

**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
COMPUTED TOMOGRAPHY STANDARD
ADVISORY COMMITTEE (CTSAC) MEETING**

Thursday January 13, 2011
Capitol View Building
201 Townsend Street
MDCH Conference Center
Lansing, Michigan 48913

APPROVED MINUTES

I. Call To Order

Chairperson Brooks called the meeting to order @ 9:40 a.m.

A. Members Present:

James R Pedersen, International UAW
Sharon L. Brooks, DDS, MS, Chairperson, Michigan Dental Assoc.
Suresh Mukherji, MD, Vice-Chairperson, University of Michigan Health System
Anthony L. Alcantara, MD, St. John Providence Health System (arrived @ 9:53 a.m.)
Robert M. Goodman, DO, Blue Cross Blue Shield/ Blue Care Network (arrived @ 9:53 a.m.)
Michael Altman, MD, Marquette General Health System
David J. Kastan, MD, FSIR, Henry Ford Health System
Bradford W. Betz, MD, Spectrum Health (arrived @ 9:42 a.m.)
Renee K. Myers, Chrysler Group, LLC
Lawerence Ashker, DO, Genesys Regional Medical Center
Rod J. Zapolski, Mid Michigan Health
Abdalmajid Katranji, MD, Michigan State Medical Society (arrived @ 10:18 a.m.)

B. Members Absent:

Stephen Meier, Xoran Technologies Inc
Daniel Shumaker, MD, FA, Michigan Radiological Society

C. Michigan Department of Community Health Staff present:

Matt Weaver
Brenda Rogers
Tania Rodriguez
Natalie Kellogg

Jessica Austin

II. Conflicts of Interest

Vice- Chairperson Mukherji stated he used to consult with GE, Phillips, and Bayer.

III. Review of Agenda

Motion by Dr. Altman and seconded by Dr. Kastan to accept the agenda as presented. Motion carried.

IV. Review of Minutes of December 9, 2010

Motion by Pedersen and seconded by Dr. Altman to accept the minutes as presented. Motion carried.

V. Volume Threshold for Initiation- Tabled from December 9, 2010 Meeting

Motion by Pedersen and seconded by Myers to remove the item from the table. Motion Carried.

Discussion Continued.

Public Comment:
Melissa Cupp, Weiner Assoc.

Motion by Pedersen and seconded by Vice-chairperson Mukherji to recommend volume requirement for initiation increase from 7500 to 10,000 equivalents. Motion carried in a vote of 11-Yes, 0-No, 0-Abstain.

VI. Review of Draft Language

Chairperson Brooks advised that the SAC would review the Draft Language provided by the Department (See attachment A).

Discussion Followed.

Motion by Dr. Goodman and seconded by Dr. Betz to approve the modified Draft CT language. Motion carried in a vote of 11-Yes, 0-No, and 1-Abstained. (See attachment B).

VII. Public Comment

None

VIII. Adjournment

Motion by Dr. Kastan and seconded by Dr. Goodman to adjourn the meeting @ 10:24 a.m. Motion carried.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR
COMPUTED TOMOGRAPHY (CT) SCANNER SERVICES

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

Section 1. Applicability

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

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

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

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

Section 2. Definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

70 (q) "Existing CT scanner" means a CON-approved and operational CT scanner used to provide CT
71 scanner services.

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

74 (s) "Expand an existing CT scanner service" means the addition of one or more CT scanners at an
75 existing CT scanner service.

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

78 **(U) "HEALTH SERVICE AREA" OR "HSA" MEANS THE GROUPS OF COUNTIES LISTED IN**
79 **SECTION 24.**

80 **(uV) "HIPAA" means the Health Insurance Portability and Accountability Act of 1996.**

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

84 **(wX) "Host site" means the site at which a mobile CT scanner is authorized to provide CT scanner**
85 **services.**

86 **(xY) "Initiate a CT scanner service" means to begin operation of a CT scanner, whether fixed or**
87 **mobile, at a site that does not perform CT scans as of the date an application is submitted to the**
88 **Department. The term does not include the acquisition or relocation of an existing CT scanner service or**
89 **the renewal of a lease.**

90 **(yZ) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6**
91 **and 1396r-8 to 1396v.**

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

96 **(aaBB) "Micropolitan statistical area county" means a county located in a micropolitan 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 **(bbCC) "Mobile CT scanner service" means a CT scanner and transporting equipment operated by a**
101 **central service coordinator and which must serve two or more host facilities.**

102 **(eeDD) "Mobile CT scanner network" means the route (all host facilities) the mobile CT scanner is**
103 **authorized to serve.**

104 **(ddEE) "Pediatric patient" means any patient less than 18 years of age.**

105 | (eeFF) "Relocate a fixed CT scanner" means a change in the location of a fixed CT scanner from the
 106 | existing site to a different site within the relocation zone.

107 | (#GG) "Relocate an existing CT scanner service" means a change in the geographic location of an
 108 | existing fixed CT scanner service from an existing site to a different site.

109 | (ggHH) "Relocation zone," means a site that is within a 10-mile radius of a site at which an existing fixed
 110 | CT scanner service is located if an existing fixed CT scanner service is located in a metropolitan
 111 | statistical area county, or a 20-mile radius if an existing fixed CT scanner service is located in a rural or
 112 | micropolitan statistical area county.

113 | (hhII) "Replace an existing CT scanner" means an equipment change of an existing CT scanner, that
 114 | requires a change in the radiation safety certificate, proposed by an applicant which results in that
 115 | applicant operating the same number of CT scanners before and after project completion, at the same
 116 | geographic location.

117 | (#JJ) "Rural county" means a county not located in a metropolitan statistical area or micropolitan
 118 | statistical areas as those terms are defined under the "standards for defining metropolitan and
 119 | micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of
 120 | the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as
 121 | shown in Appendix A.

122 | (jjKK) "Sedated patient" means a patient that meets all of the following:

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

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

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

135 |
 136 | (2) The definitions in Part 222 shall apply to these standards.
 137 |

138 | **Section 3. Requirements for approval for applicants proposing to initiate a CT scanner service** 139 | **other than a dental CT scanner service or hospital-based portable CT scanner service**

140 |
 141 | Sec. 3. An applicant proposing to initiate a CT scanner service shall demonstrate each of the
 142 | following, as applicable:

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

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

146 | (b) The hospital operates an emergency room that provides 24-hour emergency care services as
 147 | authorized by the local medical control authority to receive ambulance runs.
 148 |

149 | (2) An applicant, other than an applicant meeting all of the applicable requirements of subsection (1),
 150 | proposing to initiate a fixed CT scanner service shall project an operating level of at least 7,500 CT
 151 | equivalents per year for the second 12-month period after beginning operation of the CT scanner.
 152 |

153 | (3) An applicant proposing to initiate a mobile CT scanner service shall project an operating level of
 154 | at least 3,500 CT equivalents per year for the second 12-month period after beginning operation of the
 155 | CT scanner.
 156 |

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

159
 160 Sec. 4. An applicant proposing to initiate a dental CT scanner service shall demonstrate each of the
 161 following, as applicable:

162
 163 (1) An applicant is proposing a fixed CT scanner service for the sole purpose of performing dental
 164 CT examinations.

165
 166 (2) The CT scanner generates a peak power of 5 kilowatts or less as certified by the manufacturer.

167
 168 (3) An applicant proposing to initiate a dental CT scanner service, **OTHER THAN AN APPLICANT**
 169 **THAT IS PROPOSING A FIXED CT SCANNER SERVICE IN HSA 8**, shall project an operating level of at
 170 least 200 dental CT examinations per year for the second 12-month period after beginning operation of
 171 the dental CT scanner.

172
 173 (4) The applicant has demonstrated to the satisfaction of the Department that the person(s) (e.g.,
 174 technician, dentist) operating the dental CT scanner has been appropriately trained and/or certified by
 175 one of the following groups, as recognized by the Department: a dental radiology program in a certified
 176 dental school, an appropriate professional society, or a dental continuing education program accredited
 177 by the American Dental Association.

178
 179 (5) The applicant has demonstrated to the satisfaction of the Department that the dental CT
 180 examinations generated by the proposed dental CT scanner will be interpreted by a licensed dentist(s)
 181 trained and/or certified by one of the following groups, as recognized by the Department: a dental
 182 radiology program in a certified dental school, an appropriate professional society, or a dental continuing
 183 education program accredited by the American Dental Association.

184
 185 **Section 5. Requirements for approval for applicants proposing to expand an existing CT scanner**
 186 **service other than a dental CT scanner service or hospital-based portable CT scanner service**

187
 188 Sec. 5. (1) An applicant proposing to expand an existing fixed CT scanner service shall demonstrate
 189 that all of the applicant's fixed CT scanners, excluding CT scanners approved pursuant to sections 13
 190 and 17, have performed an average of at least 10,000 CT equivalents per fixed CT scanner for the most
 191 recent continuous 12-month period preceding the applicant's request. In computing this average, the
 192 Department will divide the total number of CT equivalents performed by the applicant's total number of
 193 fixed CT scanners, including both operational and approved but not operational fixed CT scanners.

194
 195 (2) An applicant proposing to expand an existing fixed CT scanner service approved pursuant to
 196 Section 17 shall demonstrate that all of the applicant's dedicated pediatric CT scanners have performed
 197 an average of at least 3,000 CT equivalents per dedicated pediatric CT scanner for the most recent
 198 continuous 12-month period preceding the applicant's request. In computing this average, the
 199 Department will divide the total number of CT equivalents performed by the applicant's total number of
 200 dedicated pediatric CT scanners, including both operational and approved but not operational dedicated
 201 pediatric CT scanners.

202
 203 (3) If an applicant proposes to expand an existing mobile CT scanner service, the applicant shall
 204 demonstrate that all of the applicant's mobile CT scanners have performed an average of at least 5,500
 205 CT equivalents per mobile CT scanner for the most recent continuous 12-month period preceding the
 206 applicant's request. In computing this average, the Department will divide the total number of CT
 207 equivalents performed by the applicant's total number of mobile CT scanners, including both operational
 208 and approved but not operational mobile CT scanners.

209

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

212
 213 Sec. 6. An applicant proposing to expand an existing fixed dental CT scanner service shall
 214 demonstrate that all of the applicant's dental CT scanners have performed an average of at least 300
 215 dental CT examinations per fixed dental CT scanner for the most recent continuous 12-month period
 216 preceding the applicant's request. In computing this average, the Department will divide the total number
 217 of dental CT examinations performed by the applicant's total number of fixed dental CT scanners,
 218 including both operational and approved but not operational fixed dental CT scanners.

219
 220 **Section 7. Requirements for approval for applicants proposing to replace an existing CT scanner**
 221 **other than a dental CT scanner or hospital-based portable CT scanner**

222
 223 Sec. 7. An applicant proposing to replace an existing CT scanner shall demonstrate each of the
 224 following, as applicable:

225
 226 (1) An applicant, other than an applicant meeting all of the applicable requirements of subsection (a),
 227 (b) or (c) below, proposing to replace an existing fixed CT scanner shall demonstrate that the fixed CT
 228 scanner(s) performed at least an average of 7,500 CT equivalents per fixed CT scanner in the most
 229 recent 12-month period for which the Department has verifiable data.

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

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

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

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

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

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

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

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

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

247 **(D) AN APPLICANT PROPOSING TO REPLACE AN EXISTING FIXED CT SCANNER HAVING A**
 248 **CONFIGURATION OF SUB 16 MULTIDETECTOR ROWS OR LESS SHALL BE EXEMPT ONCE, AS OF**
 249 **THE EFFECTIVE DATE OF THE STANDARDS, FROM THE MINIMUM VOLUME REQUIREMENTS**
 250 **FOR REPLACEMENT IF IT MEETS BOTH OF THE FOLLOWING:**

251 **(i) THE PROPOSED CT SCANNER TO BE OBTAINED WILL HAVE A CONFIGURATION OF**
 252 **SIXTEEN (16) OR MORE MULTIDETECTOR ROWS, AND**

253 **(ii) THE EXISTING CT SCANNER IS FULLY DEPRECIATED ACCORDING TO GENERALLY**
 254 **ACCEPTED ACCOUNTING PRINCIPLES.**

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

260
 261 (3) An applicant proposing to replace an existing dedicated pediatric CT scanner(s) shall
 262 demonstrate that the dedicated pediatric CT scanner(s) performed at least an average of 2,500 CT

263 equivalents per dedicated pediatric CT scanner in the most recent 12-month period for which the
 264 Department has verifiable data.

265
 266 (4) An applicant under this section shall demonstrate that the existing CT scanner(s) proposed to be
 267 replaced is fully depreciated according to generally accepted accounting principles, or, that the existing
 268 equipment clearly poses a threat to the safety of the public, or, that the proposed replacement CT
 269 scanner offers technological improvements which enhance quality of care, increase efficiency, and/or
 270 reduce operating costs and patient charges.

271
 272 **Section 8. Requirements for approval for applicants proposing to replace an existing dental CT**
 273 **scanner**

274
 275 Sec. 8. An applicant proposing to replace an existing dental CT scanner shall demonstrate each of the
 276 following:

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

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

286
 287 **Section 9. Requirements for approval for applicants proposing to relocate an existing CT scanner**
 288 **service and/or CT scanner(s) other than an existing dental CT scanner service and/or dental CT**
 289 **scanner(s) or hospital-based portable CT scanner(s)**

290
 291 Sec. 9. (1) An applicant proposing to relocate an existing fixed CT scanner service shall demonstrate
 292 that the proposed project meets all of the following:

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

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

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

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

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

301
 302 (2) An applicant proposing to relocate a fixed CT scanner(s) of an existing CT scanner service shall
 303 demonstrate that the proposed project meets all of the following:

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

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

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

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

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

313
 314 **Section 10. Requirements for approval for applicants proposing to relocate an existing dental CT**
 315 **scanner service and/or dental CT scanner(s)**

316

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

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

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

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

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

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

328

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

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

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

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

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

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

340

341 **Section 11. Requirements for approval for applicants proposing to acquire an existing CT**
 342 **scanner service or an existing CT scanner(s) other than an existing dental CT scanner service**
 343 **and/or an existing dental CT scanner(s) or hospital-based portable CT scanner(s)**
 344

344

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

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

348 (b) For an application for the proposed first acquisition of an existing fixed or mobile CT scanner
 349 service, for which a final decision has not been issued after June 4, 2004, an existing CT scanner service
 350 to be acquired shall not be required to be in compliance with the volume requirement applicable to the
 351 seller/lessor on the date the acquisition occurs. The CT scanner service shall be operating at the
 352 applicable volume requirements set forth in Section 19 of these standards in the second 12 months after
 353 the date the service is acquired, and annually thereafter.

354 (c) For any application for proposed acquisition of an existing fixed or mobile CT scanner service, an
 355 applicant shall be required to demonstrate that the CT scanner service to be acquired performed at least
 356 7,500 CT equivalents in the most recent 12-month period for which the Department has verifiable data.

357

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

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

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

365

366 **Section 12. Requirements for approval for applicants proposing to acquire an existing dental CT**
 367 **scanner service or an existing dental CT scanner(s)**
 368

368

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

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

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

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

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

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

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

389

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

392

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

395

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

398

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

400

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

404

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

407

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

409

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

412

413 (7) The provisions of Section 13 are part of a pilot program approved by the CON Commission and
 414 shall expire and be of no further force and effect, and shall not be applicable to any application which has
 415 **not been submitted by October DECEMBER 31, 20082013.**

416

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

419

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

422

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

425

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

428

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

430

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

434

435

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

437

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

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

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

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

446

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

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

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

452

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

456

457 **Section 16. Requirements for approval of an applicant proposing a CT scanner used for the sole 458 purpose of performing dental CT examinations exclusively for research**

459

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

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

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

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

467

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

470

471 **Section 17. Requirements for approval of an applicant proposing to establish dedicated pediatric 472 CT**

473

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

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

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

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

483 (i) pediatric radiology (at least two)

484 (ii) pediatric anesthesiology

485 (iii) pediatric cardiology

486 (iv) pediatric critical care

487 (v) pediatric gastroenterology

488 (vi) pediatric hematology/oncology

489 (vii) pediatric neurology

490 (viii) pediatric neurosurgery

491 (ix) pediatric orthopedic surgery

492 (x) pediatric pathology

493 (xi) pediatric pulmonology

494 (xii) pediatric surgery

495 (xiii) neonatology

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

498 (i) pediatric bone marrow transplant program

499 (ii) established pediatric sedation program

500 (iii) pediatric open heart program

501

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

504

505 **Section 18. Requirements for approval -- all applicants**

506

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

510

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

512

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

515 (a) Compliance with these standards

516 (b) Compliance with applicable safety and operating standards

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

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

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

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

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

527 For purposes of evaluating (ii)(A), the Department shall consider it prima facie evidence of a
528 satisfactory assurance mechanism as to screening and interpretation if the applicant requires the
529 screening of requests for and interpretations of CT procedures to be performed by physicians who are
530 board certified or eligible in radiology or are neurologists or other specialists trained in cross-sectional
531 imaging of a specific organ system. For purposes of evaluating (ii)(B) the Department shall consider it
532 prima facie evidence of a satisfactory assurance mechanism as to the operation of a CT scanner if the
533 applicant requires the CT scanner to be operated by a physician or by a technologist registered by the
534 American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical
535 Radiography Technologists (ARCRT). However, the applicant may submit and the Department may
536 accept other evidence that the applicant has established a mechanism to assure that the CT scanner
537 facility is appropriately and adequately staffed as to screening, interpretation, and/or operation of a CT
538 scanner.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- 580 (xiii) Equipment to be replaced shall be removed from service.
- 581 (xiv) The applicant shall provide the Department with a notice stating the date the approved CT
582 scanner service is placed in operation and such notice shall be submitted to the Department consistent
583 with applicable statute and promulgated rules.
- 584 (xv) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years
585 of operation and continue to participate annually thereafter.
- 586 (d) An applicant approved under Section 4 shall not be required to be in compliance with subsection
587 (c) but shall be in compliance with the following quality assurance standards:
- 588 (i) The CT scanner shall be operating at least 200 CT equivalents per year for the second 12-month
589 period after beginning operation of the dental CT scanner and annually thereafter.
- 590 (ii) The CT scanner will be used for the sole purpose of dental CT examinations.
- 591 (iii) The applicant shall demonstrate to the satisfaction of the Department that the person(s) (e.g.,
592 technician, dentist) operating the dental CT scanner has been appropriately trained and/or certified by
593 one of the following groups, as recognized by the Department: a dental radiology program in a certified
594 dental school, an appropriate professional society, or a dental continuing education program accredited
595 by the American Dental Association.
- 596 (iv) The applicant shall demonstrate to the satisfaction of the Department that the dental CT
597 examinations generated by the dental CT scanner will be interpreted by a licensed dentist(s) trained
598 and/or certified by one of the following groups, as recognized by the Department: a dental radiology
599 program in a certified dental school, an appropriate professional society, or a dental continuing education
600 program accredited by the American Dental Association.
- 601 (v) The applicant shall demonstrate to the satisfaction of the Department that the dentists using the
602 dental CT examinations for performing dental procedures has had the appropriate training and/or
603 experience certified by one of the following groups, as recognized by the Department: a dental radiology
604 program in a certified dental school, an appropriate professional society, or a dental continuing education
605 program accredited by the American Dental Association.
- 606 (vi) The applicant, to assure that the dental CT scanner will be utilized by all segments of the
607 Michigan population, shall:
- 608 (A) not deny dental CT scanner services to any individual based on ability to pay or source of
609 payment;
- 610 (B) provide dental CT scanning services to any individual based on the clinical indications of need for
611 the service; and
- 612 (C) maintain information by payor and non-paying sources to indicate the volume of care from each
613 source provided annually. Compliance with selective contracting requirements shall not be construed as
614 a violation of this term.
- 615 (vii) The applicant shall participate in a data collection network established and administered by the
616 Department or its designee. The data may include, but is not limited to, annual budget and cost
617 information, operating schedules, through-put schedules, demographic and diagnostic information, the
618 volume of care provided to patients from all payor sources, and other data requested by the Department,
619 and approved by the Commission. The applicant shall provide the required data on a separate basis for
620 each separate and distinct site as required by the Department; in a format established by the Department;
621 and in a mutually agreed upon media. The Department may elect to verify the data through on-site
622 review of appropriate records.
- 623 (viii) Equipment to be replaced shall be removed from service.
- 624 (ix) The applicant shall provide the Department with a notice stating the date the approved dental CT
625 scanner service is placed in operation and such notice shall be submitted to the Department consistent
626 with applicable statute and promulgated rules.
- 627 (x) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years
628 of operation and continue to participate annually thereafter.
- 629
- 630 (2) The agreements and assurances required by this section shall be in the form of a certification
631 agreed to by the applicant or its authorized agent.
- 632

633 (3) The operation of and referral of patients to the CT scanner shall be in conformance with 1978 PA
634 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

635
636 (4) An applicant for a CT scanner used for dental research under Section 16(1) shall agree that the
637 services provided by the CT scanner approved pursuant to Section 16(1) shall be delivered in compliance
638 with the following terms of CON approval:

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

642 (b) The CT scanner used for dental research approved pursuant to Section 16(1) shall not be used
643 for any purposes other than as approved by the institutional review board unless the applicant has
644 obtained CON approval for the CT scanner pursuant to part 222 and these standards, other than Section
645 16.

646
647 (5) An applicant approved under Section 13 shall be in compliance with the following:
648 (A) PORTABLE CT SCANNER CAN ONLY BE USED IN ADULT OR PEDIATRIC INTENSIVE CARE
649 UNITS (ICU) BY QUALIFYING PILOT PROGRAM INSTITUTIONS AND MUST BE LIMITED TO BRAIN
650 SCANNING OF THOSE PATIENTS WHO ARE BEING TREATED IN AN ICU. —

651 (aB) The applicant agrees to provide quarterly ANNUAL reports to the Department within one month
652 following the end of each calendar quarter, starting with the quarter the applicant initiates use of the
653 hospital-based portable CT scanner BY JANUARY 31ST OF EACH YEAR FOR THE PRECEDING
654 CALENDAR YEAR, BEGINNING WITH 2010 DATA TO BE REPORTED IN 2011. THE DATA TO BE
655 REPORTED IS AS FOLLOWS:

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

660 (II) NUMBER OF PEDIATRIC STUDIES (AGE < 18)

661 (III) NUMBER OF STUDIES PERFORMED USING A PORTABLE CT ON THE SAME PATIENT
662 WHILE THAT PATIENT IS IN AN ICU

663 (IV) NUMBER OF PATIENTS SCANNED ON A PORTABLE CT THAT UNDERWENT SUBSEQUENT
664 SCANNING ON A FIXED CT WITHIN 12 HOURS OF THE PORTABLE CT SCAN

665 (cC) The Department will summarize the information from the quarterly reports and provide an
666 assessment to the Commission prior to the March 2010 Commission meeting. The Commission may
667 request updates on the status of the pilot program at its discretion. ALL APPLICANTS, INCLUDING
668 CURRENT CON HOLDERS OF PORTABLE CT SCANNERS, SHALL BE SUBJECT TO THIS DATA
669 SUBMISSION REQUIREMENT. FAILURE TO COMPLY WILL RESULT IN REVOCATION OF THE
670 INSTITUTION'S CON PILOT PROGRAM PARTICIPATION AND THUS THE ALLOWANCE FOR A
671 PORTABLE CT SCANNER.

672
673 **Section 20. Project delivery requirements -- additional terms of approval for applicants involving**
674 **mobile CT scanners**

675
676 Sec. 20. (1) In addition to the provisions of Section 19, an applicant for a mobile CT scanner shall
677 agree that the services provided by the mobile CT scanner(s) shall be delivered in compliance with the
678 following terms of CON approval:

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

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

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

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

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

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

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

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

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

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

709
710 (2) The agreements and assurances required by this section shall be in the form of a certification
711 agreed to by the applicant or its authorized agent.
712

713 **Section 21. Determination of CT Equivalents**

714

715 Sec. 21. CT equivalents shall be calculated as follows:

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

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

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

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

725

726 Table 1	Number of		Conversion		CT
727 Category	Billable CT		Factor		Equivalents
728	Procedures				
729 Head Scans w/o Contrast	_____	X	1.00	=	_____
730 (includes dental CT examinations)					
731 Head Scans with Contrast	_____	X	1.25	=	_____
732 Head Scans w/o & w Contrast	_____	X	1.75	=	_____
733 Body Scans w/o Contrast	_____	X	1.50	=	_____
734 Body Scans with Contrast	_____	X	1.75	=	_____
735 Body Scans w/o & w Contrast	_____	X	2.75	=	_____
736					
737 Pediatric/Special Needs Patient					
738 Head scans w/o Contrast	_____	x	1.25	=	_____
739 (includes dental CT examinations)					
740 Pediatric/Special Needs Patient					
741 Head Scans with Contrast	_____	x	1.50	=	_____
742 Pediatric/Special Needs Patient					
743 Head Scans w/o & with Contrast	_____	x	2.00	=	_____
744 Pediatric/Special Needs Patient					
745 Body Scans w/o Contrast	_____	x	1.75	=	_____
746 Pediatric/Special Needs Patient					
747 Body Scans with Contrast	_____	x	2.00	=	_____
748 Pediatric/Special Needs Patient					
749 Body Scans w/o & with Contrast	_____	x	3.00	=	_____
750					
751					
752 TOTAL CT EQUIVALENTS					_____

753

754 **Section 22. Documentation of projections**

755

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

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

763

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

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

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

771
 772 (3) An applicant required to project under Section 5 shall demonstrate that the projection is based on
 773 historical utilization at the applicant's site for the most recent 12-month period immediately preceding the
 774 date of the application.

775
 776 (4) An applicant shall demonstrate that the projected number of referrals to be performed at the
 777 proposed site under subsections (1) and (2) are from an existing CT scanner service that is in compliance
 778 with the volume requirements applicable to that service, and will continue to be in compliance with the
 779 volume requirements applicable to that service subsequent to the initiation of the proposed CT scanner
 780 service by an applicant. In demonstrating compliance with this subsection, an applicant shall provide
 781 each of the following:

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

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

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

792

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

794

795 Sec. 23. (1) These CON review standards supersede and replace the CON Review Standards for
 796 Computed Tomography Scanner Services approved by the CON Commission on March 11 APRIL 30,
 797 2008 and effective ~~May 5~~ JUNE 20, 2008.

798

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

800

801 **SECTION 24. HEALTH SERVICE AREAS**

802

803 SEC. 18. COUNTIES ASSIGNED TO EACH OF THE HEALTH SERVICE AREAS ARE AS FOLLOWS:

804

805 HSA	806 COUNTIES		
807 1 - SOUTHEAST	LIVINGSTON	MONROE	ST. CLAIR
	MACOMB	OAKLAND	WASHTENAW
	WAYNE		
811 2 - MID-SOUTHERN	CLINTON	HILLSDALE	JACKSON
	EATON	INGHAM	LENAWEE
814 3 - SOUTHWEST	BARRY	CALHOUN	ST. JOSEPH
	BERRIEN	CASS	VAN BUREN
	BRANCH	KALAMAZOO	

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817	4 - WEST	ALLEGAN	MASON	NEWAYGO
818		IONIA	MECOSTA	OCEANA
819		KENT	MONTCALM	OSCEOLA
820		LAKE	MUSKEGON	OTTAWA
821				
822	5 - GLS	GENESEE	LAPEER	SHIAWASSEE
823				
824	6 - EAST	ARENAC	HURON	ROSCOMMON
825		BAY	IOSCO	SAGINAW
826		CLARE	ISABELLA	SANILAC
827		GLADWIN	MIDLAND	TUSCOLA
828		GRATIOT	OGEMAW	
829				
830	7 - NORTHERN LOWER	ALCONA	CRAWFORD	MISSAUKEE
831		ALPENA	EMMET	MONTMORENCY
832		ANTRIM	GD TRAVERSE	OSCODA
833		BENZIE	KALKASKA	OTSEGO
834		CHARLEVOIX	LEELANAU	PRESQUE ISLE
835		CHEBOYGAN	MANISTEE	WEXFORD
836				
837	8 - UPPER PENINSULA	ALGER	GOGEBIC	MACKINAC
838		BARAGA	HOUGHTON	MARQUETTE
839		CHIPPEWA	IRON	MENOMINEE
840		DELTA	KEWEENAW	ONTONAGON
841		DICKINSON	LUCE	SCHOOLCRAFT

APPENDIX A

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**CON REVIEW STANDARDS
FOR CT SCANNER SERVICES**

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

65 F.R., p. 82238 (December 27, 2000)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

From: Melissa Cupp <melissacupp@wienerassociates.com>
To: Brenda Rogers <rogersbre@michigan.gov>
Date: 1/9/2011 1:02 PM
Subject: Language for Agenda Item #5 CT SAC

Brenda,
I apologize for the delay. Below please find the language I suggested at the end of the last CT SAC meeting to implement agenda item #5 if it is adopted. I hope this will help with the final language review since this will be our last meeting.

Thanks,
Melissa

Proposal 2: Maintain current minimum volume requirement of 7,500 CT equivalents, but add a maximum volume of 10,000 CT equivalents before "excess" CT equivalents volume could be committed toward justifying an additional CT service in the community.

Modify Section 2 (Definitions) as follows:

(P) "EXCESS CT EQUIVALENTS" MEANS THE NUMBER OF CT EQUIVALENTS PERFORMED BY AN EXISTING CT SCANNER SERVICE IN EXCESS OF 10,000 PER FIXED CT SCANNER AND 4,500 PER MOBILE CT SCANNER. FOR EITHER A FIXED OR MOBILE CT SCANNER SERVICE, THE NUMBER OF CT SCANNERS USED TO COMPUTE EXCESS CT EQUIVALENTS SHALL INCLUDE BOTH EXISTING AND APPROVED BUT NOT YET OPERATIONAL CT SCANNERS. IN THE CASE OF A CT SCANNER SERVICE THAT OPERATES, OR HAS A VALID CON TO OPERATE, MORE THAN ONE FIXED CT SCANNER AT THE SAME SITE, THE TERM MEANS THE NUMBER OF CT EQUIVALENTS IN EXCESS OF 10,000 MULTIPLIED BY THE NUMBER OF FIXED CT SCANNERS AT THE SAME SITE. FOR EXAMPLE, IF A CT SCANNER SERVICE OPERATES, OR HAS A VALID CON TO OPERATE, TWO FIXED CT SCANNERS AT THE SAME SITE, THE EXCESS CT EQUIVALENTS IS THE NUMBER THAT IS IN EXCESS OF 20,000 (10,000 X 2) CT EQUIVALENTS. IN THE CASE OF A MOBILE CT SCANNER SERVICE, THE TERM MEANS THE SUM OF ALL CT EQUIVALENTS PERFORMED BY THE SAME MOBILE CT SCANNER SERVICE AT ALL OF THE HOST SITES COMBINED THAT IS IN EXCESS OF 4,500. FOR EXAMPLE, IF A MOBILE CT SCANNER SERVICE SERVES FIVE HOST SITES WITH 1 MOBILE CT SCANNER, THE TERM MEANS THE SUM OF MRI ADJUSTED PROCEDURES FOR ALL FIVE HOST SITES COMBINED THAT IS IN EXCESS OF 4,500 CT EQUIVALENTS.

Modify Section 22 (Documentation of Projections) as follows:

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

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