSING TO ADD A FIXED CT SCANNER TO AN EXISTING CT
479 SCANNER SERVICE FOR EXCLUSIVE RESEARCH USE SHALL DEMONSTRATE THE FOLLOWING:
480

481 | (1) THE APPLICANT AGREES THAT THE DEDICATED RESEARCH CT SCANNER WILL BE
482 USED PRIMARILY (70% OR MORE OF THE SCANS) FOR RESEARCH PURPOSES ONLY.
483

484 | (2) THE DEDICATED RESEARCH CT SCANNER SHALL OPERATE UNDER A PROTOCOL
485 APPROVED BY THE APPLICANT'S INSTITUTIONAL REVIEW BOARD, AS DEFINED BY PUBLIC LAW
486 93-348 AND REGULATED BY TITLE 45 CFR 46.

487
488 (3) THE PROPOSED SITE CAN HAVE NO MORE THAN THREE DEDICATED RESEARCH FIXED
489 CT SCANNERS APPROVED UNDER THIS SECTION.

490
491 (4) THE DEDICATED RESEARCH SCANNER APPROVED UNDER THIS SECTION MAY NOT
492 UTILIZE CT PROCEDURES PERFORMED ON THE DEDICATED CT SCANNER TO DEMONSTRATE
493 NEED OR TO SATISFY CT CON REVIEW STANDARDS REQUIREMENTS. [A7]

494
495 **Section 12. Requirements for approval of an applicant proposing a CT scanner used for the sole**
496 **purpose of performing dental CT examinations exclusively for research**

497
498 Sec. 12. (1) An applicant proposing a CT scanner used for the sole purpose of performing dental CT
499 examinations exclusively for research shall demonstrate each of the following:

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

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

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

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

507
508 **Section 13. Pilot program requirements for approval of a hospital-based portable CT scanner for**
509 **initiation, expansion, replacement, and acquisition**

510
511 Sec. 13. As a pilot program, an applicant proposing to initiate, expand, replace, or acquire a hospital-
512 based portable CT scanner shall demonstrate that it meets all of the following:

513
514 (1) An applicant is limited to the initiation, expansion, replacement, or acquisition of no more than two
515 hospital-based portable CT scanners.

516
517 (2) The proposed site is a hospital licensed under Part 215 of the Code.

518
519 (3) The hospital has been certified as a level I or level II trauma facility by the American College of
520 Surgeons, or has performed >100 craniotomies in the most recent 12- month period verifiable by the
521 Department.

522
523 (4) The applicant agrees to operate the hospital-based portable CT scanner in accordance with all
524 applicable project delivery requirements set forth in Section 19 of these standards.

525
526 (5) The approved hospital-based portable CT scanner will not be subject to CT volume requirements.

527
528 (6) The applicant may not utilize CT procedures performed on a hospital-based portable CT scanner
529 to demonstrate need or to satisfy CT CON review standards requirements.

530
531 (7) The Commission may decide to have the requirements of the pilot program described in this
532 section become a permanent part of the CT scanner services standards. If the Commission does not take
533 action to make the pilot program a permanent part of the standards, the provisions of Section 13, as part
534 of a pilot program, will expire on December 31, 2016 and be of no further force and effect after December
535 31, 2016. Any applicant seeking to be part of the pilot program described in this section must submit its
536 application on or before December 1, 2013. These provisions shall not be applicable to any application
537 which has not been submitted by December 1, 2013.

538
539 **Section 14. Requirements for approval of a PET/CT hybrid for initiation, expansion, replacement,**
540 **and acquisition**

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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 19 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

(c) SURGICAL SERVICES

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

(a) CARDIAC CATHETERIZATION LAB; OR

(b) INTERVENTIONAL RADIOLOGY SUITE; OR

(c) LICENSED OPERATING ROOM

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

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

(7) THE APPLICANT SHALL NOT UTILIZE THE PROCEDURES PERFORMED ON THE CT-ANGIO HYBRID UNIT TO DEMONSTRATE NEED OR TO SATISFY CT CON REVIEW STANDARDS REQUIREMENTS.^[A8]

Section ~~15~~16. Additional requirements for approval of a mobile CT scanner service

- 595 | Sec. ~~1516~~. (1) An applicant proposing to initiate a mobile CT scanner service in Michigan shall
596 demonstrate that it meets all of the following:
597 (a) A separate CON application shall be submitted by the central service coordinator and each
598 Michigan host facility.
599 (b) The normal route schedule, the procedures for handling emergency situations, and copies of all
600 potential contracts related to the mobile CT scanner service shall be included in the CON application
601 submitted by the central service coordinator.
602 (c) The requirements of sections 3, 5, or 7, as applicable, have been met.
603
604 (2) An applicant proposing to become a host facility on an existing mobile CT scanner network shall
605 demonstrate that it meets all of the following:
606 (a) Approval of the application will not result in an increase in the number of operating mobile CT
607 scanners for the mobile CT scanner network unless the requirements of Section 5 have been met.
608 (b) A separate CON application has been filed for each host facility.
609
610 (3) An applicant proposing to replace a central service coordinator on an existing mobile CT scanner
611 network shall demonstrate that approval of the application will not replace the CT scanner and
612 transporting equipment unless the applicable requirements of Section 7 have been met.
613

614 | **SECTION 17. ADDITIONAL REQUIREMENTS FOR APPROVAL OF A MOBILE DENTAL CT**
615 **SCANNER SERVICE**

616 | SEC. 17. (1) AN APPLICANT PROPOSING TO INITIATE A MOBILE DENTAL CT SCANNER
617 SERVICE IN MICHIGAN SHALL DEMONSTRATE THAT IT MEETS ALL OF THE FOLLOWING:

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

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

624 | (C) THE REQUIREMENTS OF SECTIONS 4, 6 OR 8, AS APPLICABLE, HAVE BEEN MET.
625

626 | (2) AN APPLICANT PROPOSING TO BECOME A HOST FACILITY ON AN EXISTING MOBILE
627 DENTAL CT SCANNER NETWORK SHALL DEMONSTRATE THAT IT MEETS ALL OF THE
628 FOLLOWING:

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

632 | (B) A SEPARATE CON APPLICATION HAS BEEN FILED FOR EACH HOST FACILITY.
633

634 | (3) AN APPLICANT PROPOSING TO REPLACE A CENTRAL SERVICE COORDINATOR ON AN
635 EXISTING MOBILE DENTAL CT SCANNER NETWORK SHALL DEMONSTRATE THAT APPROVAL OF
636 THE APPLICATION WILL NOT REPLACE THE DENTAL CT SCANNER AND TRANSPORTING
637 EQUIPMENT UNLESS THE APPLICABLE REQUIREMENTS OF SECTION 8 HAVE BEEN MET.
638

639 | ~~**Section 1615. Requirements for approval of an applicant proposing a CT scanner used for the**~~
640 ~~**sole purpose of performing dental CT examinations exclusively for research**~~
641

642 | ~~— Sec. 1615. (1) An applicant proposing a CT scanner used for the sole purpose of performing dental~~
643 ~~CT examinations exclusively for research shall demonstrate each of the following:~~
644

645 | ~~— (a) The applicant operates a dental radiology program in a certified dental school.~~
646
647

648 | ~~—(b) The research dental CT scanner shall operate under a protocol approved by the applicant's~~
649 | ~~institutional review board.~~
650 | ~~—(c) The applicant agrees to operate the research dental CT scanner in accordance with the terms of~~
651 | ~~approval in Section 19(4).~~
652 | ~~—(2) An applicant meeting the requirements of subsection (1) shall also demonstrate compliance with~~
653 | ~~the requirements of sections 4(2), 4(4) and 4(5).~~

654 |
655 | **Section 4718. Requirements for approval of an applicant proposing to establish dedicated**
656 | **pediatric CT Scanner**

657 |
658 | Sec. 4718. (1) An applicant proposing to establish dedicated pediatric CT shall demonstrate all of the
659 | following:

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

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

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

667 | (i) pediatric radiology (at least two)

668 | (ii) pediatric anesthesiology

669 | (iii) pediatric cardiology

670 | (iv) pediatric critical care

671 | (v) pediatric gastroenterology

672 | (vi) pediatric hematology/oncology

673 | (vii) pediatric neurology

674 | (viii) pediatric neurosurgery

675 | (ix) pediatric orthopedic surgery

676 | (x) pediatric pathology

677 | (xi) pediatric pulmonology

678 | (xii) pediatric surgery

679 | (xiii) neonatology

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

682 | (i) pediatric bone marrow transplant program

683 | (ii) established pediatric sedation program

684 | (iii) pediatric open heart program

685 |

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

688 |

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

690 |

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

694 |

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

696 |

697 | Sec^[A9]. 4920. (1) An applicant shall agree that, if approved, the ~~services provided by the~~ CT
698 | scanner(s) SERVICES shall be delivered in compliance with the following terms of ~~CON~~ approval:

699 | (a1) Compliance with these standards.

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

701 |

- 702 | (e2) Compliance with the following quality assurance standards:
- 703 | ~~(i) The approved CT scanners shall be operating at the applicable required volumes within the time~~
- 704 | ~~periods specified in these standards, and annually thereafter.~~
- 705 | (ii) The applicant shall establish a mechanism to assure that the CT scanner facility is staffed so that:
- 706 | (A) The screening of requests for CT procedures and interpretation of CT procedures will be
- 707 | performed by physicians with training and experience in the appropriate diagnostic use and interpretation
- 708 | of cross-sectional images of the anatomical region(s) to be examined, and
- 709 | (B) The CT scanner is operated by physicians and/or is operated by radiological technologists
- 710 | qualified by training and experience to operate the CT scanner safely and effectively.
- 711 | For purposes of evaluating (ii)(A), the Department shall consider it prima facie evidence of a
- 712 | satisfactory assurance mechanism as to screening and interpretation if the applicant requires the
- 713 | screening of requests for and interpretations of CT procedures to be performed by physicians who are
- 714 | board certified or eligible in radiology or are neurologists or other specialists trained in cross-sectional
- 715 | imaging of a specific organ system. For purposes of evaluating (ii)(B) the Department shall consider it
- 716 | prima facie evidence of a satisfactory assurance mechanism as to the operation of a CT scanner if the
- 717 | applicant requires the CT scanner to be operated by a physician or by a technologist registered by the
- 718 | American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography
- 719 | Technologists (ARCRT). However, the applicant may submit and the Department may accept other
- 720 | evidence that the applicant has established a mechanism to assure that the CT scanner facility is
- 721 | appropriately and adequately staffed as to screening, interpretation, and/or operation of a CT scanner.
- 722 | (iii) The applicant shall employ or contract with a radiation physicist to review the quality and safety of
- 723 | the operation of the CT scanner.
- 724 | (iv) The applicant shall assure that at least one of the physicians responsible for the screening and
- 725 | interpretation as defined in subsection (ii)(A) will be in the CT facility or available on a 24-hour basis
- 726 | (either on-site or through telecommunication capabilities) to make the final interpretation.
- 727 | (v) In the case of an urgent or emergency CT scan, the applicant shall assure that a physician so
- 728 | authorized by the applicant to interpret initial scans will be on-site or available through telecommunication
- 729 | capabilities within 1 hour following completion of the scanning procedure to render an initial interpretation
- 730 | of the scan. A final interpretation shall be rendered by a physician so authorized under subsection (ii)(A)
- 731 | within 24 hours.
- 732 | (vi) The applicant shall have, within the CT scanner facility, equipment and supplies to handle clinical
- 733 | emergencies that might occur within the CT unit, with CT facility staff trained in CPR and other appropriate
- 734 | emergency interventions, and a physician on site in or immediately available to the CT scanner at all times
- 735 | when patients are undergoing scans.
- 736 | (vii) Fixed CT scanner services at each facility shall be made available 24 hours a day for emergency
- 737 | patients.
- 738 | (viii) The applicant shall accept referrals for CT scanner services from all appropriately licensed
- 739 | practitioners.
- 740 | (ix) The applicant shall establish and maintain: (a) a standing medical staff and governing body (or its
- 741 | equivalent) requirement that provides for the medical and administrative control of the ordering and
- 742 | utilization of CT patient procedures, and (b) a formal program of utilization review and quality assurance.
- 743 | These responsibilities may be assigned to an existing body of the applicant, as appropriate.
- 744 | (x) An applicant approved under Section 17 must be able to prove that all radiologists, technologists
- 745 | and nursing staff working with CT patients have continuing education or in-service training on pediatric
- 746 | low-dose CT. The site must also be able to provide evidence of defined low-dose pediatric CT protocols.

747 | _____

748 | (3) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:

- 749 | ~~(xi)~~ The applicant, to assure that the CT scanner will be utilized by all segments of the Michigan
- 750 | population, shall:
- 751 | (A) not deny ANY CT scanner services to any individual based on ability to pay or source of payment;
- 752 | (B) provide ALL CT scanning services to any individual based on the clinical indications of need for
- 753 | the service; and
- 754 | (C) maintain information by payor and non-paying sources to indicate the volume of care from each
- 755 | source provided annually.

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

758 (c) The operation of and referral of patients to the CT scanner shall be in conformance with 1978 PA
759 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

760
761 Compliance with selective contracting requirements shall not be construed as a violation of this term.

762
763 (4) COMPLIANCE WITH THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:

764 (ia) The approved CT scanners shall be operating at the applicable required volumes AN AVERAGE
765 within the time periods specified in these standards, OF 7,500 CT EQUIVALENTS SCANNER PER FIXED
766 SCANNER AND 3,500 CT EQUIVALENTS PER MOBILE SCANNER PER YEAR FOR THE SECOND 12-
767 MONTH PERIOD AFTER BEGINNING OPERATION OF THE CT SCANNER, and annually thereafter.

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

776 (xiic) Equipment to be replaced shall be removed from service.

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

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

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

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

786
787
788 (5) COMPLIANCE WITH THE FOLLOWING DENTAL CT SCANNER REQUIREMENTS, IF
789 APPLICABLE:

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

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

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

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

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

808 (Ai) not deny dental CT scanner services to any individual based on ability to pay or source of
809 payment;

810 | (Bii) provide dental CT scanning services to any individual based on the clinical indications of need for
811 | the service; and

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

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

817 | (viig) The applicant shall participate in a data collection network established and administered by the
818 | Department or its designee. The data may include, but is not limited to, annual budget and cost
819 | information, operating schedules, through-put schedules, demographic and diagnostic information, the
820 | volume of care provided to patients from all payor sources, and other data requested by the Department,
821 | and approved by the Commission. The applicant shall provide the required data on a separate basis for
822 | each separate and distinct site as required by the Department; in a format established by the Department;
823 | and in a mutually agreed upon media. The Department may elect to verify the data through on-site review
824 | of appropriate records.

825 | (viiih) Equipment to be replaced shall be removed from service.

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

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

832 | ~~-(2ei) The agreements and assurances required by this section shall be in the form of a certification~~
833 | ~~agreed to by the applicant or its authorized agent.~~

834 |
835 | ~~—(3) The operation of and referral of patients to the CT scanner shall be in conformance with 1978 PA~~
836 | ~~368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).~~

838 | (46) An applicant for a CT scanner used for dental research under Section ~~4618~~(1) shall agree that the
839 | services provided by the CT scanner approved pursuant to Section 16(1) shall be delivered in compliance
840 | with the following terms of CON approval:

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

844 | (b) The CT scanner used for dental research approved pursuant to Section ~~4612~~(1) shall not be used
845 | for any purposes other than as approved by the institutional review board unless the applicant has
846 | obtained CON approval for the CT scanner pursuant to part 222 and these standards, other than Section
847 | ~~4612~~.

849 | (~~57~~) An applicant approved under Section 13 shall be in compliance with the following:

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

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

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

853 | (b) The approved applicant must provide annual reports to the Department by January 31st of each
854 | year for the preceding calendar year. This requirement applies to all applicants approved under Section
855 | 13 and begins with 2010 data which is to be reported in 2011.

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

857 | (i) Number of adult studies (age>=18)

858 | (ii) Number of pediatric studies (age<18)

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

861 | (iv) Number of patients scanned on a portable CT that underwent subsequent scanning on a fixed CT
862 | within 12 hours of the portable CT scan

863 |

864 (8) AN APPLICANT APPROVED UNDER SECTION 15 SHALL BE IN COMPLIANCE WITH THE
865 FOLLOWING^[A10]:

866 (a) THE PROPOSED SITE OFFERS THE FOLLOWING SERVICES:

867 (i) DIAGNOSTIC CARDIAC CATHETERIZATION; OR

868 (ii) INTERVENTIONAL RADIOLOGY; OR

869 (iii) SURGICAL SERVICES

870 (b) THE PROPOSED CT-ANGIO HYBRID UNIT MUST BE LOCATED IN ONE OF THE
871 FOLLOWING ROOMS:

872 (i) CARDIAC CATHETERIZATION LAB; OR

873 (ii) INTERVENTIONAL RADIOLOGY SUITE; OR

874 (iii) LICENSED OPERATING ROOM

875
876 (29) The agreements and assurances required by this section shall be in the form of a certification
877 agreed to by the applicant or its authorized agent.

878
879 **Section 2021. Project delivery requirements AND additional terms of approval for applicants**
880 **involving mobile CT scanners**

881
882 | Sec. 2021. (1) In addition to the provisions of Section 19, an applicant for a mobile CT scanner shall
883 agree that the services provided by the mobile CT scanner(s) shall be delivered in compliance with the
884 following terms of CON approval:

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

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

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

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

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

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

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

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

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

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

915
916 (2) The agreements and assurances required by this section shall be in the form of a certification
917 agreed to by the applicant or its authorized agent.

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Section 2422. Determination of CT Equivalents

Sec. 2422. CT equivalents shall be calculated as follows:

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

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

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

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

Category	Number of Billable CT Procedures		Conversion Factor	=	CT Equivalents
Head Scans w/o Contrast (includes dental CT examinations)	_____	X	1.00	=	_____
Head Scans with Contrast	_____	X	1.25	=	_____
Head Scans w/o & w Contrast	_____	X	1.75	=	_____
Body Scans w/o Contrast	_____	X	1.50	=	_____
Body Scans with Contrast	_____	X	1.75	=	_____
Body Scans w/o & w Contrast	_____	X	2.75	=	_____
Pediatric/Special Needs Patient Head scans w/o Contrast (includes dental CT examinations)	_____	x	1.25	=	_____
Pediatric/Special Needs Patient Head Scans with Contrast	_____	x	1.50	=	_____
Pediatric/Special Needs Patient Head Scans w/o & with Contrast	_____	x	2.00	=	_____
Pediatric/Special Needs Patient Body Scans w/o Contrast	_____	x	1.75	=	_____
Pediatric/Special Needs Patient Body Scans with Contrast	_____	x	2.00	=	_____
Pediatric/Special Needs Patient Body Scans w/o & with Contrast	_____	x	3.00	=	_____
Total CT Equivalents					_____

Section 2223. Documentation of projections

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

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

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

- 973 (a) the number of dental procedures performed by the applicant, and
- 974 (b) the number of committed dental procedures performed by referring licensed dentists. Further, the
975 applicant and the referring licensed dentists shall substantiate the numbers through the submission of
976 HIPAA compliant billing records.

977
978 (3) An applicant required to project under Section 5 shall demonstrate that the projection is based on
979 historical utilization at the applicant's site for the most recent 12-month period immediately preceding the
980 date of the application.

981
982 (4) An applicant shall demonstrate that the projected number of referrals to be performed at the
983 proposed site under subsections (1) ~~and (2)~~ are from an existing CT scanner service that is in compliance
984 with the volume requirements applicable to that service, and will continue to be in compliance with the
985 volume requirements applicable to that service subsequent to the initiation of the proposed CT scanner
986 service by an applicant. **THIS DOES NOT INCLUDE DENTAL CT SCANNERS.** Only excess CT
987 equivalents equal to or greater than what is being committed pursuant to this subsection may be used to
988 document projections under subsection (1). In demonstrating compliance with this subsection, an
989 applicant shall provide each of the following:

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

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

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

1000
1001 | **Section ~~2324~~. Effect on prior CON review standards; comparative reviews**

1002
1003 | Sec. ~~2324~~. (1) These CON review standards supersede and replace the CON Review Standards
1004 for Computed Tomography Scanner Services approved by the CON Commission on ~~April 30,~~
1005 ~~2008~~DECEMBER 15, 2011 and ~~effective on June 20, 2008~~FEBRUARY 27, 2012.

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1007 | (2) Projects reviewed under these standards shall not be subject to comparative review.
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Section 24. Health Service Areas

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

HEALTH SERVICE AREA

COUNTIES

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

1053 |

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1055 Rural Michigan counties are as follows:

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1057	Alcona	Hillsdale	Ogemaw
1058	Alger	Huron	Ontonagon
1059	Antrim	Iosco	Osceola
1060	Arenac	Iron	Oscoda
1061	Baraga	Lake	Otsego
1062	Charlevoix	Luce	Presque Isle
1063	Cheboygan	Mackinac	Roscommon
1064	Clare	Manistee	Sanilac
1065	Crawford	Mason	Schoolcraft
1066	Emmet	Montcalm	Tuscola
1067	Gladwin	Montmorency	
1068	Gogebic	Oceana	

1069

1070 Micropolitan statistical area Michigan counties are as follows:

1071

1072	Allegan	Gratiot	Mecosta
1073	Alpena	Houghton	Menominee
1074	Benzie	Isabella	Midland
1075	Branch	Kalkaska	Missaukee
1076	Chippewa	Keweenaw	St. Joseph
1077	Delta	Leelanau	Shiawassee
1078	Dickinson	Lenawee	Wexford
1079	Grand Traverse	Marquette	

1080

1081 Metropolitan statistical area Michigan counties are as follows:

1082

1083	Barry	Ionia	Newaygo
1084	Bay	Jackson	Oakland
1085	Berrien	Kalamazoo	Ottawa
1086	Calhoun	Kent	Saginaw
1087	Cass	Lapeer	St. Clair
1088	Clinton	Livingston	Van Buren
1089	Eaton	Macomb	Washtenaw
1090	Genesee	Monroe	Wayne
1091	Ingham	Muskegon	

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1093 Source:

1094 65 F.R., p. 82238 (December 27, 2000)

1095 Statistical Policy Office

1096 Office of Information and Regulatory Affairs

1097 United States Office of Management and Budget