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MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

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

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

Section 1. Applicability

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

Section 2. Definitions

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

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

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

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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 planning
93 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 services.

103 (b) The applicant has performed:

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

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

108 (c) The applicant shall install the fixed PET unit at the same site as the existing host site or within a

109 10-mile radius of the existing host site for a metropolitan statistical area county or a 25-mile radius for a
110 rural or micropolitan statistical area.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

198 (b) The applicant has performed:

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

202 (ii) An average of 1,700 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 rural or
204 micropolitan statistical area county.

205 (c) The applicant agrees to cease operation as a host site and not become a host site for at least
206 12 months from the date the fixed scanner becomes operational.

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

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

214
215 (1) For the first application proposing to acquire an existing fixed, mobile, or host site PET scanner
216 service, other than a renewal of lease, on or after November 21, 2011, the existing PET service and its

217 scanner(s) shall not be required to be in compliance with the applicable volume requirements set forth in
218 this section.

219

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

223

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

226

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

229

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

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

234

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

237

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

240

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

243

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

246

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

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

251

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

254

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

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

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

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

263

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

266

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

268

269 (b) anesthesiology

270

(c) cardiology

(d) critical care

(e) gastroenterology

(f) hematology/oncology

(g) neurology

(h) neurosurgery

- 271 (i) orthopedic surgery
- 272 (j) pathology
- 273 (k) pulmonology
- 274 (l) surgery
- 275 (m) neonatology

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

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

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

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

288

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

290

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

293

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

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

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

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

303

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

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

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

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

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

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

317

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

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

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

325 has a fixed or mobile PET scanner service.
326 (c) The applicant provides a proposed route schedule for the mobile PEM scanner service.
327 (d) The applicant provides a draft contract for PEM services between the host site and central
328 service coordinator.

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

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

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

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

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

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

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

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

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

350
351 (1) Compliance with these standards.

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

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

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

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

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

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

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

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

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

378 (d) The operation of and referral of patients to the PET scanner service shall be in conformance

379 with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).
380

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

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

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

395 (c) The PET scanner service shall provide the Department with timely notice of the proposed
396 project implementation consistent with applicable statute and promulgated rules.
397

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

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

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

403 (c) The dedicated research PET scanner will be used primarily (70% or more of the scans) for
404 research purposes only.
405

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

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

409 (b) Shall maintain active medical staff in the applicable pediatric specialties and pediatric specialty
410 programs as set forth in the section.
411

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

413 (a) The PEM scanner service must maintain ACR accreditation as a BICOE site verifiable by the
414 Department.
415

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

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

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

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

426 (d) A mobile PET scanner service shall operate under a contractual agreement that includes the
427 provision of PET services at each host site on a regularly scheduled basis.
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429 (9) The agreements and assurances required by this section shall be in the form of a certification
430 agreed to by the applicant or its authorized agent.

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Section 12. Methodology for computing the projected PET data units

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

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

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

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

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

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

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

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

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

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

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

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

(7) Multiply the result calculated in subsection (5) above by a factor of 2.0 if the applicant is 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.

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

592
 593 (2) No entity currently operating or approved to operate a scanner shall contribute intractable
 594 epilepsy case data.
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596 (3) The Department may not consider a withdrawal of intractable epilepsy case data during the 120-
 597 day application review cycle following the date on which the Department review of the application
 598 commences or after a proposed decision to approve the application unless the application is denied,
 599 withdrawn, or expired. The withdrawal must be submitted to the Department in the form of a governing
 600 body resolution that contains the specific CON application number to which the data were originally
 601 committed, the legal applicant entity, the committing entity, the type of data, the date of the meeting in
 602 which the governing body authorized the withdrawal of the data, the governing body president's signature,
 603 and the date of the signature.
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605 **Section 17. Methodology for computing PET equivalents**

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 607 Sec. 17. PET equivalents shall be calculated as follows:
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TABLE 1	
PET EQUIVALENTS	
Scan Category	Weight
Simple ¹	0.75
Standard ²	1.0
Complex ³	1.5
¹ Brain and single cardiac scans. ² Mid-skull to mid-thigh scans. ³ Inpatient, radiation treatment when patient position device is used, cardiac rest/stress perfusion and metabolism, standard study with additional limited scan, pediatric, and total body scans.	

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

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 612 Sec. 18. The Department shall maintain and publicly post on its web site a list of PET scanner
 613 services annually.
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615 **Section 19. Comparative reviews; effect on prior planning policies**

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 617 Sec. 19. Proposed projects reviewed under these standards shall not be subject to comparative
 618 review. These CON review standards supersede and replace the CON standards for PET scanner
 619 services approved by the CON Commission on [December 12, 2006](#)[September 22, 2011](#) and effective
 620 [March 8, 2007](#)[November 21, 2011](#).
 621

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