

1 | **MICHIGAN DEPARTMENT OF COMMUNITY HEALTH**

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

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

10 **Section 1. Applicability**

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

19 **Section 2. Definitions**

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

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

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

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

65

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

67

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

69

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

72

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

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

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

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

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

80 (e) cardiac catheterization services,

81 (f) open heart surgery,

82 (g) thoracic surgery,

83 (h) cardiology,

84 (i) oncology,

85 (j) radiation oncology,

86 (k) neurology,

87 (l) neurosurgery, and

88 (m) psychiatry.

89

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

93

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

98

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

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

102 (b) The applicant has performed:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

168
169 **Section 5. Requirements to expand a PET scanner service**
170

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

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

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

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

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

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

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

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

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

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

197 (b) The applicant has performed:

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

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

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

206
207 **Section 6. Requirements to acquire a PET scanner service or scanner(s)**
208

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

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

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

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

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

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

229
230 Sec. 7. An applicant proposing to add a fixed PET scanner to an existing PET scanner service for
231 exclusive research use shall demonstrate the following:

232
233 (1) The applicant agrees that the dedicated research PET scanner will be used primarily (70% or
234 more of the scans) for research purposes only.

235
236 (2) The dedicated research PET scanner shall operate under a protocol approved by the applicant's
237 Institutional Review Board, as defined by Public Law 93-348 and regulated by Title 45 CFR 46.

238
239 (3) The applicant has access to a cyclotron for accelerating charged particles to high energies by
240 means of electromagnetic fields.

241
242 (4) The proposed site can have no more than three dedicated research fixed PET scanners
243 approved under this Section.

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

245
246 Sec. 8. An applicant proposing to initiate a PET scanner service, or add a fixed PET scanner to
247 expand an existing PET scanner service, for dedicated pediatric PET use shall demonstrate the following:

248
249 (1) The applicant agrees that the dedicated pediatric PET scanner will be used primarily (70% or
250 more of the scans) for patients under 18 years of age.

251
252 (2) The applicant shall demonstrate the existing site provided the following for the most recent
253 calendar year or a continuous 12-month period at the time the application is submitted to the Department:

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

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

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

257
258 (3) The applicant shall have an active medical staff at the time the application is submitted to the
259 Department that includes physicians who are fellowship-trained in the following pediatric specialties:

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

261 (b) anesthesiology

262 (c) cardiology

263 (d) critical care

264 (e) gastroenterology

265 (f) hematology/oncology

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

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

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

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

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

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

288
289 Sec. 9. An applicant proposing to add a PEM scanner service to an existing PET scanner service
290 shall demonstrate the following, as applicable to the proposed project.

291
292 (1) An applicant proposing to add a fixed PEM scanner to an existing fixed PET scanner site shall
293 demonstrate the following:

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

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

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

301
302 (2) An applicant proposing to add a mobile PEM scanner to an existing mobile PET scanner service
303 shall demonstrate the following:

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

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

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

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

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

315
316 (3) An applicant, whether an existing fixed PET scanner site or host site, proposing to initiate
317 mobile PEM scanner services as a host site shall demonstrate the following:

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

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

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

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

328

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

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

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

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

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

338

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

340

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

344

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

346

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

349

350 (1) Compliance with these standards.

351

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

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

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

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

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

369

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

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

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

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

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

379

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

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

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

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

396

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

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

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

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

404

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

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

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

410

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

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

414

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

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

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

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

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

427

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

553

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

556

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

565

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

567

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

570

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

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

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

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

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

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

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

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

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

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.	

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

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

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

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

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

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

PLANNING AREA 1	COUNTIES		
HSA 1	Livingston	Monroe	St. Clair
	Macomb	Oakland	Washtenaw
	Wayne		
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

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

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
345.01	INTRACTABLE EPILEPSY CASES	G40.311	GENERALIZED IDIOPATHIC EPILEPSY AND EPILEPTIC SYNDROMES, INTRACTABLE, WITH STATUS EPILEPTICUS
		G40.319	GENERALIZED IDIOPATHIC EPILEPSY AND EPILEPTIC SYNDROMES, INTRACTABLE, WITHOUT STATUS EPILEPTICUS
		G40.A11	ABSENCE EPILEPTIC SYNDROME, INTRACTABLE, WITH STATUS EPILEPTICUS
345.11	INTRACTABLE EPILEPSY CASES	G40.311	GENERALIZED IDIOPATHIC EPILEPSY AND EPILEPTIC SYNDROMES, INTRACTABLE, WITH STATUS EPILEPTICUS
		G40.319	GENERALIZED IDIOPATHIC EPILEPSY AND EPILEPTIC SYNDROMES, INTRACTABLE, WITHOUT STATUS EPILEPTICUS
345.41	INTRACTABLE EPILEPSY CASES	G40.211	LOCALIZATION-RELATED (FOCAL) (PARTIAL) SYMPTOMATIC EPILEPSY AND EPILEPTIC SYNDROMES WITH COMPLEX PARTIAL SEIZURES, INTRACTABLE, WITH STATUS EPILEPTICUS
		G40.219	LOCALIZATION-RELATED (FOCAL) (PARTIAL) SYMPTOMATIC EPILEPSY AND EPILEPTIC SYNDROMES WITH COMPLEX PARTIAL SEIZURES, INTRACTABLE, WITHOUT STATUS EPILEPTICUS
345.51	INTRACTABLE EPILEPSY CASES	G40.011	LOCALIZATION-RELATED (FOCAL) (PARTIAL) IDIOPATHIC EPILEPSY AND EPILEPTIC SYNDROMES WITH SEIZURES OF LOCALIZED ONSET, INTRACTABLE, WITH STATUS EPILEPTICUS
		G40.019	LOCALIZATION-RELATED (FOCAL) (PARTIAL) IDIOPATHIC EPILEPSY AND EPILEPTIC SYNDROMES WITH SEIZURES OF LOCALIZED ONSET, INTRACTABLE, WITHOUT STATUS EPILEPTICUS

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APPENDIX D CONTINUED

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
345.51 CONTINUED	INTRACTABLE EPILEPSY CASES CONTINUED	G40.111	LOCALIZATION-RELATED (FOCAL) (PARTIAL) SYMPTOMATIC EPILEPSY AND EPILEPTIC SYNDROMES WITH SIMPLE PARTIAL SEIZURES, INTRACTABLE, WITH STATUS EPILEPTICUS
		G40.119	LOCALIZATION-RELATED (FOCAL) (PARTIAL) SYMPTOMATIC EPILEPSY AND EPILEPTIC SYNDROMES WITH SIMPLE PARTIAL SEIZURES, INTRACTABLE, WITHOUT STATUS EPILEPTICUS
345.61	INTRACTABLE EPILEPSY CASES	G40.411	OTHER GENERALIZED EPILEPSY AND EPILEPTIC SYNDROMES, INTRACTABLE, WITH STATUS EPILEPTICUS
		G40.419	OTHER GENERALIZED EPILEPSY AND EPILEPTIC SYNDROMES, INTRACTABLE, WITHOUT STATUS EPILEPTICUS
345.71	INTRACTABLE EPILEPSY CASES	G40.111	LOCALIZATION-RELATED (FOCAL) (PARTIAL) SYMPTOMATIC EPILEPSY AND EPILEPTIC SYNDROMES WITH SIMPLE PARTIAL SEIZURES, INTRACTABLE, WITH STATUS EPILEPTICUS
		G40.119	LOCALIZATION-RELATED (FOCAL) (PARTIAL) SYMPTOMATIC EPILEPSY AND EPILEPTIC SYNDROMES WITH SIMPLE PARTIAL SEIZURES, INTRACTABLE, WITHOUT STATUS EPILEPTICUS
345.81	INTRACTABLE EPILEPSY CASES	G40.803	OTHER EPILEPSY, INTRACTABLE, WITH STATUS EPILEPTICUS
		G40.804	OTHER EPILEPSY, INTRACTABLE, WITHOUT STATUS EPILEPTICUS
		G40.89	OTHER SEIZURES
345.91	INTRACTABLE EPILEPSY CASES	G40.411	OTHER GENERALIZED EPILEPSY AND EPILEPTIC SYNDROMES, INTRACTABLE, WITH STATUS EPILEPTICUS
		G40.419	OTHER GENERALIZED EPILEPSY AND EPILEPTIC SYNDROMES, INTRACTABLE, WITHOUT STATUS EPILEPTICUS

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APPENDIX D CONTINUED

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

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"ICD-9-CM CODE" MEANS THE DISEASE CODES AND NOMENCLATURE FOUND IN THE INTERNATIONAL CLASSIFICATION OF DISEASES - 9TH REVISION - CLINICAL MODIFICATION, PREPARED BY THE COMMISSION ON PROFESSIONAL AND HOSPITAL ACTIVITIES FOR THE U.S. NATIONAL CENTER FOR HEALTH STATISTICS.

"ICD-10-CM CODE" MEANS THE DISEASE CODES AND NOMENCLATURE FOUND IN THE INTERNATIONAL CLASSIFICATION OF DISEASES - 10TH REVISION - CLINICAL MODIFICATION, NATIONAL CENTER FOR HEALTH STATISTICS.