

1 | **MICHIGAN DEPARTMENT OF COMMUNITY HEALTH**

2  
3 **CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR**  
4 **POSITRON EMISSION TOMOGRAPHY (PET) SCANNER SERVICES**  
5

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

10 **Section 1. Applicability**

11  
12 Sec. 1. These standards are requirements for the approval of the initiation, replacement, expansion,  
13 or acquisition of PET scanner services, and the delivery of these services under Part 222 of the Code.  
14 Pursuant to Part 222 of the Code PET scanner services are a covered clinical service. The Department  
15 shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the  
16 Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the  
17 Michigan Compiled Laws.  
18

19 **Section 2. Definitions**

- 20  
21 Sec. 2. (1) For purposes of these standards:
- 22 (a) "Central service coordinator" means the legal entity that has operational responsibility for a  
23 mobile PET scanner service.
  - 24 (b) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et  
25 seq. of the Michigan Compiled Laws.
  - 26 (c) "Department" means the Michigan Department of Community Health (MDCH).
  - 27 (d) "Existing PET scanner" means an operational PET scanner used to provide PET services on  
28 the date an application is submitted to the Department.
  - 29 (e) "Existing PET scanner service" means an operational PET scanner service providing PET  
30 scanner services at one site in the case of a fixed PET service or at each host site in the case of a mobile  
31 PET service on the date an application is submitted to the Department.
  - 32 (f) "Health service area" or "HSA" means the groups of counties listed in Appendix A.
  - 33 (g) "Hospital" means a health facility licensed under Part 215 of the Code.
  - 34 (h) "Host site" means the geographic address at which a mobile PET scanner is authorized by CON  
35 to provide mobile PET scanner services.
  - 36 (i) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C.1396  
37 to 1396g and 1396i to 1396u.
  - 38 (j) "Michigan Inpatient Data Base" or "MIDB" means the data base compiled by the Michigan  
39 Health and Hospital Association or successor organization. The data base consists of inpatient discharge  
40 records from all Michigan hospitals and Michigan residents discharged from hospitals in border states for  
41 a specific calendar year.
  - 42 (k) "Mobile PET scanner" means a PET scanner unit and transporting equipment operated by a  
43 central service coordinator that serves two or more host sites.
  - 44 (l) "Mobile PET scanner network" means the route (i.e., all host sites) that the central service  
45 coordinator is authorized to serve under CON.
  - 46 (m) "Patient visit" means a single session utilizing a PET scanner during which 1 or more PET  
47 procedures are performed.
  - 48 (n) "Pediatric patient" means any patient less than 18 years of age.
  - 49 (o) "PET procedure" means the acquisition of a single image or image sequence involving a single  
50 injection of tracer.
  - 51 (p) "PET scan" means one (1) or more PET procedures performed during a single patient visit.
  - 52 (q) "PET scanner" means an FDA-approved full or partial ring scanner or coincidence system that  
53 has a crystal at least 5/8-inch thick, techniques to minimize or correct for scatter and/or randoms, and  
54 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  
150 (1) An applicant proposing to replace a PET scanner(s) shall demonstrate each of the following:

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

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

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

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

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

159

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.

218  
219 (2) An applicant proposing to acquire an existing fixed or mobile PET scanner service shall  
220 demonstrate that the existing fixed or mobile scanner(s) performed an average of 500 PET equivalents  
221 per scanner in the most recent 12-month period verifiable by the Department.

222  
223 (3) An applicant proposing to acquire an existing host site shall demonstrate that the existing host  
224 site has performed 50 PET equivalents in the most recent 12-month period verifiable by the Department.

225  
226 (4) An applicant proposing to renew a lease for an existing fixed or mobile PET scanner(s) shall  
227 demonstrate that the renewal of the lease is more cost effective than replacing the scanner(s).

228  
229 **Section 7. Requirements for a dedicated research fixed PET scanner**

230  
231 Sec. 7. An applicant proposing to add a fixed PET scanner to an existing PET scanner service for  
232 exclusive research use shall demonstrate the following:

233  
234 (1) The applicant agrees that the dedicated research PET scanner will be used primarily (70% or  
235 more of the scans) for research purposes only.

236  
237 (2) The dedicated research PET scanner shall operate under a protocol approved by the applicant's  
238 Institutional Review Board, as defined by Public Law 93-348 and regulated by Title 45 CFR 46.

239  
240 (3) The applicant has access to a cyclotron for accelerating charged particles to high energies by  
241 means of electromagnetic fields.

242  
243 (4) The proposed site can have no more than three dedicated research fixed PET scanners  
244 approved under this Section.

245  
246 **Section 8. Requirements for a dedicated pediatric PET scanner**

247  
248 Sec. 8. An applicant proposing to initiate a PET scanner service, or add a fixed PET scanner to  
249 expand an existing PET scanner service, for dedicated pediatric PET use shall demonstrate the following:

250  
251 (1) The applicant agrees that the dedicated pediatric PET scanner will be used primarily (70% or  
252 more of the scans) for patients under 18 years of age.

253  
254 (2) The applicant shall demonstrate the existing site provided the following for the most recent  
255 calendar year or a continuous 12-month period at the time the application is submitted to the Department:

- 256 (a) at least 7,000 pediatric (< 18 years old) discharges, excluding normal newborns,  
257 (b) at least 5,000 pediatric (< 18 years old) surgeries, and  
258 (c) at least 50 new pediatric cancer cases on its cancer registry.

259  
260 (3) The applicant shall have an active medical staff at the time the application is submitted to the  
261 Department that includes physicians who are fellowship-trained in the following pediatric specialties:

- 262 (a) radiology (at least two staff members)  
263 (b) anesthesiology  
264 (c) cardiology  
265 (d) critical care  
266 (e) gastroenterology  
267 (f) hematology/oncology

- 268 (g) neurology
- 269 (h) neurosurgery
- 270 (i) orthopedic surgery
- 271 (j) pathology
- 272 (k) pulmonology
- 273 (l) surgery
- 274 (m) neonatology

275  
276 (4) The applicant shall have in operation the following pediatric specialty programs at the time the  
277 application is submitted to the Department:

- 278 (a) bone marrow transplant program
- 279 (b) sedation program
- 280 (c) open heart program

281  
282 (5) The applicant meets the requirements of Section 3(1) through 3(4) if the applicant is initiating a  
283 PET scanner service with a dedicated pediatric fixed PET scanner.

284  
285 (6) The proposed site can have no more than two dedicated pediatric fixed PET scanners approved  
286 under this section.

287  
288 **Section 9. Requirements for a positron emission mammography (PEM) scanner**

289  
290 Sec. 9. An applicant proposing to add a PEM scanner service to an existing PET scanner service  
291 shall demonstrate the following, as applicable to the proposed project.

292  
293 (1) An applicant proposing to add a fixed PEM scanner to an existing fixed PET scanner site shall  
294 demonstrate the following:

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

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

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

302  
303 (2) An applicant proposing to add a mobile PEM scanner to an existing mobile PET scanner service  
304 shall demonstrate the following:

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

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

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

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

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

316  
317 (3) An applicant, whether an existing fixed PET scanner site or host site, proposing to initiate  
318 mobile PEM scanner services as a host site shall demonstrate the following:

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

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

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

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

328

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

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

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

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

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

338

### 339 **Section 10. Requirement for Medicaid participation**

340

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

344

### 345 **Section 11. Project delivery Requirements and terms of approval for all applicants**

346

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

349

350 (1) Compliance with these standards.

351

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

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

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

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

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

369

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

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

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

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

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

379

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

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

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

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

396

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

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

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

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

404

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

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

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

410

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

412 (a) The PEM scanner service must maintain ACR accreditation as a BICOE site verifiable by the  
413 Department.

414

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

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

418 (b) Each host site must have at least one physician who is board certified or board eligible in  
419 nuclear medicine or nuclear radiology on its medical staff. The physician(s) shall be responsible for  
420 establishing patient examination and infusion protocol, and providing for the interpretation of scans  
421 performed.

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

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

427



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

430  
431 **Section 12. Methodology for computing the projected PET data units**  
432

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

435  
436 (1) Identify the number of diagnosis-specific new cancer cases documented in accordance with the  
437 requirements of Section 13.

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

443 (b) Multiply the number resulting from the calculation in “combined” cancer cases identified in  
444 subsection (1)(a) by 0.8, which is the estimated probability that a “combined” cancer case will require a  
445 PET scan.

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

448  
449 (2) Identify the number of diagnosis-specific new cancer cases documented in accord with the  
450 requirements of section 13.

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

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

455  
456 (3) Multiply the number of diagnostic cardiac catheterization cases identified in accord with the  
457 requirements of Section 15 by 0.1, which is the estimated probability that a patient having a diagnostic  
458 cardiac catheterization will require a PET scan.

459  
460 (4) Multiply the number of intractable epilepsy cases (ICD-9-CM codes 345.01, 345.11, 345.41,  
461 345.51, 345.61, 345.71, 345.81, or 345.91, **SEE APPENDIX D FOR ICD-10-CM CODES**) identified in  
462 accord with the requirements of Section 16 by 1.0, which is the estimated probability that a patient having  
463 an intractable epilepsy procedure will require a PET scan. Multiply the number resulting from the  
464 calculation in subsection (3) by 1.0, which is the estimated number of PET scans needed for each patient  
465 requiring a PET scan.

466  
467 (5) Sum the numbers resulting from the calculations in subsections (1) through (4) to determine the  
468 total number of projected PET data units.

469  
470 (6) Multiply the result calculated in subsection (5) above by a factor of 3.0 if the applicant is  
471 proposing to serve only planning area 6 to determine the total number of projected PET data units.

472  
473 (7) Multiply the result calculated in subsection (5) above by a factor of 2.0 if the applicant is  
474 proposing to serve only planning area 5 to determine the total number of projected PET data units.

475  
476 **Section 13. Commitment of diagnosis-specific new cancer cases**  
477

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

480  
481 (1) Only those cancer diagnoses identified in Section 12(1) and 12(2) shall be included.

482  
483 (2) Each entity contributing diagnosis-specific new cancer case data provides, as part of the  
484 application at the time it is submitted to the Department, a signed governing body resolution that identifies  
485 the number of diagnosis-specific cancer cases being committed to the application and that states no  
486 current or future diagnosis-specific new cancer case data will be used in support of any other application  
487 for a PET unit for a period of five (5) years from the date of start of operations of the approved PET  
488 scanner service for which data are being committed. If the required documentation for this subsection is  
489 not submitted with the application on the designated application date, the application will be deemed filed  
490 on the first applicable designated application date after all required documentation is received by the  
491 Department.

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

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

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

501  
502 (3) No entity currently operating or approved to operate a PET scanner service shall contribute  
503 diagnosis-specific new cancer cases.

504  
505 (4) The Department may not consider a withdrawal of diagnosis-specific new cancer case data  
506 during the 120-day application review cycle following the date on which the Department review of the  
507 application commences or after a proposed decision to approve the application has been issued unless  
508 the application is denied, withdrawn, or expired. The withdrawal must be submitted to the Department in  
509 the form of a governing body resolution that contains the specific CON application number to which the  
510 data were originally committed, the legal applicant entity, the committing entity, the type of data, the date  
511 of the meeting in which the governing body authorized the withdrawal of the data, the governing body  
512 president's signature, and the date of the signature.

#### 513 514 **Section 14. Documentation of diagnosis-specific new cancer case data**

515  
516 Sec. 14. An applicant required to document volumes of diagnosis-specific new cancer cases shall  
517 submit, as part of its application at the time it is submitted to the Department, documentation from the  
518 Division for Vital Records and Health Statistics verifying the number of diagnosis-specific new cancer  
519 cases provided in support of the application for the most recent calendar year for which verifiable data are  
520 available from the state registrar. If the required documentation for this subsection is not submitted with  
521 the application on the designated application date, the application will be deemed filed on the first  
522 applicable designated application date after all required documentation is received by the Department.  
523 Diagnosis-specific new cancer case data supporting an application under these standards shall be  
524 submitted to the Division for Vital Records and Health Statistics using a format and media specified in  
525 instructions from the Department of Community Health.

#### 526 527 **Section 15. Commitment and documentation of diagnostic cardiac catheterization data**

528  
529 Sec. 15. An applicant proposing to use diagnostic cardiac catheterization data shall demonstrate all  
530 of the following:

531  
532 (1) Each entity contributing diagnostic cardiac catheterization data provides, as part of the  
533 application at the time it is submitted to the Department, a signed governing body resolution that identifies  
534 the number of diagnostic cardiac catheterization cases (sessions) committed to the application and that  
535 states no current or future diagnostic cardiac catheterization data will be used in support of any other

536 application for a PET unit for the duration of the PET service for which data are being committed for a  
537 period of five (5) years from the date of start of operations of the approved PET service for which data are  
538 being committed. If the required documentation for this subsection is not submitted with the application on  
539 the designated application date, the application will be deemed filed on the first applicable designated  
540 application date after all required documentation is received by the Department.

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

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

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

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

553

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

556

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

565

## 566 **Section 16. Commitment and documentation of intractable epilepsy data**

567

568 Sec. 16. An applicant proposing to use intractable epilepsy cases shall demonstrate all of the  
569 following:

570

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

580 (a) For fixed PET scanner services, the geographic location of each entity contributing intractable  
581 epilepsy case data is in the same planning area as the proposed PET unit/service.

582 (b) For mobile PET scanner services, the geographic location of each entity contributing intractable  
583 epilepsy case data in the planning area(s) for which the proposed PET scanner service contains a  
584 proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical  
585 area counties or 25-mile radius for metropolitan statistical area counties.

586 (c) No entity contributing intractable epilepsy case data has previously committed or is committing  
587 data to another service that is less than five (5) years from the start of operations of that service.

588 (d) The intractable epilepsy case data is from the most recent Michigan Inpatient Data Base (MIDB)  
589 available to the Department.

590  
591 (2) No entity currently operating or approved to operate a scanner shall contribute intractable  
592 epilepsy case data.

593  
594 (3) The Department may not consider a withdrawal of intractable epilepsy case data during the 120-  
595 day application review cycle following the date on which the Department review of the application  
596 commences or after a proposed decision to approve the application unless the application is denied,  
597 withdrawn, or expired. The withdrawal must be submitted to the Department in the form of a governing  
598 body resolution that contains the specific CON application number to which the data were originally  
599 committed, the legal applicant entity, the committing entity, the type of data, the date of the meeting in  
600 which the governing body authorized the withdrawal of the data, the governing body president's signature,  
601 and the date of the signature.

602  
603 **Section 17. Methodology for computing PET equivalents**

604  
605 Sec. 17. PET equivalents shall be calculated as follows:  
606

<b>TABLE 1</b>	
<b>PET EQUIVALENTS</b>	
<b>Scan Category</b>	<b>Weight</b>
Simple <sup>1</sup>	0.75
Standard <sup>2</sup>	1.0
Complex <sup>3</sup>	1.5
<sup>1</sup> Brain and single cardiac scans. <sup>2</sup> Mid-skull to mid-thigh scans. <sup>3</sup> 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.	

607  
608 **Section 18. Department inventory of PET scanners**

609  
610 Sec. 18. The Department shall maintain and publicly post on its web site a list of PET scanner  
611 services annually.

612  
613 **Section 19. Comparative reviews; effect on prior planning policies**

614  
615 Sec. 19. Proposed projects reviewed under these standards shall not be subject to comparative  
616 review. These CON review standards supersede and replace the CON standards for PET scanner  
617 services approved by the CON Commission on September 22, 2011 and effective November 21, 2011.  
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Counties assigned to each health service area are as follows:

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

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		
<b>PLANNING AREA 2</b>			
HSA 2	Clinton	Hillsdale	Jackson
	Eaton	Ingham	Lenawee
HSA 3	Barry	Calhoun	St. Joseph
	Berrien	Cass	Van Buren
	Branch	Kalamazoo	
<b>PLANNING AREA 3</b>			
HSA 4	Allegan	Mason	Newaygo
	Ionia	Mecosta	Oceana
	Kent	Montcalm	Osceola
	Lake	Muskegon	Ottawa
<b>PLANNING AREA 4</b>			
HSA 5	Genesee	Lapeer	Shiawassee
HSA 6	Arenac	Huron	Roscommon
	Bay	Iosco	Saginaw
	Clare	Isabella	Sanilac
	Gladwin	Midland	Tuscola
	Gratiot	Ogemaw	
<b>PLANNING AREA 5</b>			
HSA 7	Alcona	Crawford	Missaukee
	Alpena	Emmet	Montmorency
	Antrim	Gd Traverse	Oscoda
	Benzie	Kalkaska	Otsego
	Charlevoix	Leelanau	Presque Isle
	Cheboygan	Manistee	Wexford
<b>PLANNING AREA 6</b>			
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	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

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

<b>ICD-9 CODE</b>	<b>DESCRIPTION</b>	<b>ICD-10 CODE</b>	<b>DESCRIPTION</b>
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

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**APPENDIX D CONTINUED**

<b>ICD-9 CODE</b>	<b>DESCRIPTION</b>	<b>ICD-10 CODE</b>	<b>DESCRIPTION</b>
345.51 CONTINUED	INTRACTABLE EPILEPSY CASES CONTINUED	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
345.61	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

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**APPENDIX D CONTINUED**

<b>ICD-9 CODE</b>	<b>DESCRIPTION</b>	<b>ICD-10 CODE</b>	<b>DESCRIPTION</b>
		<b>G40.911</b>	<b>EPILEPSY, UNSPECIFIED, INTRACTABLE, WITH STATUS EPILEPTICUS</b>
		<b>G40.919</b>	<b>EPILEPSY, UNSPECIFIED, INTRACTABLE, WITHOUT STATUS EPILEPTICUS</b>

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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.**