

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  
35 CON 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  
40 discharge records from all Michigan hospitals and Michigan residents discharged from hospitals in border  
41 states for 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

55 **TOMOGRAPHY (CT) AND FDA-APPROVED PET/MAGNETIC RESONANCE IMAGING (MRI) scanner**  
56 **hybrids. If the PET/CT scanner HYBRID will be used for ~~computed tomography (CT)~~ scans only in**  
57 **conjunction with the PET scan, then no separate CON is required for that CT use. IF THE FDA-**  
58 **APPROVED PET/MRI SCANNER HYBRID WILL BE USED FOR MRI SCANS ONLY IN CONJUNCTION**  
59 **WITH THE PET SCAN, THEN NO SEPARATE CON IS REQUIRED FOR THAT MRI USE.** The term  
60 does not include single-photon emission computed tomography systems (SPECT), x-ray CT systems,  
61 magnetic resonance, ultrasound computed tomographic systems, gamma cameras modified for either  
62 non-coincidence or coincidence imaging, or similar technology.

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

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

66  
67 (2) The definitions in Part 222 shall apply to these standards.  
68

### 69 **Section 3. Requirements to initiate a PET scanner service**

70  
71 Sec. 3. An applicant proposing to initiate PET scanner services shall demonstrate the following, as  
72 applicable to the proposed project.  
73

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

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

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

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

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

81 (e) cardiac catheterization services,

82 (f) open heart surgery,

83 (g) thoracic surgery,

84 (h) cardiology,

85 (i) oncology,

86 (j) radiation oncology,

87 (k) neurology,

88 (l) neurosurgery, and

89 (m) psychiatry.  
90

91 (2) If the proposed site does not provide any of the services listed in subsection (1) on-site, the  
92 applicant shall provide written contracts or agreements with a hospital(s) located within the same  
93 planning area or 25-mile radius of the proposed site for the services not provided.  
94

95 (3) The applicant shall demonstrate the proposed site has an on-site source of  
96 radiopharmaceuticals. If the proposed site does not provide an on-site source of radiopharmaceuticals,  
97 the applicant shall provide a written contract or agreement that demonstrates a reliable supply of  
98 radiopharmaceuticals.  
99

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

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

104 (b) The applicant has performed:

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

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

109 (c) The applicant shall install the fixed PET unit at the same site as the existing host site or within a  
110 10-mile radius of the existing host site for a metropolitan statistical area county or a 25-mile radius for a  
111 rural or micropolitan statistical area.

112 (d) The applicant agrees to cease operation as a host site and not become a host site for at least  
113 12 months from the date the fixed PET scanner becomes operational. **THIS REQUIREMENT SHALL**  
114 **NOT APPLY IF THE APPLICANT IS INSTALLING AN FDA-APPROVED PET/MRI SCANNER HYBRID.**  
115

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

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

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

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

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

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

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

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

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

134 (d) An applicant initiating a host site in HSA 8 on a mobile PET scanner service that operates  
135 predominantly outside of Michigan shall demonstrate 240 PET data units from planning area 6.  
136

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

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

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

142 (c) 50 PET equivalents were performed in the most recent 12-month period verifiable by the  
143 Department from an existing mobile PET scanner service at the existing host site.  
144

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

146

147 Sec. 4. Replacing a PET scanner(s) means a change in the scanner equipment or relocation of the  
148 service to a new site. An upgrade to software or components of an existing scanner does not constitute  
149 replacement of a PET scanner. An applicant proposing to replace an existing PET scanner(s) or PET  
150 scanner service shall demonstrate the following, as applicable to the proposed project.  
151

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

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

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

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

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

160 (c) The applicant agrees that the PET scanner(s) to be replaced will be removed from service on  
161 or before beginning operation of the replacement scanner(s).  
162

- 163 (2) An applicant proposing to replace a fixed PET scanner service to a new site shall demonstrate  
164 the following:
- 165 (a) The proposed site is within a 10-mile radius of the existing site for a metropolitan statistical  
166 area county or a 25-mile radius for a rural or micropolitan statistical area county.
- 167 (b) The existing fixed PET scanner(s) performed 500 PET equivalents per fixed scanner in the  
168 most recent 12-month period verifiable by the Department.
- 169 (c) The existing fixed PET scanner service has been in operation for at least 36 months as of the  
170 date of the application submitted to the Department.

171

## 172 **Section 5. Requirements to expand a PET scanner service**

173

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

177

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

180 (a) 1,900 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 metropolitan statistical  
182 area county, or

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

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

187

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

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

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

196

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

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

201 (b) The applicant has performed:

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

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

208 (c) The applicant agrees to cease operation as a host site and not become a host site for at least  
209 12 months from the date the fixed scanner becomes operational.

210

## 211 **Section 6. Requirements to acquire a PET scanner service or scanner(s)**

212

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

217  
218 (1) For the first application proposing to acquire an existing fixed, mobile, or host site PET scanner  
219 service, other than a renewal of lease, on or after November 21, 2011, the existing PET service and its  
220 scanner(s) shall not be required to be in compliance with the applicable volume requirements set forth in  
221 this section.

222  
223 (2) An applicant proposing to acquire an existing fixed or mobile PET scanner service shall  
224 demonstrate that the existing fixed or mobile scanner(s) performed an average of 500 PET equivalents  
225 per scanner in the most recent 12-month period verifiable by the Department.

226  
227 (3) An applicant proposing to acquire an existing host site shall demonstrate that the existing host  
228 site has performed 50 PET equivalents in the most recent 12-month period verifiable by the Department.

229  
230 (4) An applicant proposing to renew a lease for an existing fixed or mobile PET scanner(s) shall  
231 demonstrate that the renewal of the lease is more cost effective than replacing the scanner(s).

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

233  
234 Sec. 7. An applicant proposing to add a fixed PET scanner to an existing PET scanner service for  
235 exclusive research use shall demonstrate the following:

236  
237 (1) The applicant agrees that the dedicated research PET scanner will be used primarily (70% or  
238 more of the scans) for research purposes only.

239  
240 (2) The dedicated research PET scanner shall operate under a protocol approved by the  
241 applicant's Institutional Review Board, as defined by Public Law 93-348 and regulated by Title 45 CFR  
242 46.

243  
244 (3) The applicant has access to a cyclotron for accelerating charged particles to high energies by  
245 means of electromagnetic fields.

246  
247 (4) The proposed site can have no more than three dedicated research fixed PET scanners  
248 approved under this Section.

### 249 **Section 8. Requirements for a dedicated pediatric PET scanner**

250  
251 Sec. 8. An applicant proposing to initiate a PET scanner service, or add a fixed PET scanner to  
252 expand an existing PET scanner service, for dedicated pediatric PET use shall demonstrate the following:

253  
254 (1) The applicant agrees that the dedicated pediatric PET scanner will be used primarily (70% or  
255 more of the scans) for patients under 18 years of age.

256  
257 (2) The applicant shall demonstrate the existing site provided the following for the most recent  
258 calendar year or a continuous 12-month period at the time the application is submitted to the Department:

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

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

261 (c) at least 50 new pediatric cancer cases on its cancer registry.

262  
263 (3) The applicant shall have an active medical staff at the time the application is submitted to the  
264 Department that includes physicians who are fellowship-trained in the following pediatric specialties:

265 (a) radiology (at least two staff members)

266 (b) anesthesiology

267 (c) cardiology

268 (d) critical care

- 271 (e) gastroenterology
- 272 (f) hematology/oncology
- 273 (g) neurology
- 274 (h) neurosurgery
- 275 (i) orthopedic surgery
- 276 (j) pathology
- 277 (k) pulmonology
- 278 (l) surgery
- 279 (m) neonatology

280  
281 (4) The applicant shall have in operation the following pediatric specialty programs at the time the  
282 application is submitted to the Department:

- 283 (a) bone marrow transplant program
- 284 (b) sedation program
- 285 (c) open heart program

286  
287 (5) The applicant meets the requirements of Section 3(1) through 3(4) if the applicant is initiating a  
288 PET scanner service with a dedicated pediatric fixed PET scanner.

289  
290 (6) The proposed site can have no more than two dedicated pediatric fixed PET scanners  
291 approved under this section.

292  
293 **Section 9. Requirements for a positron emission mammography (PEM) scanner**

294  
295 Sec. 9. An applicant proposing to add a PEM scanner service to an existing PET scanner service  
296 shall demonstrate the following, as applicable to the proposed project.

297  
298 (1) An applicant proposing to add a fixed PEM scanner to an existing fixed PET scanner site shall  
299 demonstrate the following:

- 300 (a) The applicant is certified through the American College of Radiology (ACR) as a Breast  
301 Imaging Center of Excellence (BICOE) at the time the application is submitted to the Department.
- 302 (b) The applicant has a fixed PET scanner service and has performed 1,000 PET equivalents per  
303 scanner at the site in the most recent 12-month period verifiable by the Department, or the applicant  
304 operates a comprehensive cancer center recognized by the National Cancer Institute and contracts with  
305 a facility that has a fixed PET scanner service.

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

307  
308 (2) An applicant proposing to add a mobile PEM scanner to an existing mobile PET scanner  
309 service shall demonstrate the following:

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

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

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

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

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

321  
322 (3) An applicant, whether an existing fixed PET scanner site or host site, proposing to initiate  
323 mobile PEM scanner services as a host site shall demonstrate the following:

324 (a) The applicant is certified through the ACR as a BICOE site at the time the application is

- 325 submitted to the Department.
- 326 (b) The applicant has a fixed PET scanner site or host site and has performed 100 PET  
327 equivalents in the most recent 12-month period verifiable by the Department, or the applicant operates a  
328 comprehensive cancer center recognized by the National Cancer Institute and contracts with a facility that  
329 has a fixed or mobile PET scanner service.
- 330 (c) The applicant provides a proposed route schedule for the mobile PEM scanner service.
- 331 (d) The applicant provides a draft contract for PEM services between the host site and central  
332 service coordinator.
- 333
- 334 (4) An applicant proposing to add an existing PEM scanner host site to an existing mobile PEM  
335 scanner service shall demonstrate the following:
- 336 (a) The host site has performed mobile PEM scanner service within the most recent 12-month  
337 period as of the date an application is submitted to the Department.
- 338 (b) The proposed site is certified through the ACR as a BICOE site at the time the application is  
339 submitted to the Department.
- 340 (c) The applicant provides a proposed route schedule for the mobile PEM scanner service.
- 341 (d) The applicant provides a draft contract for PEM services between the host site and central  
342 service coordinator.
- 343

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

345

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

349

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

351

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

354

355 (1) Compliance with these standards.

356

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

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

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

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

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

374

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

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

378 (b) The PET scanner service shall participate in Medicaid at least 12 consecutive months within

379 the first two years of operation and continue to participate annually thereafter.  
380 (c) The PET scanner service shall not deny PET scanner services to any individual based on  
381 ability to pay or source of payment.  
382 (d) The operation of and referral of patients to the PET scanner service shall be in conformance  
383 with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).  
384  
385 (4) Compliance with the following monitoring and reporting requirements:  
386 (a) The PET scanners shall be operating at an average of 500 PET equivalents per scanner during  
387 the second 12 months of operations, and annually thereafter. This requirement shall be waived during  
388 review of applications under sections 4(1) and 6(4), if applicable. In meeting these requirements, an  
389 applicant shall not include any PET scans performed on a PET scanner used exclusively for research  
390 approved pursuant to Section 7, for a dedicated pediatric PET scanner approved pursuant to Section 8,  
391 or for a PEM scanner approved pursuant to Section 9.  
392 (b) The PET scanner service shall participate in a data collection system established and  
393 administered by the Department or its designee. The data may include, but are not limited to, clinical  
394 scan data, annual budget and cost information, operating schedules, through-put schedules,  
395 demographic and diagnostic information, and the volume of care provided to patients from all payor  
396 sources. The applicant shall provide the required data on a separate basis for each separate and distinct  
397 site, PET scanner, or PET scanner service as required by the Department, in a format established by the  
398 Department. The Department may elect to verify the data through on-site review of appropriate records.  
399 (c) The PET scanner service shall provide the Department with timely notice of the proposed  
400 project implementation consistent with applicable statute and promulgated rules.  
401  
402 (5) Compliance with the following dedicated research PET scanner requirements, if applicable:  
403 (a) The capital and operating costs relating to the dedicated research PET scanner shall be  
404 charged only to a specific research account(s) and not to any patient or third- party payor.  
405 (b) The dedicated research pet scanner shall not be used for any purposes other than as approved  
406 by the Institutional Review Board.  
407 (c) The dedicated research PET scanner will be used primarily (70% or more of the scans) for  
408 research purposes only.  
409  
410 (6) Compliance with the following dedicated pediatric PET scanner requirements, if applicable:  
411 (a) The dedicated pediatric PET scanner will be used primarily (70% or more of the scans) for  
412 patients under 18 years of age.  
413 (b) Shall maintain active medical staff in the applicable pediatric specialties and pediatric specialty  
414 programs as set forth in the section.  
415  
416 (7) Compliance with the following PEM scanner requirements, if applicable:  
417 (a) The PEM scanner service must maintain ACR accreditation as a BICOE site verifiable by the  
418 Department.  
419  
420 (8) Compliance with the following mobile PET scanner requirements, if applicable:  
421 (a) The central service coordinator for a mobile PET scanner service shall notify the Department  
422 30 days prior to dropping an existing host site.  
423 (b) Each host site must have at least one physician who is board certified or board eligible in  
424 nuclear medicine or nuclear radiology on its medical staff. The physician(s) shall be responsible for  
425 establishing patient examination and infusion protocol, and providing for the interpretation of scans  
426 performed.  
427 (c) Each host site shall provide a properly prepared parking pad for the mobile PET scanner unit, a  
428 waiting area for patients, and a means for patients to enter the vehicle without going outside (such as an  
429 enclosed canopy or an enclosed corridor).  
430 (d) A mobile PET scanner service shall operate under a contractual agreement that includes the  
431 provision of PET services at each host site on a regularly scheduled basis.  
432

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

435

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

437

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

440

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

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

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

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

453

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

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

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

460

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

464

465 (4) Multiply the number of intractable epilepsy cases (ICD-9-CM codes 345.01, 345.11, 345.41,  
466 345.51, 345.61, 345.71, 345.81, or 345.91) identified in accord with the requirements of Section 16 by  
467 1.0, which is the estimated probability that a patient having an intractable epilepsy procedure will require  
468 a PET scan. Multiply the number resulting from the calculation in subsection (3) by 1.0, which is the  
469 estimated number of PET scans needed for each patient requiring a PET scan.

470

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

473

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

476

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- 586 (a) For fixed PET scanner services, the geographic location of each entity contributing intractable  
 587 epilepsy case data is in the same planning area as the proposed PET unit/service.
- 588 (b) For mobile PET scanner services, the geographic location of each entity contributing intractable  
 589 epilepsy case data in the planning area(s) for which the proposed PET scanner service contains a  
 590 proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical  
 591 area counties or 25-mile radius for metropolitan statistical area counties.
- 592 (c) No entity contributing intractable epilepsy case data has previously committed or is committing  
 593 data to another service that is less than five (5) years from the start of operations of that service.
- 594 (d) The intractable epilepsy case data is from the most recent Michigan Inpatient Data Base  
 595 (MIDB) available to the Department.
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- 597 (2) No entity currently operating or approved to operate a scanner shall contribute intractable  
 598 epilepsy case data.
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- 600 (3) The Department may not consider a withdrawal of intractable epilepsy case data during the  
 601 120-day application review cycle following the date on which the Department review of the application  
 602 commences or after a proposed decision to approve the application unless the application is denied,  
 603 withdrawn, or expired. The withdrawal must be submitted to the Department in the form of a governing  
 604 body resolution that contains the specific CON application number to which the data were originally  
 605 committed, the legal applicant entity, the committing entity, the type of data, the date of the meeting in  
 606 which the governing body authorized the withdrawal of the data, the governing body president's  
 607 signature, and the date of the signature.
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609 **Section 17. Methodology for computing PET equivalents**

610 Sec. 17. PET equivalents shall be calculated as follows:

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<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.	

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614 **Section 18. Department inventory of PET scanners**

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

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

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621 Sec. 19. Proposed projects reviewed under these standards shall not be subject to comparative  
 622 review. These CON review standards supersede and replace the CON standards for PET scanner  
 623 services approved by the CON Commission on December 12, 2006 September 22, 2011 and effective  
 624 March 8, 2007 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
2	Clinton Eaton
3	Barry Berrien Branch
4	Allegan Ionia Kent Lake
5	Genesee
6	Arenac Bay Clare Gladwin Gratiot
7	Alcona Alpena Antrim Benzie Charlevoix Cheboygan
8	Alger Baraga Chippewa Delta Dickinson

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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	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