

1 MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

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

10 **Section 1. Applicability**

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

18 **Section 2. Definitions**

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

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

25 (b) "Billable procedure" means a CT procedure billed as a single unit and performed in Michigan.

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

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

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

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

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

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

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

42 (j) "CT equivalents" means the resulting number of units produced when the number of billable  
43 procedures for each category is multiplied by its respective conversion factor tabled in Section 16.

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

- 53 (l) "CT scanner services" means the CON-approved utilization of a CT scanner(s) at one site in the  
 54 case of a fixed CT scanner service or at each host site in the case of a mobile CT scanner service.
- 55 (m) "CT ABLATIONS" MEANS
- 56 (n) "CT NON-ABLATIONS" MEANS
- 57 (o) "Dedicated pediatric CT" means a fixed CT scanner on which at least 70% of the CT procedures  
 58 are performed on patients under 18 years of age.
- 59 (p) "Department" means the Michigan Department of Health and Human Services (MDHHS).
- 60 (q) "Emergency room" means a designated area physically part of a licensed hospital and  
 61 recognized by the Department as having met the staffing and equipment requirements for the treatment  
 62 of emergency patients.
- 63 (r) "Excess CT Equivalents" means the number of CT equivalents performed by an existing CT  
 64 scanner service in excess of 10,000 per fixed CT scanner and 4,500 per mobile CT scanner or either an  
 65 existing fixed or mobile CT scanner service, the number of CT scanners used to compute excess CT  
 66 equivalents shall include both existing and approved but not yet operational CT scanners. In the case of  
 67 a CT scanner service that operates or has a valid CON to operate that has more than one fixed CT  
 68 scanner at the same site, the term means number of CT equivalents in excess of 10,000 multiplied by the  
 69 number of fixed CT scanners at the same site. For example, if a CT scanner service operates, or has a  
 70 valid CON to operate, two fixed CT scanners at the same site, the excess CT equivalents is the number  
 71 that is in excess of 20,000 (10,000 x 2) CT equivalents. In the case of an existing mobile CT scanner  
 72 service, the term means the sum of all CT equivalents performed by the same mobile CT scanner service  
 73 at all of the host sites combined that is in excess of 4,500. For example, if a mobile CT scanner service  
 74 serves five host sites with 1 mobile CT scanner, the term means the sum of CT equivalents for all five  
 75 host sites combined that is in excess of 4,500 CT equivalents.
- 76 (s) "Existing CT scanner service" means the utilization of a CON-approved and operational CT  
 77 scanner(s) at one site in the case of a fixed CT scanner service or at each host site in the case of a  
 78 mobile CT scanner service.
- 79 (t) "Existing CT scanner" means a CON-approved and operational CT scanner used to provide CT  
 80 scanner services.
- 81 (u) "Existing mobile CT scanner service" means a CON-approved and operational CT scanner and  
 82 transporting equipment operated by a central service coordinator serving two or more host sites.
- 83 (v) "Expand an existing CT scanner service" means the addition of one or more CT scanners at an  
 84 existing CT scanner service.
- 85 (w) "Head scans" include head or brain CT scans; including the maxillofacial area; the orbit, sella, or  
 86 posterior fossa; or the outer, middle, or inner ear; or any other CT scan occurring above the neck.
- 87 (x) "Health Service Area" or "HSA" means the groups of counties listed in Appendix A.
- 88 (y) "HIPAA" means the Health Insurance Portability and Accountability Act of 1996.
- 89 (z) "Hospital-based portable CT scanner or portable CT scanner" means a CT scanner capable of  
 90 being transported into patient care areas (i.e., ICU rooms, operating rooms, etc.) to provide high-quality  
 91 imaging of critically ill patients.
- 92 (aa) "Host site" means the site at which a mobile CT scanner is authorized to provide CT scanner  
 93 services.
- 94 (abb) "Initiate a CT scanner service" means to begin operation of a CT scanner, whether fixed or  
 95 mobile, at a site that does not perform CT scans as of the date an application is submitted to the  
 96 Department. The term does not include the acquisition or replacement of an existing CT scanner service  
 97 at the existing site or to a different site or the renewal of a lease.
- 98 (acc) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396 to 1396w-5.
- 99 (bdd) "Mobile CT scanner service" means a CT scanner and transporting equipment operated by a  
 100 central service coordinator and which must serve two or more host facilities.
- 101 (eee) "Mobile CT scanner network" means the route (all host facilities) the mobile CT scanner is  
 102 authorized to serve.
- 103 (eff) "Pediatric patient" means any patient less than 18 years of age.
- 104 (egg) "Replace an existing CT scanner" means an equipment change of an existing CT scanner, that  
 105 requires a change in the radiation safety certificate, proposed by an applicant which results in that

106 applicant operating the same number of CT scanners before and after project completion, at the same  
107 geographic location. The term also includes relocating an existing CT scanner or CT scanner service  
108 from an existing site to a different site.

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

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

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

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

122  
123 (2) Terms defined in the Code have the same meanings when used in these standards.  
124

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

126  
127 Sec. 3. An applicant proposing to initiate a CT scanner service, other than a hospital-based portable  
128 CT scanner service, shall demonstrate the following, as applicable:  
129

130 (1) A hospital proposing to initiate its first fixed CT scanner service shall demonstrate, **WITH**  
131 **DOCUMENTATION SATISFACTORY TO THE DEPARTMENT**, each of the following:

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

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

135  
136 **(2) A FREESTANDING SURGICAL OUTPATIENT FACILITY (FSOF) PROPOSING TO INITIATE**  
137 **ITS FIRST FIXED CT SCANNER SERVICE SHALL DEMONSTRATE, WITH DOCUMENTATION**  
138 **SATISFACTORY TO THE DEPARTMENT, EACH OF THE FOLLOWING:**

139 **(a) THE PROPOSED SITE IS A FSOF LICENSED UNDER PART 208 OF THE CODE.**

140 **(b) THE FSOF OPERATES AN EMERGENCY ROOM THAT PROVIDES 24-HOUR EMERGENCY**  
141 **CARE SERVICES AS AUTHORIZED BY THE LOCAL MEDICAL CONTROL AUTHORITY TO RECEIVE**  
142 **AMBULANCE RUNS.**

143  
144 **(3) AN OFF-CAMPUS EMERGENCY DEPARTMENT OF A HOSPITAL PROPOSING TO INITIATE**  
145 **ITS FIRST FIXED CT SCANNER SERVICE SHALL DEMONSTRATE, WITH DOCUMENTATION**  
146 **SATISFACTORY TO THE DEPARTMENT, EACH OF THE FOLLOWING:**

147 **(a) THE PROPOSED SITE IS AN OFF-CAMPUS EMERGENCY DEPARTMENT OF A HOSPITAL**  
148 **LICENSED UNDER PART 215 OF THE CODE.**

149 **(b) THE OFF-CAMPUS EMERGENCY DEPARTMENT OF A HOSPITAL IS AVAILABLE FOR**  
150 **TREATING EMERGENCY PATIENTS 24 HOURS A DAY, 7 DAYS A WEEK, COMPLIES WITH**  
151 **MEDICAL CONTROL AUTHORITY PROTOCOLS, AND HAS OBTAINED PROVIDER-BASED STATUS**  
152 **UNDER 42 CFR 413.65.**

153  
154 **(24) An applicant, other than an applicant meeting all of the applicable requirements of subsection (1),**  
155 **(2), OR (3),** proposing to initiate a fixed CT scanner service shall project an operating level of at least  
156 7,500 CT equivalents per year for the second 12-month period after beginning operation of the CT  
157 scanner.  
158

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

162  
163 (46) An applicant proposing to initiate CT scanner services as an existing host site on a different  
164 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 proposed host site and central  
167 service coordinator.

168  
169 **Section 4. Requirements for approval for applicants proposing to expand an existing CT scanner**  
170 **service**

171  
172 Sec. 4. An applicant proposing to expand an existing CT scanner service, other than a hospital-based  
173 portable CT scanner service, shall demonstrate the following, as applicable:

174  
175 (1) An applicant proposing to expand an existing fixed CT scanner service shall demonstrate that all  
176 of the applicant's fixed CT scanners, excluding CT scanners approved pursuant to sections 8, 9, and 12,  
177 have performed an average of at least 10,000 CT equivalents per fixed CT scanner for the most recent  
178 continuous 12-month period preceding the applicant's request. In computing this average, the  
179 Department will divide the total number of CT equivalents performed by the applicant's total number of  
180 fixed CT scanners, including both operational and approved but not operational fixed CT scanners.

181  
182 (2) An applicant proposing to expand an existing fixed CT scanner service approved pursuant to  
183 Section 12 shall demonstrate that all of the applicant's dedicated pediatric CT scanners have performed  
184 an average of at least 3,000 CT equivalents per dedicated pediatric CT scanner for the most recent  
185 continuous 12-month period preceding the applicant's request. In computing this average, the  
186 Department will divide the total number of CT equivalents performed by the applicant's total number of  
187 dedicated pediatric CT scanners, including both operational and approved but not operational dedicated  
188 pediatric CT scanners.

189  
190 (3) If an applicant proposes to expand an existing mobile CT scanner service, the applicant shall  
191 demonstrate that all of the applicant's mobile CT scanners have performed an average of at least 5,500  
192 CT equivalents per mobile CT scanner for the most recent continuous 12-month period preceding the  
193 applicant's request. In computing this average, the Department will divide the total number of CT  
194 equivalents performed by the applicant's total number of mobile CT scanners, including both operational  
195 and approved but not operational mobile CT scanners.

196  
197 **Section 5. Requirements for approval for applicants proposing to replace an existing CT scanner**  
198

199 Sec. 5. An applicant proposing to replace an existing CT scanner or service, other than a hospital-  
200 based portable CT scanner service, shall demonstrate the following, as applicable:

201  
202 (1) An applicant proposing to replace an existing fixed, mobile, or dedicated pediatric CT scanner  
203 shall demonstrate all of the following:

- 204 (a) The replacement CT scanner will be located at the same site as the CT scanner to be replaced.
- 205 (b) The existing CT scanner(s) proposed to be replaced is fully depreciated according to generally  
206 accepted accounting principles, or, that the existing equipment clearly poses a threat to the safety of the  
207 public, or, that the proposed replacement CT scanner offers technological improvements which enhance  
208 quality of care, increase efficiency, and/or reduce operating costs and patient charges.

209  
210 (2) An applicant proposing to replace an existing fixed CT scanner service to a different site shall  
211 demonstrate that the proposed project meets all of the following:

212 (a) The existing fixed CT scanner service to be replaced has been in operation for at least 36 months  
213 as of the date an application is submitted to the Department unless the applicant meets the requirement  
214 in subsection (c)(ii) or (iii).

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

219 (c) The CT scanner service to be replaced performed at least an average of 7,500 CT equivalents  
220 per fixed scanner in the most recent 12-month period for which the Department has verifiable data unless  
221 one of the following requirements are met:

222 (i) An applicant meets all of the requirements of Section 3(1), (2), OR (3);

223 (ii) the owner of the building where the site is located has incurred a filing for bankruptcy under  
224 Chapter Seven (7) within the last three years;

225 (iii) the ownership of the building where the site is located has changed within 24 months of the date  
226 of the service being operational; or

227 (iv) the CT service being replaced is part of the replacement of an entire hospital to a new geographic  
228 site and has only one (1) CT unit.

229 (d) The applicant agrees to operate the CT scanner service in accordance with all applicable project  
230 delivery requirements set forth in Section 14 of these standards.

231  
232 (3) An applicant proposing to replace a fixed CT scanner(s) of an existing CT scanner service to a  
233 different site shall demonstrate that the proposed project meets all of the following:

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

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

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

243 (d) The applicant agrees to operate the CT scanner(s) at the proposed site in accordance with all  
244 applicable project delivery requirements set forth in Section 14 of these standards.

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

247  
248 **Section 6. Requirements for approval for applicants proposing to acquire an existing CT scanner**  
249 **service or an existing CT scanner(s)**

250  
251 Sec. 6. An applicant proposing to acquire an existing fixed or mobile CT scanner service, other than a  
252 hospital-based portable CT scanner service, shall demonstrate the following, as applicable:

253  
254 (1) The applicant shall not be required to be in compliance with the volume requirement applicable to  
255 the seller/lessor on the date the acquisition occurs if the proposed project meets one of the following:

256 (a) It is the first acquisition of the existing fixed or mobile CT scanner service for which a final  
257 decision has not been issued after June 4, 2004.

258 (b) The existing fixed or mobile CT scanner service is owned by, is under common control of, or has  
259 a common parent as the applicant, and the CT scanner service shall remain at the same site.

260  
261 (2) For any application for proposed acquisition of an existing fixed or mobile CT scanner service, an  
262 applicant shall be required to demonstrate the following, as applicable:

263 (a) The fixed CT scanner service to be acquired performed at least 7,500 CT equivalents per fixed  
264 CT scanner in the most recent 12-month period for which the Department has verifiable data, unless an

265 applicant meets all of the requirements of Section 3(1), (2), OR (3) or meets the requirements of Section  
266 6(1)(b).

267 (b) The mobile CT scanner service to be acquired performed at least 3,500 CT equivalents per  
268 mobile CT scanner in the most recent 12-month period for which the Department has verifiable data,  
269 unless an applicant meets the requirements of Section 6(1)(b).

270  
271 (3) An applicant proposing to acquire an existing fixed or mobile CT scanner(s) of an existing fixed or  
272 mobile CT scanner service shall demonstrate that the proposed project meets the following:

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

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

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

280  
281 (4) The CT scanner service shall be operating at the applicable volume requirements set forth in  
282 Section 14 of these standards in the second 12 months after the date the service is acquired, and  
283 annually thereafter.

#### 284 **Section 7. Requirements for a dedicated research fixed CT scanner**

285  
286 Sec. 7. An applicant proposing to add a fixed CT scanner to an existing CT scanner service for  
287 exclusive research use shall demonstrate the following:

288  
289 (1) The applicant agrees that the dedicated research CT scanner will be used primarily (70% or more  
290 of the scans) for research purposes.

291  
292 (2) The dedicated research CT scanner shall operate under a protocol approved by the applicant's  
293 Institutional Review Board, as defined by Public Law 93-348 and regulated by Title 45 CFR 46.

294  
295 (3) The proposed site can have no more than three dedicated research fixed CT scanners approved  
296 under this section.

297  
298 (4) The dedicated research scanner approved under this section may not utilize CT procedures  
299 performed on the dedicated CT scanner to demonstrate need or to satisfy CT CON review standards  
300 requirements.

#### 301 **Section 8. Requirements for approval of a hospital-based portable CT scanner for initiation, 302 expansion, replacement, and acquisition**

303  
304 Sec. 8. An applicant proposing to initiate, expand, replace, or acquire a hospital-based portable CT  
305 scanner shall demonstrate that it meets all of the following:

306  
307 (1) An applicant is limited to the initiation, expansion, replacement, or acquisition of no more than two  
308 hospital-based portable CT scanners.

309  
310 (2) The proposed site is a hospital licensed under Part 215 of the Code.

311  
312 (3) The hospital has been certified as a level I or level II trauma facility by the American College of  
313 Surgeons, or has performed >100 craniotomies in the most recent 12- month period verifiable by the  
314 Department.

318 (4) The applicant agrees to operate the hospital-based portable CT scanner in accordance with all  
319 applicable project delivery requirements set forth in Section 14 of these standards.

320  
321 (5) The approved hospital-based portable CT scanner will not be subject to CT volume requirements.  
322

323 (6) The applicant may not utilize CT procedures performed on a hospital-based portable CT scanner  
324 to demonstrate need or to satisfy CT CON review standards requirements.  
325

326 **Section 9. Requirements for approval of a PET/CT hybrid for initiation, expansion, replacement,  
327 and acquisition**  
328

329 Sec. 9. An applicant proposing to initiate, expand, replace, or acquire a PET/CT hybrid shall  
330 demonstrate that it meets all of the following:  
331

332 (1) There is an approved PET CON for the PET/CT hybrid, and the PET/CT hybrid is in compliance  
333 with all applicable project delivery requirements as set forth in the CON review standards for PET.  
334

335 (2) The applicant agrees to operate the PET/CT hybrid in accordance with all applicable project  
336 delivery requirements set forth in Section 14 of these standards.  
337

338 (3) The approved PET/CT hybrid will not be subject to CT volume requirements.  
339

340 (4) A PET/CT scanner hybrid approved under the CON Review Standards for PET Scanner Services  
341 and the Review Standards for CT Scanner Services may not utilize CT procedures performed on a hybrid  
342 scanner to demonstrate need or to satisfy CT CON review standards requirements.  
343

344 **Section 10. Requirements for approval of a CT-angio hybrid unit for initiation, replacement, and  
345 acquisition**  
346

347 Sec. 10. An applicant proposing to initiate, replace, or acquire a hospital-based CT-angio hybrid unit  
348 shall demonstrate each of the following, as applicable to the proposed project:  
349

350 (1) The proposed site is a licensed hospital under Part 215 of the Code.  
351

352 (2) The proposed site has an existing fixed CT scanner service that has been operational for the  
353 previous 36 consecutive months and is meeting its minimum volume requirements.  
354

355 (3) The proposed site offers the following services:

356 (a) diagnostic cardiac catheterization; or

357 (b) interventional radiology; or

358 (c) surgical services  
359

360 (4) The proposed CT-angio hybrid unit must be located in one of the following rooms:

361 (a) cardiac catheterization lab; or

362 (b) interventional radiology suite; or

363 (c) licensed operating room  
364

365 (5) Diagnostic CT studies shall not be performed on a CT-angio hybrid unit approved under this  
366 section unless the patient is currently undergoing a CT-angio hybrid interventional procedure and is in  
367 need of a secondary diagnostic CT study.  
368

369 (6) The approved CT-angio hybrid shall not be subject to CT volume requirements.  
370

371 (7) The applicant shall not utilize the procedures performed on the CT-angio hybrid unit to  
372 demonstrate need or to satisfy CT CON review standards requirements.

373  
374 **Section 11. Additional requirements for approval of a mobile CT scanner service**

375  
376 Sec. 11. (1) An applicant proposing to initiate a mobile CT scanner service in Michigan shall  
377 demonstrate that it meets all of the following additional requirements:

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

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

383  
384 (2) An applicant proposing to become a host facility on an existing mobile CT scanner network shall  
385 demonstrate that it meets all of the following additional requirements:

386 (a) Approval of the application will not result in an increase in the number of operating mobile CT  
387 scanners for the mobile CT scanner network unless the requirements of Section 4 have been met.

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

389  
390 **Section 12. Requirements for approval of an applicant proposing to establish dedicated pediatric**  
391 **CT Scanner**

392  
393 Sec. 12. (1) An applicant proposing to establish dedicated pediatric CT shall demonstrate all of the  
394 following:

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

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

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

402 (i) pediatric radiology (at least two)

403 (ii) pediatric anesthesiology

404 (iii) pediatric cardiology

405 (iv) pediatric critical care

406 (v) pediatric gastroenterology

407 (vi) pediatric hematology/oncology

408 (vii) pediatric neurology

409 (viii) pediatric neurosurgery

410 (ix) pediatric orthopedic surgery

411 (x) pediatric pathology

412 (xi) pediatric pulmonology

413 (xii) pediatric surgery

414 (xiii) neonatology

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

417 (i) pediatric bone marrow transplant program

418 (ii) established pediatric sedation program

419 (iii) pediatric open heart program

420  
421 (2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the  
422 requirements of Section 3 of these standards.



424 **Section 13. Requirements for Medicaid participation**

425  
426 Sec. 13. An applicant shall provide verification of Medicaid participation. An applicant that is a new  
427 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided  
428 to the Department within six (6) months from the offering of services if a CON is approved.  
429

430 **Section 14. Project delivery requirements and terms of approval for all applicants**

431  
432 Sec. 14. An applicant shall agree that, if approved, the CT scanner(s) services shall be delivered in  
433 compliance with the following terms of approval.  
434

435 (1) Compliance with these standards.  
436

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

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

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

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

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

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

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

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

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

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

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

475 (h) The applicant shall establish and maintain: (a) a standing medical staff and governing body (or its  
476 equivalent) requirement that provides for the medical and administrative control of the ordering and

477 utilization of CT patient procedures, and (b) a formal program of utilization review and quality assurance.  
478 These responsibilities may be assigned to an existing body of the applicant, as appropriate.

479 (i) An applicant approved under Section 12 must be able to prove that all radiologists, technologists  
480 and nursing staff working with CT patients have continuing education or in-service training on pediatric  
481 low-dose CT. The site must also be able to provide evidence of defined low-dose pediatric CT protocols.  
482

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

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

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

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

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

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

493 (c) The operation of and referral of patients to the CT scanner shall be in conformance with 1978 PA  
494 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).  
495

496 Compliance with selective contracting requirements shall not be construed as a violation of this term.  
497

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

499 (a) The approved CT scanners shall be operating AS FOLLOWS FOR THE SECOND 12-MONTH  
500 PERIOD AFTER BEGINNING OPERATION OF THE CT SCANNER, AND ANNUALLY THEREAFTER,  
501 EXCEPT FOR THOSE SCANNERS EXEMPT UNDER APPLICABLE SECTIONS:

502 (i) at an An average of 7,500 CT equivalents scanner per fixed scanner PER YEAR UNLESS ONE  
503 OF THE FOLLOWING HAS BEEN MET:

504 (A) 5,000 CT EQUIVALENTS PER FIXED SCANNER PER YEAR FOR CT SERVICES WITH ONE  
505 FIXED SCANNER.

506 (B) 2,500 CT EQUIVALENTS PER FIXED SCANNER PER YEAR FOR CT SERVICES WITH ONE  
507 FIXED SCANNER LOCATED 20 OR MORE AERIAL MILES FROM THE NEXT CLOSEST FIXED CT  
508 SERVICE.

509 (ii) and 31,500 CT equivalents per mobile scanner per year for the second 12-month period after  
510 beginning operation of the CT scanner, and annually thereafter, except for those scanners exempt under  
511 applicable sections.

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

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

521 (d) The applicant shall provide the Department with timely notice of the proposed project  
522 implementation consistent with applicable statute and promulgated rules.  
523

524 (5) An applicant approved under Section 8 shall be in compliance with the following:

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

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

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

528 (b) The approved applicant must provide annual reports to the Department by January 31<sup>st</sup> of each  
529 year for the preceding calendar year. This requirement applies to all applicants approved under Section  
530 8.

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

532 (i) Number of adult studies (age $\geq$ 18)

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

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

536

537 (6) An applicant approved under Section 10 shall be in compliance with the following:

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

539 (i) diagnostic cardiac catheterization; or

540 (ii) interventional radiology; or

541 (iii) surgical services

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

543 (i) cardiac catheterization lab; or

544 (ii) interventional radiology suite; or

545 (iii) licensed operating room

546

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

549

#### 550 **Section 15. Project delivery requirements and additional terms of approval for applicants** 551 **involving mobile CT scanners**

552

553 Sec. 15. (1) In addition to the provisions of Section 14, an applicant for a mobile CT scanner shall  
554 agree that the services provided by the mobile CT scanner(s) shall be delivered in compliance with the  
555 following terms of CON approval:

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

558 (b) A mobile CT scanner with an approved CON shall notify the Department prior to ending service  
559 with an existing host facility.

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

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

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

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

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

576 (h) Each host facility must provide a properly prepared parking pad for the mobile CT scanner of  
577 sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for  
578 patients to enter the vehicle without going outside (such as a canopy or enclosed corridor). Each host  
579 facility must also provide the capability for processing the film and maintaining the confidentiality of

580 patient records. A communication system must be provided between the mobile vehicle and each host  
 581 facility to provide for immediate notification of emergency medical situations.

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

584 (j) The volume of utilization at each host facility shall be reported to the Department by the central  
 585 service coordinator under the terms of Section 14(2)(i).

586  
 587 (2) The agreements and assurances required by this section shall be in the form of a certification  
 588 agreed to by the applicant or its authorized agent.

589  
 590 **Section 16. Determination of CT Equivalents**

591  
 592 Sec. 16. CT equivalents shall be calculated as follows:

593  
 594 (a1) Each billable procedure for the time period specified in the applicable section(s) of these  
 595 standards shall be assigned to a category set forth in Table 1.

596  
 597 (b2) The number of billable procedures for each category in the time period specified in the applicable  
 598 section(s) of these standards shall be multiplied by the corresponding conversion factor in Table 1 to  
 599 determine the number of CT equivalents for that category for that time period.

600  
 601 (c3) The number of CT equivalents for each category shall be summed to determine the total CT  
 602 equivalents for the time period specified in the applicable section(s) of these standards.

603  
 604 (d4) THE WEIGHTING IN TABLE 1 IS BASED ON TYPICAL TREATMENT TIMES AND ASSUMES  
 605 THE CONVERSION FACTOR EQUALS APPROXIMATELY 15 MINUTES OF TIME ON THE CT UNIT.

606  
 607 (5) The conversion factor for pediatric/special needs patients does not apply to procedures  
 608 performed on a dedicated pediatric CT scanner.

609  
 610 Table 1

611 Category	612 Number of Billable CT Procedures		613 Conversion Factor		614 CT Equivalents
615 <u>Adult Patient</u>					
616 Head Scans w/o Contrast	_____	X	1.00	=	_____
617 Head Scans with Contrast	_____	X	1.25	=	_____
618 Head Scans w/o & w Contrast	_____	X	1.75	=	_____
619 Body Scans w/o Contrast	_____	X	1.50	=	_____
620 Body Scans with Contrast	_____	X	1.75	=	_____
621 Body Scans w/o & w Contrast	_____	X	2.75	=	_____
622 Bundled body Scan	_____	X	3.50	=	_____
623 CT NON-ABLATIONS	_____	X	4.00	=	_____
624 CT ABLATIONS	_____	X	8.00	=	_____
625 <u>Pediatric/Special Needs Patient</u>					
626 Head scans w/o Contrast	_____	x	1.25	=	_____
627 Head Scans with Contrast	_____	x	1.50	=	_____
628 Head Scans w/o & with Contrast	_____	x	2.00	=	_____
629 Body Scans w/o Contrast	_____	x	1.75	=	_____
630 Body Scans with Contrast	_____	x	2.00	=	_____
631 Body Scans w/o & with Contrast	_____	x	3.00	=	_____
632 Bundled body Scan	_____	X	4.00	=	_____

633	CT NON-ABLATIONS	X	4.00	=
634	CT ABLATIONS	X	8.00	=

635  
636 Total CT Equivalents \_\_\_\_\_  
637

638 **Section 17. Documentation of projections**  
639

640 Sec. 17. An applicant required to project volumes under Section 3 shall demonstrate the following, as  
641 applicable:

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

647  
648 (2) An applicant shall demonstrate that the projected number of referrals to be performed at the  
649 proposed site under subsection (1) are from an existing CT scanner service that is in compliance with the  
650 volume requirements applicable to that service, and will continue to be in compliance with the volume  
651 requirements applicable to that service subsequent to the initiation of the proposed CT scanner service by  
652 an applicant. Only excess CT equivalents equal to or greater than what is being committed pursuant to  
653 this subsection may be used to document projections under subsection (1). In demonstrating compliance  
654 with this subsection, an applicant shall provide each of the following:

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

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

663 (c) The projected referrals are from an existing CT scanner service within a 75-mile radius for rural  
664 and micropolitan statistical area counties or 20-mile radius for metropolitan statistical area counties.  
665

666 **Section 18. Effect on prior CON review standards; comparative reviews**  
667

668 Sec. 18. (1) These CON review standards supersede and replace the CON Review Standards  
669 for Computed Tomography Scanner Services approved by the CON Commission on September ~~25~~21,  
670 2014-2016 and effective on December ~~22~~9, 2014-2016.  
671

672 (2) Projects reviewed under these standards shall not be subject to comparative review.  
673  
674  
675

676  
677  
678  
679  
680  
681  
682  
683  
684  
685  
686  
687  
688  
689  
690  
691  
692  
693  
694  
695  
696  
697  
698  
699  
700  
701  
702  
703  
704  
705  
706  
707  
708  
709  
710  
711  
712  
713  
714  
715  
716  
717

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

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

718  
719  
720  
721  
722  
723  
724  
725  
726  
727  
728  
729  
730  
731  
732  
733  
734  
735  
736  
737  
738  
739  
740  
741  
742  
743  
744  
745  
746  
747  
748  
749  
750  
751  
752  
753  
754  
755  
756  
757  
758  
759  
760  
761  
762  
763

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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