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MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

**CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR
POSITRON EMISSION TOMOGRAPHY (PET) 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. These standards are requirements for the approval of the initiation, replacement, expansion, or acquisition of PET scanner services, and the delivery of these services under Part 222 of the Code. Pursuant to Part 222 of the Code PET scanner services are a covered clinical service. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws 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) "Central service coordinator" means the legal entity that has operational responsibility for a mobile PET scanner service.
- (b) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.
- (c) "Department" means the Michigan Department of Community Health (MDCH).
- (d) "Existing PET scanner" means an operational PET scanner used to provide PET services on the date an application is submitted to the Department.
- (e) "Existing PET scanner service" means an operational PET scanner service providing PET scanner services at one site in the case of a fixed PET service or at each host site in the case of a mobile PET service on the date an application is submitted to the Department.
- (f) "Health service area" or "HSA" means the groups of counties listed in Appendix A.
- (g) "Hospital" means a health facility licensed under Part 215 of the Code.
- (h) "Host site" means the geographic address at which a mobile PET scanner is authorized by CON to provide mobile PET scanner services.
- (i) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C.1396 to 1396g and 1396i to 1396u.
- (j) "Michigan Inpatient Data Base" or "MIDB" means the data base compiled by the Michigan Health and Hospital Association or successor organization. The data base consists of inpatient discharge records from all Michigan hospitals and Michigan residents discharged from hospitals in border states for a specific calendar year.
- (k) "Mobile PET scanner" means a PET scanner unit and transporting equipment operated by a central service coordinator that serves two or more host sites.
- (l) "Mobile PET scanner network" means the route (i.e., all host sites) that the central service coordinator is authorized to serve under CON.
- (m) "Patient visit" means a single session utilizing a PET scanner during which 1 or more PET procedures are performed.
- (n) "Pediatric patient" means any patient less than 18 years of age.
- (o) "PET procedure" means the acquisition of a single image or image sequence involving a single injection of tracer.
- (p) "PET scan" means one (1) or more PET procedures performed during a single patient visit.
- (q) "PET scanner" means an FDA-approved full or partial ring scanner or coincidence system that has a crystal at least 5/8-inch thick, techniques to minimize or correct for scatter and/or randoms, and digital detectors and iterative reconstruction. Further, the term does include PET/computed tomography

55 (CT) and FDA-approved PET/magnetic resonance imaging (MRI) scanner hybrids. If the PET/CT
56 scanner hybrid will be used for CT scans only in conjunction with the PET scan, then no separate CON is
57 required for that CT use. If the FDA-approved PET/MRI scanner hybrid will be used for MRI scans only in
58 conjunction with the PET scan, then no separate CON is required for that MRI use. The term does not
59 include single-photon emission computed tomography systems (SPECT), x-ray CT systems, magnetic
60 resonance, ultrasound computed tomographic systems, gamma cameras modified for either non-
61 coincidence or coincidence imaging, or similar technology.

62 (r) "PET scanner services" or "PET services" means either the utilization of a PET unit(s) at one
63 site in the case of a fixed PET service or at each host site in the case of a mobile PET service.

64 (s) "SPECT" means single photon emission computed tomography.

65

66 (2) The definitions in Part 222 shall apply to these standards.

67

68 **Section 3. Requirements to initiate a PET scanner service**

69

70 Sec. 3. An applicant proposing to initiate PET scanner services shall demonstrate the following, as
71 applicable to the proposed project.

72

73 (1) The applicant shall demonstrate the proposed site provides the following services and
74 specialties:

75 (a) nuclear medicine services as documented by a certificate from the US Nuclear Regulatory
76 Commission,

77 (b) single photon emission computed tomography (SPECT) services,

78 (c) computed tomography (CT) scanning services,

79 (d) magnetic resonance imaging (MRI) services,

80 (e) cardiac catheterization services,

81 (f) open heart surgery,

82 (g) thoracic surgery,

83 (h) cardiology,

84 (i) oncology,

85 (j) radiation oncology,

86 (k) neurology,

87 (l) neurosurgery, and

88 (m) psychiatry.

89

90 (2) If the proposed site does not provide any of the services listed in subsection (1) on-site, the
91 applicant shall provide written contracts or agreements with a hospital(s) located within the same planning
92 area or 25-mile radius of the proposed site for the services not provided.

93

94 (3) The applicant shall demonstrate the proposed site has an on-site source of
95 radiopharmaceuticals. If the proposed site does not provide an on-site source of radiopharmaceuticals,
96 the applicant shall provide a written contract or agreement that demonstrates a reliable supply of
97 radiopharmaceuticals.

98

99 (4) An applicant proposing to initiate a fixed PET scanner service with its first PET scanner shall
100 project 2,600 PET data units or shall demonstrate all of the following:

101 (a) The applicant is currently a host site being served by one or more mobile PET scanner services.

102 (b) The applicant has performed:

103 (i) 1,700 PET equivalents in the most recent 12-month period verifiable by the Department for a
104 host site in a metropolitan statistical area county, or

105 (ii) 1,500 PET equivalents in the most recent 12-month period verifiable by the Department for a
106 host site in a rural or micropolitan statistical area county.

107 (c) The applicant shall install the fixed PET unit at the same site as the existing host site or within a
108 10-mile radius of the existing host site for a metropolitan statistical area county or a 25-mile radius for a
109 rural or micropolitan statistical area.

110 (d) The applicant agrees to cease operation as a host site and not become a host site for at least
111 12 months from the date the fixed PET scanner becomes operational. This requirement shall not apply if
112 the applicant is installing an FDA-approved PET/MRI scanner hybrid.

113
114 (5) An applicant proposing to initiate a mobile PET scanner service with its first mobile PET
115 scanner shall project 2,100 PET data units.

116 (a) Of the 2,100 PET data units, the applicant shall project a minimum of 360 PET data units within
117 a 20-mile radius of each proposed host site for planning area 1, or 240 PET data units per host site for any
118 other planning area, for the proposed service.

119 (b) The application for the mobile PET scanner service is accompanied by at least two host site
120 applications.

121 (c) Each applicant provides a route schedule for the proposed mobile PET scanner service.

122 (d) The applicant provides a draft contract for services between the proposed host site and central
123 service coordinator.

124
125 (6) An applicant proposing to initiate a host site on a proposed or existing mobile PET scanner
126 service shall demonstrate the following:

127 (a) The applicant provides a proposed route schedule.

128 (b) The applicant provides a draft contract for services between the proposed host site and central
129 service coordinator.

130 (c) The applicant has not initiated fixed PET scanner services under subsection 3(4) within the
131 most recent 12-month period as of the date the application is submitted to the Department.

132 (d) An applicant initiating a host site in HSA 8 on a mobile PET scanner service that operates
133 predominantly outside of Michigan shall demonstrate 240 PET data units from planning area 6.

134
135 (7) An applicant proposing to initiate PET scanner services as an existing host site on a different
136 mobile PET scanner service shall demonstrate the following:

137 (a) The applicant provides a proposed route schedule.

138 (b) The applicant provides a draft contract for services between the proposed host site and central
139 service coordinator.

140 (c) 50 PET equivalents were performed in the most recent 12-month period verifiable by the
141 Department from an existing mobile PET scanner service at the existing host site.

142 143 **Section 4. Requirements to replace an existing PET scanner(s) or PET scanner service**

144
145 Sec. 4. Replacing a PET scanner(s) means a change in the scanner equipment or relocation of the
146 service to a new site. An upgrade to software or components of an existing scanner does not constitute
147 replacement of a PET scanner. An applicant proposing to replace an existing PET scanner(s) or PET
148 scanner service shall demonstrate the following, as applicable to the proposed project.

149 (1) An applicant proposing to replace a PET scanner(s) shall demonstrate each of the following:

150 (a) The replacement scanner(s) is the same type (fixed or mobile) as the scanner(s) to be replaced.

151 (b) The scanner(s) to be replaced is fully depreciated according to generally accepted accounting
152 principles or either of the following:

153 (i) The existing scanner(s) poses a threat to the safety of the patients.

154 (ii) The replacement scanner(s) offers technological improvements that enhance quality of care,
155 increase efficiency, and reduce operating costs and patient charges.

156 (c) The applicant agrees that the PET scanner(s) to be replaced will be removed from service on or
157 before beginning operation of the replacement scanner(s).

160 (2) An applicant proposing to replace a fixed PET scanner service to a new site shall demonstrate
161 the following:

162 (a) The proposed site is within a 10-mile radius of the existing site for a metropolitan statistical area
163 county or a 25-mile radius for a rural or micropolitan statistical area county.

164 (b) The existing fixed PET scanner(s) performed 500 PET equivalents per fixed scanner in the
165 most recent 12-month period verifiable by the Department.

166 (c) The existing fixed PET scanner service has been in operation for at least 36 months as of the
167 date of the application submitted to the Department.

168 169 **Section 5. Requirements to expand a PET scanner service**

170
171 Sec. 5. An applicant proposing to expand a PET scanner service shall demonstrate the following, as
172 applicable to the proposed project. This section does not apply to dedicated research, dedicated
173 pediatric, or positron emission mammography (PEM) scanners.

174
175 (1) An applicant proposing to add a fixed PET scanner(s) to an existing fixed PET scanner service
176 shall demonstrate the following:

177 (a) 1,900 PET equivalents were performed per existing and approved fixed PET scanner(s) in the
178 most recent 12-month period verifiable by the Department for an applicant in a metropolitan statistical
179 area county, or

180 (b) 1,700 PET equivalents were performed per existing and approved fixed PET scanner(s) in the
181 most recent 12-month period verifiable by the Department for an applicant in a rural or micropolitan
182 statistical area county.

183 (c) The additional PET scanner(s) shall be located at the same site.

184
185 (2) An applicant proposing to add a mobile PET scanner(s) to an existing mobile PET scanner
186 service shall demonstrate the following:

187 (a) 2,000 PET equivalents were performed per existing and approved mobile scanner(s) in the
188 most recent 12-month period verifiable by the Department for an applicant serving at least one existing
189 host site in a metropolitan statistical area county, or

190 (b) 1,800 PET equivalents were performed per existing and approved scanner(s) in the most recent
191 12-month period verifiable by the Department for an applicant serving only host sites in rural or
192 micropolitan statistical area counties.

193
194 (3) An applicant proposing to add a fixed PET scanner to an existing fixed PET scanner service
195 that also receives mobile PET scanner services shall demonstrate the following:

196 (a) The applicant is currently a host site being served by one or more mobile PET scanner services.

197 (b) The applicant has performed:

198 (i) An average of 1,900 pet equivalents for the host site and each of the existing and approved
199 fixed scanners in the most recent 12-month period verifiable by the Department for a host site in a
200 metropolitan statistical area county, or

201 (ii) An average of 1,700 PET equivalents for the host site and each of the existing and approved
202 fixed scanners in the most recent 12-month period verifiable by the Department for a host site in a rural or
203 micropolitan statistical area county.

204 (c) The applicant agrees to cease operation as a host site and not become a host site for at least
205 12 months from the date the fixed scanner becomes operational.

206 207 **Section 6. Requirements to acquire a PET scanner service or scanner(s)**

208
209 Sec. 6. Acquiring a PET scanner service and its scanner(s) means obtaining possession and control
210 by contract, ownership, lease, or other comparable arrangement and renewal of lease for an existing fixed
211 or mobile PET scanner. An applicant proposing to acquire a PET scanner service shall demonstrate the
212 following, as applicable to the proposed project.

214 (1) For the first application proposing to acquire an existing fixed, mobile, or host site PET scanner
215 service, other than a renewal of lease, on or after November 21, 2011, the existing PET service and its
216 scanner(s) shall not be required to be in compliance with the applicable volume requirements set forth in
217 this section. The PET SCANNER SERVICE SHALL BE OPERATING AT THE APPLICABLE VOLUMES
218 SET FORTH IN THE PROJECT DELIVERY REQUIREMENTS IN THE SECOND 12 MONTHS OF
219 OPERATION OF THE SERVICE BY THE APPLICANT AND ANNUALLY THEREAFTER.

220
221 (2) FOR ANY APPLICATION PROPOSING TO ACQUIRE AN EXISTING PET SCANNER
222 SERVICE, EXCEPT THE FIRST APPLICATION APPROVED PURSUANT TO SUBSECTION (1), AN
223 APPLICANT SHALL BE REQUIRED TO DOCUMENT THAT THE PET SCANNER SERVICE TO BE
224 ACQUIRED IS OPERATING IN COMPLIANCE WITH THE VOLUME REQUIREMENTS SET FORTH IN
225 SECTION 11 OF THESE STANDARDS APPLICABLE TO AN EXISTING PET SCANNER SERVICE ON
226 THE DATE THE APPLICATION IS SUBMITTED TO THE DEPARTMENT.

227
228 (23) An applicant proposing to acquire an existing fixed or mobile PET scanner service shall
229 demonstrate that the existing fixed or mobile scanner(s) performed an average of 500 PET equivalents
230 per scanner in the most recent 12-month period verifiable by the Department.

231
232 (34) An applicant proposing to acquire an existing host site shall demonstrate that the existing host
233 site has performed 50 PET equivalents in the most recent 12-month period verifiable by the Department.

234
235 (45) An applicant proposing to renew a lease for an existing fixed or mobile PET scanner(s) shall
236 demonstrate that the renewal of the lease is more cost effective than replacing the scanner(s).

237 **Section 7. Requirements for a dedicated research fixed PET scanner**

238
239 Sec. 7. An applicant proposing to add a fixed PET scanner to an existing PET scanner service for
240 exclusive research use shall demonstrate the following:

241
242 (1) The applicant agrees that the dedicated research PET scanner will be used primarily (70% or
243 more of the scans) for research purposes only.

244
245 (2) The dedicated research PET scanner shall operate under a protocol approved by the applicant's
246 Institutional Review Board, as defined by Public Law 93-348 and regulated by Title 45 CFR 46.

247
248 (3) The applicant has access to a cyclotron for accelerating charged particles to high energies by
249 means of electromagnetic fields.

250
251 (4) The proposed site can have no more than three dedicated research fixed PET scanners
252 approved under this Section.

253 **Section 8. Requirements for a dedicated pediatric PET scanner**

254
255 Sec. 8. An applicant proposing to initiate a PET scanner service, or add a fixed PET scanner to
256 expand an existing PET scanner service, for dedicated pediatric PET use shall demonstrate the following:

257
258 (1) The applicant agrees that the dedicated pediatric PET scanner will be used primarily (70% or
259 more of the scans) for patients under 18 years of age.

260
261 (2) The applicant shall demonstrate the existing site provided the following for the most recent
262 calendar year or a continuous 12-month period at the time the application is submitted to the Department:

263 (a) at least 7,000 pediatric (< 18 years old) discharges, excluding normal newborns,

264 (b) at least 5,000 pediatric (< 18 years old) surgeries, and

265 (c) at least 50 new pediatric cancer cases on its cancer registry.
266
267

268
269 (3) The applicant shall have an active medical staff at the time the application is submitted to the
270 Department that includes physicians who are fellowship-trained in the following pediatric specialties:

- 271 (a) radiology (at least two staff members)
- 272 (b) anesthesiology
- 273 (c) cardiology
- 274 (d) critical care
- 275 (e) gastroenterology
- 276 (f) hematology/oncology
- 277 (g) neurology
- 278 (h) neurosurgery
- 279 (i) orthopedic surgery
- 280 (j) pathology
- 281 (k) pulmonology
- 282 (l) surgery
- 283 (m) neonatology

284
285 (4) The applicant shall have in operation the following pediatric specialty programs at the time the
286 application is submitted to the Department:

- 287 (a) bone marrow transplant program
- 288 (b) sedation program
- 289 (c) open heart program

290
291 (5) The applicant meets the requirements of Section 3(1) through 3(4) if the applicant is initiating a
292 PET scanner service with a dedicated pediatric fixed PET scanner.

293
294 (6) The proposed site can have no more than two dedicated pediatric fixed PET scanners approved
295 under this section.

296
297 **Section 9. Requirements for a positron emission mammography (PEM) scanner**

298
299 Sec. 9. An applicant proposing to add a PEM scanner service to an existing PET scanner service
300 shall demonstrate the following, as applicable to the proposed project.

301
302 (1) An applicant proposing to add a fixed PEM scanner to an existing fixed PET scanner site shall
303 demonstrate the following:

304 (a) The applicant is certified through the American College of Radiology (ACR) as a Breast Imaging
305 Center of Excellence (BICOE) at the time the application is submitted to the Department.

306 (b) The applicant has a fixed PET scanner service and has performed 1,000 PET equivalents per
307 scanner at the site in the most recent 12-month period verifiable by the Department, or the applicant
308 operates a comprehensive cancer center recognized by the National Cancer Institute and contracts with a
309 facility that has a fixed PET scanner service.

310 (c) The proposed site can have no more than one fixed PEM scanner approved under this section.

311
312 (2) An applicant proposing to add a mobile PEM scanner to an existing mobile PET scanner service
313 shall demonstrate the following:

314 (a) The central service coordinator application for a mobile PEM scanner shall be accompanied by
315 at least five (5) companion host site applications for initiation of mobile PEM scanner services. The
316 proposed host sites have not received mobile PEM scanner services within the most recent 12-month
317 period.

318 (b) The applicant has performed an average of 500 PET equivalents per scanner on the existing
319 mobile PET network in the most recent 12-month period verifiable by the Department.

320 (c) The applicant provides a route schedule for the proposed mobile PEM scanner service.

321 (d) The applicant provides a draft contract for PEM services between the proposed host sites and
322 central service coordinator.

323 (e) The proposed network can have no more than one mobile PEM scanner approved under this
324 section.

325
326 (3) An applicant, whether an existing fixed PET scanner site or host site, proposing to initiate
327 mobile PEM scanner services as a host site shall demonstrate the following:

328 (a) The applicant is certified through the ACR as a BICOE site at the time the application is
329 submitted to the Department.

330 (b) The applicant has a fixed PET scanner site or host site and has performed 100 PET equivalents
331 in the most recent 12-month period verifiable by the Department, or the applicant operates a
332 comprehensive cancer center recognized by the National Cancer Institute and contracts with a facility that
333 has a fixed or mobile PET scanner service.

334 (c) The applicant provides a proposed route schedule for the mobile PEM scanner service.

335 (d) The applicant provides a draft contract for PEM services between the host site and central
336 service coordinator.

337
338 (4) An applicant proposing to add an existing PEM scanner host site to an existing mobile PEM
339 scanner service shall demonstrate the following:

340 (a) The host site has performed mobile PEM scanner service within the most recent 12-month
341 period as of the date an application is submitted to the Department.

342 (b) The proposed site is certified through the ACR as a BICOE site at the time the application is
343 submitted to the Department.

344 (c) The applicant provides a proposed route schedule for the mobile PEM scanner service.

345 (d) The applicant provides a draft contract for PEM services between the host site and central
346 service coordinator.

347

348 **Section 10. Requirement for Medicaid participation**

349

350 Sec. 10. An applicant shall provide verification of Medicaid participation. An applicant that is a new
351 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided
352 to the Department within (6) months from the offering of services if a CON is approved.

353

354 **Section 11. Project delivery requirements and terms of approval for all applicants**

355

356 Sec. 11. An applicant shall agree that, if approved, the PET scanner services shall be delivered in
357 compliance with the following terms of approval.

358

359 (1) Compliance with these standards.

360

361 (2) Compliance with the following quality assurance requirements:

362 (a) A PET scanner service shall be staffed so that screening of requests for and interpretation of
363 PET procedures will be carried out by a physician(s) with appropriate training and familiarity with the
364 appropriate diagnostic use and interpretation of cross-sectional images of the anatomical region(s) to be
365 examined. For purposes of evaluating this subsection, the Department shall consider it prima facie
366 evidence as to the training of the physician(s) if the physician is board certified or board qualified in
367 nuclear medicine or nuclear radiology. However, an applicant may submit, and the Department may
368 accept, other evidence that the physician(s) is qualified to operate the PET service/scanner. The
369 physician(s) must be on-site or available through telecommunication capabilities to participate in the
370 screening of patients for PET procedures and to provide other consultation services.

371 (b) The PET scanner service shall include the following personnel, employed directly or on a
372 contractual basis: a technologist with training in PET scanning and a physicist. The physicist must be
373 board certified or eligible for certification by the American Board of Radiology or an equivalent
374 organization.

375 (c) The PET scanner service shall have a physician on-site or immediately available to the PET
376 scanner service at all times when patients are undergoing PET procedures.

377 (d) The applicant maintains the services and specialties as set forth in Section 3(1) through 3(4).
378

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

380 (a) The PET scanner service shall accept referrals for PET scanner services from all appropriately
381 licensed practitioners.

382 (b) The PET scanner service shall participate in Medicaid at least 12 consecutive months within the
383 first two years of operation and continue to participate annually thereafter.

384 (c) The PET scanner service shall not deny PET scanner services to any individual based on ability
385 to pay or source of payment.

386 (d) The operation of and referral of patients to the PET scanner service shall be in conformance
387 with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).
388

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

390 (a) The PET scanners shall be operating at an average of 500 PET equivalents per scanner during
391 the second 12 months of operations, and annually thereafter. This requirement shall be waived during
392 review of applications under sections 4(1) and 6(45), if applicable. In meeting these requirements, an
393 applicant shall not include any PET scans performed on a PET scanner used exclusively for research
394 approved pursuant to Section 7, for a dedicated pediatric PET scanner approved pursuant to Section 8, or
395 for a PEM scanner approved pursuant to Section 9.

396 (b) The PET scanner service shall participate in a data collection system established and
397 administered by the Department or its designee. The data may include, but are not limited to, clinical scan
398 data, annual budget and cost information, operating schedules, through-put schedules, demographic and
399 diagnostic information, and the volume of care provided to patients from all payor sources. The applicant
400 shall provide the required data on a separate basis for each separate and distinct site, PET scanner, or
401 PET scanner service as required by the Department, in a format established by the Department. The
402 Department may elect to verify the data through on-site review of appropriate records.

403 (c) The PET scanner service shall provide the Department with timely notice of the proposed
404 project implementation consistent with applicable statute and promulgated rules.
405

406 (5) Compliance with the following dedicated research PET scanner requirements, if applicable:

407 (a) The capital and operating costs relating to the dedicated research PET scanner shall be
408 charged only to a specific research account(s) and not to any patient or third- party payor.

409 (b) The dedicated research PET scanner shall not be used for any purposes other than as
410 approved by the Institutional Review Board.

411 (c) The dedicated research PET scanner will be used primarily (70% or more of the scans) for
412 research purposes only.
413

414 (6) Compliance with the following dedicated pediatric PET scanner requirements, if applicable:

415 (a) The dedicated pediatric PET scanner will be used primarily (70% or more of the scans) for
416 patients under 18 years of age.

417 (b) Shall maintain active medical staff in the applicable pediatric specialties and pediatric specialty
418 programs as set forth in the section.
419

420 (7) Compliance with the following PEM scanner requirements, if applicable:

421 (a) The PEM scanner service must maintain ACR accreditation as a BICOE site verifiable by the
422 Department.
423

424 (8) Compliance with the following mobile PET scanner requirements, if applicable:

425 (a) The central service coordinator for a mobile PET scanner service shall notify the Department 30
426 days prior to dropping an existing host site.

427 (b) Each host site must have at least one physician who is board certified or board eligible in
428 nuclear medicine or nuclear radiology on its medical staff. The physician(s) shall be responsible for

429 establishing patient examination and infusion protocol, and providing for the interpretation of scans
430 performed.

431 (c) Each host site shall provide a properly prepared parking pad for the mobile PET scanner unit, a
432 waiting area for patients, and a means for patients to enter the vehicle without going outside (such as an
433 enclosed canopy or an enclosed corridor).

434 (d) A mobile PET scanner service shall operate under a contractual agreement that includes the
435 provision of PET services at each host site on a regularly scheduled basis.

436
437 (9) The agreements and assurances required by this section shall be in the form of a certification
438 agreed to by the applicant or its authorized agent.

439

440 **Section 12. Methodology for computing the projected PET data units**

441

442 Sec. 12. An applicant being reviewed under Section 3 shall apply the methodology set forth in this
443 section in computing the projected number of PET data units.

444

445 (1) Identify the number of diagnosis-specific new cancer cases documented in accordance with the
446 requirements of Section 13.

447 (a) Combine the number of cancer cases for lung (site codes C340-C349), esophagus (site codes
448 C150-C159), colorectal (site codes C180-C209), lymphoma (morphology codes (9590-9729), melanoma
449 (morphology codes 8720-8790), and head & neck [site codes C000-C148, C300-C329, C410, C411, C470
450 or C490 excluding C440-C444 (skin of head and neck), and additional codes approved by national
451 coverage determination]. Use the name "combined" for this grouping.

452 (b) Multiply the number resulting from the calculation in "combined" cancer cases identified in
453 subsection (1)(a) by 0.8, which is the estimated probability that a "combined" cancer case will require a
454 PET scan.

455 (c) Multiply the number resulting from the calculation in subsection (1)(b) by 2.5, which is the
456 estimated number of PET scans needed for each patient requiring a PET scan.

457

458 (2) Identify the number of diagnosis-specific new cancer cases documented in accord with the
459 requirements of section 13.

460 (a) Multiply the number of breast cancer cases (site codes C500-C509) by 0.25, which is the
461 estimated probability that a breast cancer case will require a PET scan.

462 (b) Multiply the number resulting from the calculation in subsection (2)(a) by 1.0, which is the
463 estimated number of PET scans needed for each patient requiring a PET scan.

464

465 (3) Multiply the number of diagnostic cardiac catheterization cases identified in accord with the
466 requirements of Section 15 by 0.1, which is the estimated probability that a patient having a diagnostic
467 cardiac catheterization will require a PET scan.

468

469 (4) Multiply the number of intractable epilepsy cases (ICD-9-CM codes 345.01, 345.11, 345.41,
470 345.51, 345.61, 345.71, 345.81, or 345.91, see Appendix D for ICD-10-CM Codes) identified in accord
471 with the requirements of Section 16 by 1.0, which is the estimated probability that a patient having an
472 intractable epilepsy procedure will require a PET scan. Multiply the number resulting from the calculation
473 in subsection (3) by 1.0, which is the estimated number of PET scans needed for each patient requiring a
474 PET scan.

475

476 (5) Sum the numbers resulting from the calculations in subsections (1) through (4) to determine the
477 total number of projected PET data units.

478

479 (6) Multiply the result calculated in subsection (5) above by a factor of 3.0 if the applicant is
480 proposing to serve only planning area 6 to determine the total number of projected PET data units.

481

482 (7) Multiply the result calculated in subsection (5) above by a factor of 2.0 if the applicant is
483 proposing to serve only planning area 5 to determine the total number of projected PET data units.
484

485 **Section 13. Commitment of diagnosis-specific new cancer cases**
486

487 Sec. 13. An applicant proposing to use diagnosis-specific new cancer cases shall demonstrate all of
488 the following:
489

490 (1) Only those cancer diagnoses identified in Section 12(1) and 12(2) shall be included.
491

492 (2) Each entity contributing diagnosis-specific new cancer case data provides, as part of the
493 application at the time it is submitted to the Department, a signed governing body resolution that identifies
494 the number of diagnosis-specific cancer cases being committed to the application and that states no
495 current or future diagnosis-specific new cancer case data will be used in support of any other application
496 for a PET unit for a period of five (5) years from the date of start of operations of the approved PET
497 scanner service for which data are being committed. If the required documentation for this subsection is
498 not submitted with the application on the designated application date, the application will be deemed filed
499 on the first applicable designated application date after all required documentation is received by the
500 Department.

501 (a) For fixed PET scanner services, the geographic location of each entity contributing diagnosis-
502 specific new cancer case data is in the same planning area as the proposed PET service.

503 (b) For mobile PET scanner services, the geographic location of each entity contributing diagnosis-
504 specific new cancer case data in the planning area(s) for which the proposed PET service contains a
505 proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical
506 area counties or 25-mile radius for metropolitan statistical area counties.

507 (c) No entity contributing diagnosis-specific new cancer case data has previously committed or is
508 committing data to another service that is less than five (5) years from the start of operations of that
509 service.
510

511 (3) No entity currently operating or approved to operate a PET scanner service shall contribute
512 diagnosis-specific new cancer cases.
513

514 (4) The Department may not consider a withdrawal of diagnosis-specific new cancer case data
515 during the 120-day application review cycle following the date on which the Department review of the
516 application commences or after a proposed decision to approve the application has been issued unless
517 the application is denied, withdrawn, or expired. The withdrawal must be submitted to the Department in
518 the form of a governing body resolution that contains the specific CON application number to which the
519 data were originally committed, the legal applicant entity, the committing entity, the type of data, the date
520 of the meeting in which the governing body authorized the withdrawal of the data, the governing body
521 president's signature, and the date of the signature.
522

523 **Section 14. Documentation of diagnosis-specific new cancer case data**
524

525 Sec. 14. An applicant required to document volumes of diagnosis-specific new cancer cases shall
526 submit, as part of its application at the time it is submitted to the Department, documentation from the
527 Division for Vital Records and Health Statistics verifying the number of diagnosis-specific new cancer
528 cases provided in support of the application for the most recent calendar year for which verifiable data are
529 available from the state registrar. If the required documentation for this subsection is not submitted with
530 the application on the designated application date, the application will be deemed filed on the first
531 applicable designated application date after all required documentation is received by the Department.
532 Diagnosis-specific new cancer case data supporting an application under these standards shall be
533 submitted to the Division for Vital Records and Health Statistics using a format and media specified in
534 instructions from the Department of Community Health.
535

536 **Section 15. Commitment and documentation of diagnostic cardiac catheterization data**
537

538 Sec. 15. An applicant proposing to use diagnostic cardiac catheterization data shall demonstrate all
539 of the following:
540

541 (1) Each entity contributing diagnostic cardiac catheterization data provides, as part of the
542 application at the time it is submitted to the Department, a signed governing body resolution that identifies
543 the number of diagnostic cardiac catheterization cases (sessions) committed to the application and that
544 states no current or future diagnostic cardiac catheterization data will be used in support of any other
545 application for a PET unit for the duration of the PET service for which data are being committed for a
546 period of five (5) years from the date of start of operations of the approved PET service for which data are
547 being committed. If the required documentation for this subsection is not submitted with the application on
548 the designated application date, the application will be deemed filed on the first applicable designated
549 application date after all required documentation is received by the Department.

550 (a) For fixed PET scanner services, the geographic location of each entity contributing diagnostic
551 cardiac catheterization data is in the same planning area as the proposed PET unit/service.

552 (b) For mobile PET scanner services, the geographic location of each entity contributing diagnostic
553 cardiac catheterization case data in the planning area(s) for which the proposed PET service contains a
554 proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical
555 area counties or 25-mile radius for metropolitan statistical area counties.

556 (c) No entity contributing diagnostic cardiac catheterization data has previously committed or is
557 committing data to another service that is less than five (5) years from the start of operations of that
558 service.

559 (d) The diagnostic cardiac catheterization case data is from the most recently completed report(s)
560 of the annual survey produced by the Department, and the contributing entity has CON approval to provide
561 diagnostic cardiac catheterization services.
562

563 (2) No entity currently operating or approved to operate a PET scanner service shall contribute
564 diagnostic cardiac catheterization case data.
565

566 (3) The Department may not consider a withdrawal of diagnostic cardiac catheterization case data
567 during the 120-day application review cycle following the date on which the Department review of the
568 application commences or after a proposed decision to approve the application has been denied unless
569 the application is denied, withdrawn, or expired. The withdrawal must be submitted to the Department in
570 the form of a governing body resolution that contains the specific CON application number to which the
571 data were originally committed, the legal applicant entity, the committing entity, the type of data, the date
572 of the meeting in which the governing body authorized the withdrawal of the data, the governing body
573 president's signature, and the date of the signature.
574

575 **Section 16. Commitment and documentation of intractable epilepsy data**
576

577 Sec. 16. An applicant proposing to use intractable epilepsy cases shall demonstrate all of the
578 following:
579

580 (1) Each entity contributing intractable epilepsy data provides, as part of the application at the time
581 it is submitted to the Department, a signed governing body resolution that identifies the number of
582 intractable epilepsy cases committed to the application and that states no current or future intractable
583 epilepsy case data will be used in support of any other application for a PET unit for the duration of the
584 PET service for which the data are being committed for a period of five (5) years from the date of start of
585 operations of the approved PET service for which data are being committed. If the required
586 documentation for this subsection is not submitted with the application on the designated application date,
587 the application will be deemed filed on the first applicable designated application date after all required
588 documentation is received by the Department.

589 (a) For fixed PET scanner services, the geographic location of each entity contributing intractable
 590 epilepsy case data is in the same planning area as the proposed PET unit/service.
 591 (b) For mobile PET scanner services, the geographic location of each entity contributing intractable
 592 epilepsy case data in the planning area(s) for which the proposed PET scanner service contains a
 593 proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical
 594 area counties or 25-mile radius for metropolitan statistical area counties.
 595 (c) No entity contributing intractable epilepsy case data has previously committed or is committing
 596 data to another service that is less than five (5) years from the start of operations of that service.
 597 (d) The intractable epilepsy case data is from the most recent Michigan Inpatient Data Base (MIDB)
 598 available to the Department.

599
 600 (2) No entity currently operating or approved to operate a scanner shall contribute intractable
 601 epilepsy case data.

602
 603 (3) The Department may not consider a withdrawal of intractable epilepsy case data during the 120-
 604 day application review cycle following the date on which the Department review of the application
 605 commences or after a proposed decision to approve the application unless the application is denied,
 606 withdrawn, or expired. The withdrawal must be submitted to the Department in the form of a governing
 607 body resolution that contains the specific CON application number to which the data were originally
 608 committed, the legal applicant entity, the committing entity, the type of data, the date of the meeting in
 609 which the governing body authorized the withdrawal of the data, the governing body president's signature,
 610 and the date of the signature.

611
 612 **Section 17. Methodology for computing PET equivalents**

613
 614 Sec. 17. PET equivalents shall be calculated as follows:
 615

TABLE 1	
PET EQUIVALENTS	
Scan Category	Weight
Simple ¹	0.75
Standard ²	1.0
Complex ³	1.5
¹ Brain and single cardiac scans. ² Mid-skull to mid-thigh scans. ³ Inpatient, radiation treatment when patient position device is used, cardiac rest/stress perfusion and metabolism, standard study with additional limited scan, pediatric, and total body scans.	

616
 617 **Section 18. Department inventory of PET scanners**

618
 619 Sec. 18. The Department shall maintain and publicly post on its web site a list of PET scanner
 620 services annually.

621
 622 **Section 19. Comparative reviews; effect on prior planning policies**

623
 624 Sec. 19. Proposed projects reviewed under these standards shall not be subject to comparative
 625 review. These CON review standards supersede and replace the CON standards for PET scanner
 626 services approved by the CON Commission on ~~June 14, 2012~~MARCH 18, 2014 and effective ~~September~~
 627 ~~28, 2012~~JUNE 2, 2014.
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631 Counties assigned to each health service area are as follows:

632

633 **HEALTH SERVICE AREA**

COUNTIES

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635	1	Livingston	Monroe	St. Clair
636		Macomb	Oakland	Washtenaw
637		Wayne		

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639	2	Clinton	Hillsdale	Jackson
640		Eaton	Ingham	Lenawee

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642	3	Barry	Calhoun	St. Joseph
643		Berrien	Cass	Van Buren
644		Branch	Kalamazoo	

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646	4	Allegan	Mason	Newaygo
647		Ionia	Mecosta	Oceana
648		Kent	Montcalm	Osceola
649		Lake	Muskegon	Ottawa

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651	5	Genesee	Lapeer	Shiawassee
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653	6	Arenac	Huron	Roscommon
654		Bay	Iosco	Saginaw
655		Clare	Isabella	Sanilac
656		Gladwin	Midland	Tuscola
657		Gratiot	Ogemaw	

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659	7	Alcona	Crawford	Missaukee
660		Alpena	Emmet	Montmorency
661		Antrim	Gd Traverse	Oscoda
662		Benzie	Kalkaska	Otsego
663		Charlevoix	Leelanau	Presque Isle
664		Cheboygan	Manistee	Wexford

665

666	8	Alger	Gogebic	Mackinac
667		Baraga	Houghton	Marquette
668		Chippewa	Iron	Menominee
669		Delta	Keweenaw	Ontonagon
670		Dickinson	Luce	Schoolcraft

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Counties by Health service areas assigned to each planning area are as follows:

PLANNING AREA 1

COUNTIES

HSA 1	Livingston	Monroe	St. Clair
	Macomb	Oakland	Washtenaw
	Wayne		

PLANNING AREA 2

HSA 2	Clinton	Hillsdale	Jackson
	Eaton	Ingham	Lenawee
HSA 3	Barry	Calhoun	St. Joseph
	Berrien	Cass	Van Buren
	Branch	Kalamazoo	

PLANNING AREA 3

HSA 4	Allegan	Mason	Newaygo
	Ionia	Mecosta	Oceana
	Kent	Montcalm	Osceola
	Lake	Muskegon	Ottawa

PLANNING AREA 4

HSA 5	Genesee	Lapeer	Shiawassee
HSA 6	Arenac	Huron	Roscommon
	Bay	Iosco	Saginaw
	Clare	Isabella	Sanilac
	Gladwin	Midland	Tuscola
	Gratiot	Ogemaw	

PLANNING AREA 5

HSA 7	Alcona	Crawford	Missaukee
	Alpena	Emmet	Montmorency
	Antrim	Gd Traverse	Oscoda
	Benzie	Kalkaska	Otsego
	Charlevoix	Leelanau	Presque Isle
	Cheboygan	Manistee	Wexford

PLANNING AREA 6

HSA 8	Alger	Gogebic	Mackinac
	Baraga	Houghton	Marquette
	Chippewa	Iron	Menominee
	Delta	Keweenaw	Ontonagon
	Dickinson	Luce	Schoolcraft

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Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

Allegan	<u>HILLSDALE</u>	<u>MASON</u>
Alpena	Houghton	Mecosta
<u>Benzie</u>	<u>IONIA</u>	Menominee
Branch	Isabella	Midland
<u>Chippewa</u>	Kalkaska	Missaukee
Delta	Keweenaw	St. Joseph
Dickinson	Leelanau	Shiawassee
Grand Traverse	Lenawee	Wexford
Gratiot	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	onia	<u>MONTCALM</u> Newaygo
Bay	Jackson	Muskegon
Berrien	Kalamazoo	Oakland
Calhoun	Kent	Ottawa
Cass	Lapeer	Saginaw
Clinton	Livingston	St. Clair
Eaton	Macomb	Van Buren
Genesee	<u>MIDLAND</u>	Washtenaw
Ingham	Monroe	Wayne

Source:

65-75 F.R., p. 82238-37245 (~~December 27~~JUNE 28, 2000~~2010~~)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

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APPENDIX D

ICD-9-CM TO ICD-10-CM CODE TRANSLATION

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
345.01	Intractable Epilepsy Cases	G40.311	Generalized Idiopathic Epilepsy and Epileptic Syndromes, Intractable, with Status Epilepticus
		G40.319	Generalized Idiopathic Epilepsy and Epileptic Syndromes, Intractable, without Status Epilepticus
		G40.A11	Absence Epileptic Syndrome, Intractable, with Status Epilepticus
345.11	Intractable Epilepsy Cases	G40.311	Generalized Idiopathic Epilepsy and Epileptic Syndromes, Intractable, with Status Epilepticus
		G40.319	Generalized Idiopathic Epilepsy and Epileptic Syndromes, Intractable, without Status Epilepticus
345.41	Intractable Epilepsy Cases	G40.211	Localization-Related (Focal) (Partial) Symptomatic Epilepsy and Epileptic Syndromes with Complex Partial Seizures, Intractable, with Status Epilepticus
		G40.219	Localization-Related (Focal) (Partial) Symptomatic Epilepsy and Epileptic Syndromes with Complex Partial Seizures, Intractable, without Status Epilepticus
345.51	Intractable Epilepsy Cases	G40.011	Localization-Related (Focal) (Partial) Idiopathic Epilepsy and Epileptic Syndromes with Seizures of Localized Onset, Intractable, with Status Epilepticus
		G40.019	Localization-Related (Focal) (Partial) Idiopathic Epilepsy and Epileptic Syndromes with Seizures of Localized Onset, Intractable, without Status Epilepticus
		G40.111	Localization-Related (Focal) (Partial) Symptomatic Epilepsy and Epileptic Syndromes with Simple Partial Seizures, Intractable, with Status Epilepticus
		G40.119	Localization-Related (Focal) (Partial) Symptomatic Epilepsy and Epileptic Syndromes with Simple Partial Seizures, Intractable, without Status Epilepticus

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APPENDIX D continued

ICD-9 Code	Description	ICD-10 Code	Description
345.61	Intractable Epilepsy Cases	G40.411	Other Generalized Epilepsy and Epileptic Syndromes, Intractable, with Status Epilepticus
		G40.419	Other Generalized Epilepsy and Epileptic Syndromes, Intractable, Without Status Epilepticus
345.71	Intractable Epilepsy Cases	G40.111	Localization-Related (Focal)(Partial) Symptomatic Epilepsy and Epileptic Syndromes with Simple Partial Seizures, Intractable, with Status Epilepticus
		G40.119	Localization-Related (Focal) (Partial) Symptomatic Epilepsy and Epileptic Syndromes With Simple Partial Seizures, Intractable, without Status Epilepticus
345.81	INTRACTABLE EPILEPSY CASES	G40.803	Other Epilepsy, Intractable, with Status Epilepticus
		G40.804	Other Epilepsy, Intractable, without Status Epilepticus
		G40.89	Other Seizures
345.91	INTRACTABLE EPILEPSY CASES	G40.411	Other Generalized Epilepsy and Epileptic Syndromes, Intractable, with Status Epilepticus
		G40.419	Other Generalized Epilepsy and Epileptic Syndromes, Intractable, without Status Epilepticus
		G40.911	Epilepsy, Unspecified, Intractable, with Status Epilepticus
		G40.919	Epilepsy, Unspecified, Intractable, without Status Epilepticus

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"ICD-9-CM CODE" means the disease codes and nomenclature found in the International Classification of Diseases - 9th Revision - Clinical Modification, prepared by the Commission on Professional and Hospital Activities for the U.S. National Center for Health statistics.

"ICD-10-CM CODE" means the disease codes and nomenclature found in the International Classification of Diseases - 10th Revision - Clinical Modification, National Center for Health Statistics.