

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

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

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

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

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

Comment [A1]: Need definition for CT-angio hybrid unit including correct terminology if adding requirements to the standards.

Comment [A2]: Remainder of subsection (1) will need to be renumbered if definition for CT-angio is added.

- 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, 1396-6 and 1396-  
95 8 to ~~1396v1396w-5~~ 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.

Comment [A3]: Response to #4 CT Workgroup charge and evaluation section.

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

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

175 (1) An applicant is proposing a DENTAL ~~fixed~~ CT scanner service for the sole purpose of performing dental CT examinations.

Comment [A4]: Response to #1 CT Workgroup Charge

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

Comment [A5]: Will this be different for mobile?

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

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

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

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

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

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

214 (3) If an applicant proposes to expand an existing mobile CT scanner service, the applicant shall demonstrate that all of the applicant's mobile CT scanners have performed an average of at least 5,500 CT equivalents per mobile CT scanner for the most recent continuous 12-month period preceding the

217 applicant's request. In computing this average, the Department will divide the total number of CT  
218 equivalents performed by the applicant's total number of mobile CT scanners, including both operational  
219 and approved but not operational mobile CT scanners.

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

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

Comment [A6]: Response to #1 CT  
Workgroup Charge

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

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

237  
238 (1) An applicant, other than an applicant meeting all of the applicable requirements of subsection (a),  
239 (b) or (c) below, proposing to replace an existing fixed CT scanner shall demonstrate that the fixed CT  
240 scanner(s) performed at least an average of 7,500 CT equivalents per fixed CT scanner in the most  
241 recent 12-month period for which the Department has verifiable data.

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

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

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

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

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

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

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

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

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

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

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

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

266  
267 (2) An applicant proposing to replace an existing mobile CT scanner(s) shall demonstrate that the  
268 mobile CT scanner(s) performed at least 3,500 CT equivalents if the applicant operates only one mobile  
269 CT scanner or an average of 5,500 CT equivalents for each CT scanner if the applicant operates more

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

272  
273 (3) An applicant proposing to replace an existing dedicated pediatric CT scanner(s) shall demonstrate  
274 that the dedicated pediatric CT scanner(s) performed at least an average of 2,500 CT equivalents per  
275 dedicated pediatric CT scanner in the most recent 12-month period for which the Department has  
276 verifiable data.

277  
278 (4) An applicant under this section shall demonstrate that the existing CT scanner(s) proposed to be  
279 replaced is fully depreciated according to generally accepted accounting principles, or, that the existing  
280 equipment clearly poses a threat to the safety of the public, or, that the proposed replacement CT scanner  
281 offers technological improvements which enhance quality of care, increase efficiency, and/or reduce  
282 operating costs and patient charges.

283  
284 (5) An applicant proposing to ~~relocate~~REPLACE an existing fixed CT scanner service TO A  
285 DIFFERENT SITE shall demonstrate that the proposed project meets all of the following:

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

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

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

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

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

297  
298 (6) An applicant proposing to ~~relocate~~REPLACE a fixed CT scanner(s) of an existing CT scanner  
299 service TO A DIFFERENT SITE shall demonstrate that the proposed project meets all of the following:

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

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

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

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

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

312

313

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

316

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

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

323

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

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

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

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

336  
337 ~~(c) The proposed new site is in the relocation ZONE~~WITHIN A 10-MILE RADIUS OF A SITE AT  
338 WHICH AN EXISTING FIXED DENTAL CT SCANNER SERVICE IS LOCATED IF AN EXISTING FIXED  
339 DENTAL CT SCANNER SERVICE IS LOCATED IN A METROPOLITAN STATISTICAL AREA COUNTY,  
340 OR A 20-MILE RADIUS IF AN EXISTING FIXED DENTAL CT SCANNER SERVICE IS LOCATED IN A  
341 RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY.

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

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

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

348  
349 ~~(4) An applicant proposing to relocate~~REPLACE a fixed dental CT scanner(s) of an existing dental  
350 CT scanner service TO A DIFFERENT SITE shall demonstrate that the proposed project meets all of the  
351 following:

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

355  
356 ~~(B) FOR VOLUME PURPOSES, THE NEW SITE SHALL REMAIN ASSOCIATED WITH THE~~  
357 ~~EXISTING CT SERVICE FOR A MINIMUM OF THREE YEARS.~~

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

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

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

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

369  
370 ~~**Section 9. Requirements for approval for applicants proposing to relocate an existing CT scanner**~~  
371 ~~**service and/or CT scanner(s) other than an existing dental CT scanner service and/or dental CT**~~  
372 ~~**scanner(s) or hospital-based portable CT scanner(s)**~~

373  
374 ~~Sec. 9. (1) An applicant proposing to relocate an existing fixed CT scanner service shall demonstrate~~  
375 ~~that the proposed project meets all of the following:~~

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

- 378 ~~—(b) The proposed new site is in the relocation zone.~~  
379 ~~—(c) The requirements of sections 5 or 7, as applicable, have been met.~~  
380 ~~—(d) The CT scanner service to be relocated performed at least an average of 7,500 CT equivalents~~  
381 ~~per fixed scanner in the most recent 12-month period for which the Department has verifiable data.~~  
382 ~~—(e) The applicant agrees to operate the CT scanner service in accordance with all applicable project~~  
383 ~~delivery requirements set forth in Section 19 of these standards.~~  
384  
385 ~~—(2) An applicant proposing to relocate a fixed CT scanner(s) of an existing CT scanner service shall~~  
386 ~~demonstrate that the proposed project meets all of the following:~~  
387 ~~—(a) The existing CT scanner service from which the CT scanner(s) is to be relocated has been in~~  
388 ~~operation for at least 36 months as of the date an application is submitted to the Department.~~  
389 ~~—(b) The proposed new site is in the relocation zone.~~  
390 ~~—(c) The requirements of sections 5 or 7, as applicable, have been met.~~  
391 ~~—(d) Each existing CT scanner at the service from which a scanner is to be relocated performed at~~  
392 ~~least an average of 7,500 CT equivalents per fixed scanner in the most recent 12-month period for which~~  
393 ~~the Department has verifiable data.~~  
394 ~~—(e) The applicant agrees to operate the CT scanner(s) at the proposed site in accordance with all~~  
395 ~~applicable project delivery requirements set forth in Section 19 of these standards.~~  
396  
397

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

- 400  
401 ~~—Sec. 10. (1) An applicant proposing to relocate an existing fixed dental CT scanner service shall~~  
402 ~~demonstrate that the proposed project meets all of the following:~~  
403 ~~—(a) The existing fixed dental CT scanner service to be relocated has been in operation for at least 36~~  
404 ~~month as of the date an application is submitted to the Department.~~  
405 ~~—(b) The proposed new site is in the relocation zone.~~  
406 ~~—(c) The requirements of sections 6 or 8, as applicable, have been met.~~  
407 ~~—(d) The dental CT scanner service to be relocated performed at least an average of 200 dental CT~~  
408 ~~examinations per fixed dental CT scanner in the most recent 12-month period for which the Department~~  
409 ~~has verifiable data.~~  
410 ~~—(e) The applicant agrees to operate the dental CT scanner service in accordance with all applicable~~  
411 ~~project delivery requirements set forth in Section 19 of these standards.~~  
412  
413 ~~—(2) An applicant proposing to relocate a fixed dental CT scanner(s) of an existing dental CT scanner~~  
414 ~~service shall demonstrate that the proposed project meets all of the following:~~  
415 ~~—(a) The existing dental CT scanner service from which the dental CT scanner(s) is to be relocated~~  
416 ~~has been in operation for at least 36 months as of the date an application is submitted to the Department.~~  
417 ~~—(b) The proposed new site is in the relocation zone.~~  
418 ~~—(c) The requirements of sections 6 or 8, as applicable have been met.~~  
419 ~~—(d) Each existing dental CT scanner at the service from which a scanner is to be relocated performed~~  
420 ~~at least an average of 200 dental CT examinations per fixed dental CT scanner in the most recent 12-~~  
421 ~~month period for which the Department has verifiable data.~~  
422 ~~—(e) The applicant agrees to operate the dental CT scanner(s) at the proposed site in accordance with~~  
423 ~~all applicable project delivery requirements set forth in Section 19 of these standards.~~  
424

425 **Section 449. Requirements for approval for applicants proposing to acquire an existing CT**  
426 **scanner service or an existing CT scanner(s) other than an existing dental CT scanner service**  
427 **and/or an existing dental CT scanner(s) or hospital-based portable CT scanner(s)**

- 428  
429 ~~Sec. 449. (1) An applicant proposing to acquire an existing fixed or mobile CT scanner service,~~  
430 ~~EXCEPT FOR AN APPLICANT APPROVED UNDER SECTION 3(1), shall demonstrate that a proposed~~  
431 ~~project meets all of the following:~~

432 (a) The requirements of sections 5, 7, or 9, as applicable, have been met.  
433 (b) For an application for the proposed first acquisition of an existing fixed or mobile CT scanner  
434 service, for which a final decision has not been issued after June 4, 2004, an existing CT scanner service  
435 to be acquired shall not be required to be in compliance with the volume requirement applicable to the  
436 seller/lessor on the date the acquisition occurs. The CT scanner service shall be operating at the  
437 applicable volume requirements set forth in Section 19 of these standards in the second 12 months after  
438 the date the service is acquired, and annually thereafter.

439 (c) For any application for proposed acquisition of an existing fixed or mobile CT scanner service, an  
440 applicant shall be required to demonstrate that the CT scanner service to be acquired performed at least  
441 7,500 CT equivalents in the most recent 12-month period for which the Department has verifiable data.  
442

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

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

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

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

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

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

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

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

473 | **SECTION 11. REQUIREMENTS FOR A DEDICATED RESEARCH FIXED CT SCANNER**

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

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

478 | **(2) THE DEDICATED RESEARCH CT SCANNER SHALL OPERATE UNDER A PROTOCOL**  
479 **APPROVED BY THE APPLICANT'S INSTITUTIONAL REVIEW BOARD, AS DEFINED BY PUBLIC LAW**  
480 **93-348 AND REGULATED BY TITLE 45 CFR 46.**  
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(3) THE PROPOSED SITE CAN HAVE NO MORE THAN THREE DEDICATED RESEARCH FIXED CT SCANNERS APPROVED UNDER THIS SECTION.

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

Comment [A7]: Response to #3 CT Workgroup Charge

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

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

- (a) The applicant operates a dental radiology program in a certified dental school.
  - (b) The research dental CT scanner shall operate under a protocol approved by the applicant's institutional review board.
  - (c) The applicant agrees to operate the research dental CT scanner in accordance with the terms of approval in Section 19(4).
- (2) An applicant meeting the requirements of subsection (1) shall also demonstrate compliance with the requirements of sections 4(2), 4(4) and 4(5).

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

Sec. 13. As a pilot program, 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 19 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.
- (7) The Commission may decide to have the requirements of the pilot program described in this section become a permanent part of the CT scanner services standards. If the Commission does not take action to make the pilot program a permanent part of the standards, the provisions of Section 13, as part of a pilot program, will expire on December 31, 2016 and be of no further force and effect after December 31, 2016. Any applicant seeking to be part of the pilot program described in this section must submit its application on or before December 1, 2013. These provisions shall not be applicable to any application which has not been submitted by December 1, 2013.

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

- 540  
541 Sec. 14. An applicant proposing to initiate, expand, replace, or acquire a PET/CT hybrid shall  
542 demonstrate that it meets all of the following:  
543  
544 (1) There is an approved PET CON for the PET/CT hybrid, and the PET/CT hybrid is in compliance  
545 with all applicable project delivery requirements as set forth in the CON review standards for PET.  
546  
547 (2) The applicant agrees to operate the PET/CT hybrid in accordance with all applicable project  
548 delivery requirements set forth in Section 19 of these standards.  
549  
550 (3) The approved PET/CT hybrid will not be subject to CT volume requirements.  
551  
552 (4) A PET/CT scanner hybrid approved under the CON Review Standards for PET Scanner Services  
553 and the Review Standards for CT Scanner Services may not utilize CT procedures performed on a hybrid  
554 scanner to demonstrate need or to satisfy CT CON review standards requirements.  
555

556 **SECTION 15. REQUIREMENTS FOR APPROVAL OF A CT-ANGIO HYBRID UNIT FOR INITIATION,**  
557 **REPLACEMENT, AND ACQUISITION**

558 **SEC. 15. AN APPLICANT PROPOSING TO INITIATE, REPLACE, OR ACQUIRE A HOSPITAL-**  
559 **BASED CT-ANGIO HYBRID UNIT SHALL DEMONSTRATE EACH OF THE FOLLOWING, AS**  
560 **APPLICABLE TO THE PROPOSED PROJECT:**  
561

562 **(1) THE PROPOSED SITE IS A LICENSED HOSPITAL UNDER PART 215 OF THE CODE.**  
563

564 **(2) THE PROPOSED SITE HAS AN EXISTING FIXED CT SCANNER SERVICE THAT HAS BEEN**  
565 **OPERATIONAL FOR THE PREVIOUS 36 CONSECUTIVE MONTHS AND IS MEETING ITS MINIMUM**  
566 **VOLUME REQUIREMENTS.**  
567

568 **(3) THE PROPOSED SITE OFFERS THE FOLLOWING SERVICES:**

569 **(a) DIAGNOSTIC CARDIAC CATHETERIZATION; OR**

570 **(b) INTERVENTIONAL RADIOLOGY; OR**

571 **(c) SURGICAL SERVICES**  
572

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

575 **(a) CARDIAC CATHETERIZATION LAB; OR**

576 **(b) INTERVENTIONAL RADIOLOGY SUITE; OR**

577 **(c) LICENSED OPERATING ROOM**  
578

579 **(5) DIAGNOSTIC CT STUDIES SHALL NOT BE PERFORMED ON A CT-ANGIO HYBRID UNIT**  
580 **APPROVED UNDER THIS SECTION UNLESS THE PATIENT IS CURRENTLY UNDERGOING A CT-**  
581 **ANGIO HYBRID INTERVENTIONAL PROCEDURE AND IS IN NEED OF A SECONDARY DIAGNOSTIC**  
582 **CT STUDY.**  
583

584 **(6) THE APPROVED CT-ANGIO HYBRID SHALL NOT BE SUBJECT TO CT VOLUME**  
585 **REQUIREMENTS.**  
586

587 **(7) THE APPLICANT SHALL NOT UTILIZE THE PROCEDURES PERFORMED ON THE CT-ANGIO**  
588 **HYBRID UNIT TO DEMONSTRATE NEED OR TO SATISFY CT CON REVIEW STANDARDS**  
589 **REQUIREMENTS.**  
590

591 **Section 4516. Additional requirements for approval of a mobile CT scanner service**  
592  
593

**Comment [A8]:** Response to Workgroup Charge #6 (which was added at the Workgroup meeting)

594 | Sec. ~~4516~~. (1) An applicant proposing to initiate a mobile CT scanner service in Michigan shall  
595 demonstrate that it meets all of the following:  
596 (a) A separate CON application shall be submitted by the central service coordinator and each  
597 Michigan host facility.  
598 (b) The normal route schedule, the procedures for handling emergency situations, and copies of all  
599 potential contracts related to the mobile CT scanner service shall be included in the CON application  
600 submitted by the central service coordinator.  
601 (c) The requirements of sections 3, 5, or 7, as applicable, have been met.  
602  
603 (2) An applicant proposing to become a host facility on an existing mobile CT scanner network shall  
604 demonstrate that it meets all of the following:  
605 (a) Approval of the application will not result in an increase in the number of operating mobile CT  
606 scanners for the mobile CT scanner network unless the requirements of Section 5 have been met.  
607 (b) A separate CON application has been filed for each host facility.  
608  
609 (3) An applicant proposing to replace a central service coordinator on an existing mobile CT scanner  
610 network shall demonstrate that approval of the application will not replace the CT scanner and  
611 transporting equipment unless the applicable requirements of Section 7 have been met.  
612

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

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

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

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

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

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

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

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

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

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

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

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

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

653  
654 | **Section 4718. Requirements for approval of an applicant proposing to establish dedicated**  
655 **pediatric CT Scanner**

656  
657 | Sec. 4718. (1) An applicant proposing to establish dedicated pediatric CT shall demonstrate all of the  
658 following:

- 659 (a) The applicant shall have experienced at least 7,000 pediatric (< 18 years old) discharges  
660 (excluding normal newborns) in the most recent year of operation.  
661 (b) The applicant shall have performed at least 5,000 pediatric (< 18 years old) surgeries in the most  
662 recent year of operation.  
663 (c) The applicant shall have an active medical staff, at the time the application is submitted to the  
664 Department that includes, but is not limited to, physicians who are fellowship-trained in the following  
665 pediatric specialties:  
666 (i) pediatric radiology (at least two)  
667 (ii) pediatric anesthesiology  
668 (iii) pediatric cardiology  
669 (iv) pediatric critical care  
670 (v) pediatric gastroenterology  
671 (vi) pediatric hematology/oncology  
672 (vii) pediatric neurology  
673 (viii) pediatric neurosurgery  
674 (ix) pediatric orthopedic surgery  
675 (x) pediatric pathology  
676 (xi) pediatric pulmonology  
677 (xii) pediatric surgery  
678 (xiii) neonatology  
679 (d) The applicant shall have in operation the following pediatric specialty programs at the time the  
680 application is submitted to the Department:  
681 (i) pediatric bone marrow transplant program  
682 (ii) established pediatric sedation program  
683 (iii) pediatric open heart program

684  
685 (2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the  
686 requirements of Section 3 of these standards.

687  
688 | **Section 4819. Requirements for MEDICAID approval ~~— all applicants~~ PARTICIPATION**

689  
690 | Sec. 4819. An applicant shall provide verification of Medicaid participation. An applicant that is a new  
691 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided  
692 to the Department within six (6) months from the offering of services if a CON is approved.

693  
694 | **Section 4920. Project delivery requirements ~~— AND~~ terms of approval for all applicants**

695  
696 | Sec. 4920. (1) An applicant shall agree that, if approved, the services provided by the CT scanner(s)  
697 SERVICES shall be delivered in compliance with the following terms of CON approval:  
698 (a1) Compliance with these standards.  
699 ~~— (b) Compliance with applicable safety and operating standards~~

Comment [A9]: CT Workgroup needs to Review the Project Delivery Requirements.

701 (e2) Compliance with the following quality assurance standards:

702 ~~—(i) The approved CT scanners shall be operating at the applicable required volumes within the time~~

703 ~~periods specified in these standards, and annually thereafter.~~

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

705 (Ai) The screening of requests for CT procedures and interpretation of CT procedures will be

706 performed by physicians with training and experience in the appropriate diagnostic use and interpretation

707 of cross-sectional images of the anatomical region(s) to be examined, and

708 (Bii) The CT scanner is operated by physicians and/or is operated by radiological technologists

709 qualified by training and experience to operate the CT scanner safely and effectively.

710 For purposes of evaluating (ia)(Ai), the Department shall consider it prima facie evidence of a

711 satisfactory assurance mechanism as to screening and interpretation if the applicant requires the

712 screening of requests for and interpretations of CT procedures to be performed by physicians who are

713 board certified or eligible in radiology or are neurologists or other specialists trained in cross-sectional

714 imaging of a specific organ system. For purposes of evaluating (ia)(B) the Department shall consider it

715 prima facie evidence of a satisfactory assurance mechanism as to the operation of a CT scanner if the

716 applicant requires the CT scanner to be operated by a physician or by a technologist registered by the

717 American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography

718 Technologists (ARCRT). However, the applicant may submit and the Department may accept other

719 evidence that the applicant has established a mechanism to assure that the CT scanner facility is

720 appropriately and adequately staffed as to screening, interpretation, and/or operation of a CT scanner.

721 (ib) The applicant shall employ or contract with a radiation physicist to review the quality and safety of

722 the operation of the CT scanner.

723 (ic) The applicant shall assure that at least one of the physicians responsible for the screening and

724 interpretation as defined in subsection (ia)(Ai) will be in the CT facility or available on a 24-hour basis

725 (either on-site or through telecommunication capabilities) to make the final interpretation.

726 (id) In the case of an urgent or emergency CT scan, the applicant shall assure that a physician so

727 authorized by the applicant to interpret initial scans will be on-site or available through telecommunication

728 capabilities within 1 hour following completion of the scanning procedure to render an initial interpretation

729 of the scan. A final interpretation shall be rendered by a physician so authorized under subsection (ia)(Ai)

730 within 24 hours.

731 (ie) The applicant shall have, within the CT scanner facility, equipment and supplies to handle clinical

732 emergencies that might occur within the CT unit, with CT facility staff trained in CPR and other appropriate

733 emergency interventions, and a physician on site in or immediately available to the CT scanner at all times

734 when patients are undergoing scans.

735 (if) Fixed CT scanner services at each facility shall be made available 24 hours a day for emergency

736 patients.

737 (iig) The applicant shall accept referrals for CT scanner services from all appropriately licensed

738 practitioners.

739 (ih) The applicant shall establish and maintain: (a) a standing medical staff and governing body (or its

740 equivalent) requirement that provides for the medical and administrative control of the ordering and

741 utilization of CT patient procedures, and (b) a formal program of utilization review and quality assurance.

742 These responsibilities may be assigned to an existing body of the applicant, as appropriate.

743 (xi) An applicant approved under Section 17 must be able to prove that all radiologists, technologists

744 and nursing staff working with CT patients have continuing education or in-service training on pediatric

745 low-dose CT. The site must also be able to provide evidence of defined low-dose pediatric CT protocols.

746

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

748 (xa) The applicant, to assure that the CT scanner will be utilized by all segments of the Michigan

749 population, shall:

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

751 (Bii) provide ALL CT scanning services to any individual based on the clinical indications of need for

752 the service; and

753 (Ciii) maintain information by payor and non-paying sources to indicate the volume of care from each

754 source provided annually.

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

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

759  
760 Compliance with selective contracting requirements shall not be construed as a violation of this term.

761  
762 (4) COMPLIANCE WITH THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:

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

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

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

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

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

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

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

785  
786  
787 (5) COMPLIANCE WITH THE FOLLOWING DENTAL CT SCANNER REQUIREMENTS, IF  
788 APPLICABLE:

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

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

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

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

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

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

809 | ~~(Bii)~~ provide dental CT scanning services to any individual based on the clinical indications of need for  
810 | the service; and  
811 | ~~(Ciii)~~ maintain information by payor and non-paying sources to indicate the volume of care from each  
812 | source provided annually. Compliance with selective contracting requirements shall not be construed as a  
813 | violation of this term.  
814 | ~~(f) The CT scanner shall be operating at least 200 CT equivalents per year for the second 12-month~~  
815 | ~~period after beginning operation of the dental CT scanner and annually thereafter.~~  
816 | ~~(viii)~~ The applicant shall participate in a data collection network established and administered by the  
817 | Department or its designee. The data may include, but is not limited to, annual budget and cost  
818 | information, operating schedules, through-put schedules, demographic and diagnostic information, the  
819 | volume of care provided to patients from all payor sources, and other data requested by the Department,  
820 | and approved by the Commission. The applicant shall provide the required data on a separate basis for  
821 | each separate and distinct site as required by the Department; in a format established by the Department;  
822 | and in a mutually agreed upon media. The Department may elect to verify the data through on-site review  
823 | of appropriate records.  
824 | ~~(viii)~~ Equipment to be replaced shall be removed from service.  
825 | ~~(ix)~~ The applicant shall provide the Department with a TIMELY notice ~~stating the date the approved~~  
826 | ~~dental CT scanner service is placed in operation and such notice shall be submitted to the Department OF~~  
827 | THE PROPOSED PROJECT IMPLEMENTATION consistent with applicable statute and promulgated  
828 | rules.  
829 | ~~(x)~~ An applicant shall participate in Medicaid at least 12 consecutive months within the first two years  
830 | of operation and continue to participate annually thereafter.  
831 | ~~(2e)~~ ~~The agreements and assurances required by this section shall be in the form of a certification~~  
832 | ~~agreed to by the applicant or its authorized agent.~~  
833 |  
834 | ~~(3) The operation of and referral of patients to the CT scanner shall be in conformance with 1978 PA~~  
835 | ~~368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).~~  
836 |  
837 | ~~(46)~~ An applicant for a CT scanner used for dental research under Section ~~4618~~(1) shall agree that the  
838 | services provided by the CT scanner approved pursuant to Section 16(1) shall be delivered in compliance  
839 | with the following terms of CON approval:  
840 | (a) The capital and operating costs relating to the CT scanner used for dental research pursuant to  
841 | Section ~~4612~~(1) shall be charged only to a specific research account(s) and not to any patient or third-  
842 | party payor.  
843 | (b) The CT scanner used for dental research approved pursuant to Section ~~4612~~(1) shall not be used  
844 | for any purposes other than as approved by the institutional review board unless the applicant has  
845 | obtained CON approval for the CT scanner pursuant to part 222 and these standards, other than Section  
846 | ~~4612~~.  
847 |  
848 | ~~(57)~~ An applicant approved under Section 13 shall be in compliance with the following:  
849 | (a) Portable CT scanner can only be used by a qualifying pilot program for the following purposes:  
850 | (i) Brain scanning of patients being treated in an adult or pediatric Intensive Care Unit (ICU).  
851 | (ii) Non-diagnostic, intraoperative guidance in an operating room.  
852 | (b) The approved applicant must provide annual reports to the Department by January 31<sup>st</sup> of each  
853 | year for the preceding calendar year. This requirement applies to all applicants approved under Section  
854 | 13 and begins with 2010 data which is to be reported in 2011.  
855 | (c) The following data must be reported to the Department:  
856 | (i) Number of adult studies (age>=18)  
857 | (ii) Number of pediatric studies (age<18)  
858 | (iii) Number of studies performed using a portable CT on the same patient while that patient is in an  
859 | ICU  
860 | (iv) Number of patients scanned on a portable CT that underwent subsequent scanning on a fixed CT  
861 | within 12 hours of the portable CT scan  
862 |

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

864 |  
865 | (29) The agreements and assurances required by this section shall be in the form of a certification  
866 | agreed to by the applicant or its authorized agent.

Comment [A10]: Need to add project delivery requirements for CT-angio hybrid units.

867 |  
868 | **Section 2021. Project delivery requirements AND additional terms of approval for applicants**  
869 | **involving mobile CT scanners**

870 |  
871 | Sec. 2021. (1) In addition to the provisions of Section 19, an applicant for a mobile CT scanner shall  
872 | agree that the services provided by the mobile CT scanner(s) shall be delivered in compliance with the  
873 | following terms of CON approval:

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

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

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

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

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

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

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

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

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

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

904 |  
905 | (2) The agreements and assurances required by this section shall be in the form of a certification  
906 | agreed to by the applicant or its authorized agent.

907 |  
908 | **Section 2422. Determination of CT Equivalents**

909 |  
910 | Sec. 2422. CT equivalents shall be calculated as follows:

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

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

- 916 (c) The number of CT equivalents for each category shall be summed to determine the total CT  
 917 equivalents for the time period specified in the applicable section(s) of these standards.  
 918 (d) The conversion factor for pediatric/special needs patients does not apply to procedures performed  
 919 on a dedicated pediatric CT scanner.

920

921 Table 1

922 Category	Number of 923 Billable CT Procedures		Conversion 924 Factor	=	CT 925 Equivalents
926 Head Scans w/o Contrast (includes dental CT examinations)	_____	X	1.00	=	_____
927 Head Scans with Contrast	_____	X	1.25	=	_____
928 Head Scans w/o & w Contrast	_____	X	1.75	=	_____
929 Body Scans w/o Contrast	_____	X	1.50	=	_____
930 Body Scans with Contrast	_____	X	1.75	=	_____
931 Body Scans w/o & w Contrast	_____	X	2.75	=	_____
932 Pediatric/Special Needs Patient					
933 Head scans w/o Contrast (includes dental CT examinations)	_____	x	1.25	=	_____
934 Pediatric/Special Needs Patient					
935 Head Scans with Contrast	_____	x	1.50	=	_____
936 Pediatric/Special Needs Patient					
937 Head Scans w/o & with Contrast	_____	x	2.00	=	_____
938 Pediatric/Special Needs Patient					
939 Body Scans w/o Contrast	_____	x	1.75	=	_____
940 Pediatric/Special Needs Patient					
941 Body Scans with Contrast	_____	x	2.00	=	_____
942 Pediatric/Special Needs Patient					
943 Body Scans w/o & with Contrast	_____	x	3.00	=	_____
944 Total CT Equivalents					_____

948

949 | **Section 2223. Documentation of projections**

950

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

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

958

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

- 962 (a) the number of dental procedures performed by the applicant, and  
 963 (b) the number of committed dental procedures performed by referring licensed dentists. Further, the  
 964 applicant and the referring licensed dentists shall substantiate the numbers through the submission of  
 965 HIPAA compliant billing records.

966

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

970  
971 (4) An applicant shall demonstrate that the projected number of referrals to be performed at the  
972 | proposed site under subsections (1) ~~and (2)~~ are from an existing CT scanner service that is in compliance  
973 with the volume requirements applicable to that service, and will continue to be in compliance with the  
974 volume requirements applicable to that service subsequent to the initiation of the proposed CT scanner  
975 | service by an applicant. **THIS DOES NOT INCLUDE DENTAL CT SCANNERS.** Only excess CT  
976 equivalents equal to or greater than what is being committed pursuant to this subsection may be used to  
977 document projections under subsection (1). In demonstrating compliance with this subsection, an  
978 applicant shall provide each of the following:

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

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

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

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

991 | Sec. 2324. (1) These CON review standards supersede and replace the CON Review Standards  
992 for Computed Tomography Scanner Services approved by the CON Commission on ~~April 30,~~  
993 ~~2008~~DECEMBER 15, 2011 and effective on ~~June 20, 2008~~FEBRUARY 27, 2012.

995 |  
996 | (2) Projects reviewed under these standards shall not be subject to comparative review.  
997 |

APPENDIX A

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**Section 24. Health Service Areas**

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

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

**APPENDIX A-B**

1042 |  
1043  
1044 Rural Michigan counties are as follows:  
1045

1046	Alcona	Hillsdale	Ogemaw
1047	Alger	Huron	Ontonagon
1048	Antrim	Iosco	Osceola
1049	Arenac	Iron	Oscoda
1050	Baraga	Lake	Otsego
1051	Charlevoix	Luce	Presque Isle
1052	Cheboygan	Mackinac	Roscommon
1053	Clare	Manistee	Sanilac
1054	Crawford	Mason	Schoolcraft
1055	Emmet	Montcalm	Tuscola
1056	Gladwin	Montmorency	
1057	Gogebic	Oceana	

1058  
1059 Micropolitan statistical area Michigan counties are as follows:  
1060

1061	Allegan	Gratiot	Mecosta
1062	Alpena	Houghton	Menominee
1063	Benzie	Isabella	Midland
1064	Branch	Kalkaska	Missaukee
1065	Chippewa	Keweenaw	St. Joseph
1066	Delta	Leelanau	Shiawassee
1067	Dickinson	Lenawee	Wexford
1068	Grand Traverse	Marquette	

1069  
1070 Metropolitan statistical area Michigan counties are as follows:  
1071

1072	Barry	Ionia	Newaygo
1073	Bay	Jackson	Oakland
1074	Berrien	Kalamazoo	Ottawa
1075	Calhoun	Kent	Saginaw
1076	Cass	Lapeer	St. Clair
1077	Clinton	Livingston	Van Buren
1078	Eaton	Macomb	Washtenaw
1079	Genesee	Monroe	Wayne
1080	Ingham	Muskegon	

1081  
1082 Source:  
1083 65 F.R., p. 82238 (December 27, 2000)  
1084 Statistical Policy Office  
1085 Office of Information and Regulatory Affairs  
1086 United States Office of Management and Budget