

**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) "COMPREHENSIVE FIXED PET REFERRAL SERVICE" MEANS A PET SCANNER SERVICE THAT MUST INCLUDE AT LEAST ONE OF THE FOLLOWING FDA-APPROVED PET SCANNERS: FIXED WHOLE-BODY PET/CT, FIXED DIGITAL PET/CT SCANNER, OR FIXED PET/MRI SCANNER HYBRID. THE SERVICE SHALL BE LOCATED IN THE SAME OR IN A CONTIGUOUS BUILDING AS A FIXED CYCLOTRON-EQUIPPED RADIOPHARMACY CAPABLE OF PRODUCING A BROAD SPECTRUM OF RADIOISOTOPES, INCLUDING THOSE WITH SHORT HALF-LIVES.

(d) "Department" means the Michigan Department of Community Health (MDCH).

(~~de~~) "Existing PET scanner" means an operational PET scanner used to provide PET services on the date an application is submitted to the Department.

(~~ef~~) "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.

(~~fg~~) "FIXED CYCLOTRON" MEANS A FIXED PARTICLE ACCELERATOR USED FOR THE PRODUCTION OF MULTIPLE MEDICAL ISOTOPES.

(h) "FIXED DIGITAL PET/CT" SCANNER" MEANS A FIXED PET/CT HYBRID WITH SILICON PHOTOMULTIPLIERS (SIPM) WITH DIGITAL READOUT FOR HIGH-RESOLUTION IMAGE RECONSTRUCTION.

(i) "Health service area" or "HSA" means the groups of counties listed in Appendix A.

(~~gj~~) "Hospital" means a health facility licensed under Part 215 of the Code.

(~~hk~~) "Host site" means the geographic address at which a mobile PET scanner is authorized by CON to provide mobile PET scanner services.

(~~il~~) "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.

(~~jm~~) "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.

53 (kn) "Mobile PET scanner" means a PET scanner unit and transporting equipment operated by a  
54 central service coordinator that serves two or more host sites.

55 (lo) "Mobile PET scanner network" means the route (i.e., all host sites) that the central service  
56 coordinator is authorized to serve under CON.

57 (mp) "Patient visit" means a single session utilizing a PET scanner during which 1 or more PET  
58 procedures are performed.

59 (nq) "Pediatric patient" means any patient less than 18 years of age.

60 (or) "PET procedure" means the acquisition of a single image or image sequence involving a single  
61 injection of tracer.

62 (ps) "PET scan" means one (1) or more PET procedures performed during a single patient visit.

63 (qt) "PET scanner" means an FDA-approved full or partial ring scanner or coincidence system that  
64 has a crystal at least 5/8-inch thick, techniques to minimize or correct for scatter and/or randoms, and  
65 digital detectors and iterative reconstruction. Further, the term does include PET/computed tomography  
66 (CT) and FDA-approved PET/magnetic resonance imaging (MRI) scanner hybrids. If the PET/CT  
67 scanner hybrid will be used for CT scans only in conjunction with the PET scan, then no separate CON is  
68 required for that CT use. If the FDA-approved PET/MRI scanner hybrid will be used for MRI scans only in  
69 conjunction with the PET scan, then no separate CON is required for that MRI use. The term does not  
70 include single-photon emission computed tomography systems (SPECT), x-ray CT systems, magnetic  
71 resonance, ultrasound computed tomographic systems, gamma cameras modified for either non-  
72 coincidence or coincidence imaging, or similar technology.

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

75 (sv) "SPECT" means single photon emission computed tomography.

76 (w) "WHOLE BODY PET/CT SCANNER" MEANS A FIXED PET/CT SCANNER WITH AN AXIAL  
77 FIELD OF VIEW OF >130CM.

78  
79 (2) The definitions in Part 222 shall apply to these standards.  
80

### 81 Section 3. Requirements to initiate a PET scanner service

82  
83 Sec. 3. An applicant proposing to initiate PET scanner services shall demonstrate the following, as  
84 applicable to the proposed project.

85  
86 (1) The applicant shall demonstrate the proposed site provides the following services and  
87 specialties:

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

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

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

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

93 (e) cardiac catheterization services,

94 (f) open heart surgery,

95 (g) thoracic surgery,

96 (h) cardiology,

97 (i) oncology,

98 (j) radiation oncology,

99 (k) neurology,

100 (l) neurosurgery, and

101 (m) psychiatry.  
102

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

- 106  
107 (3) The applicant shall demonstrate the proposed site has an on-site source of  
108 radiopharmaceuticals. If the proposed site does not provide an on-site source of radiopharmaceuticals,  
109 the applicant shall provide a written contract or agreement that demonstrates a reliable supply of  
110 radiopharmaceuticals.  
111
- 112 (4) An applicant proposing to initiate a fixed PET scanner service with its first PET scanner shall  
113 project 2,600 PET data units or shall demonstrate all of the following:  
114 (a) The applicant is currently a host site being served by one or more mobile PET scanner  
115 services.  
116 (b) The applicant has performed:  
117 (i) 1,7001,500 PET equivalents in the most recent 12-month period verifiable by the Department  
118 for a host site in a metropolitan statistical area county, or  
119 (ii) 1,5001,325 PET equivalents in the most recent 12-month period verifiable by the Department  
120 for a host site in a rural or micropolitan statistical area county.  
121 (c) The applicant shall install the fixed PET unit at the same site as the existing host site or within a  
122 10-mile radius of the existing host site for a metropolitan statistical area county or a 25-mile radius for a  
123 rural or micropolitan statistical area.  
124 (d) The applicant agrees to cease operation as a host site and not become a host site for at least  
125 12 months from the date the fixed PET scanner becomes operational. This requirement shall not apply if  
126 the applicant is installing an FDA-approved PET/MRI scanner hybrid.  
127
- 128 (5) An applicant proposing to initiate a mobile PET scanner service with its first mobile PET  
129 scanner shall project 2,100 PET data units.  
130 (a) Of the 2,100 PET data units, the applicant shall project a minimum of 360 PET data units within  
131 a 20-mile radius of each proposed host site for planning area 1, or 240 PET data units per host site for  
132 any other planning area, for the proposed service.  
133 (b) The application for the mobile PET scanner service is accompanied by at least two host site  
134 applications.  
135 (c) Each applicant provides a route schedule for the proposed mobile PET scanner service.  
136 (d) The applicant provides a draft contract for services between the proposed host site and central  
137 service coordinator.  
138
- 139 (6) An applicant proposing to initiate a host site on a proposed or existing mobile PET scanner  
140 service shall demonstrate the following:  
141 (a) The applicant provides a proposed route schedule.  
142 (b) The applicant provides a draft contract for services between the proposed host site and central  
143 service coordinator.  
144 (c) The applicant has not initiated fixed PET scanner services under subsection 3(4) within the  
145 most recent 12-month period as of the date the application is submitted to the Department.  
146 (d) An applicant initiating a host site in HSA 8 on a mobile PET scanner service that operates  
147 predominantly outside of Michigan shall demonstrate 240 PET data units from planning area 6.  
148
- 149 (7) An applicant proposing to initiate PET scanner services as an existing host site on a different  
150 mobile PET scanner service shall demonstrate the following:  
151 (a) The applicant provides a proposed route schedule.  
152 (b) The applicant provides a draft contract for services between the proposed host site and central  
153 service coordinator.  
154 (c) 50 PET equivalents were performed in the most recent 12-month period verifiable by the  
155 Department from an existing mobile PET scanner service at the existing host site.  
156

157 **Section 4. Requirements to replace an existing PET scanner(s) or PET scanner service**  
158

159 Sec. 4. Replacing a PET scanner(s) means a change in the scanner equipment or relocation of the  
160 service to a new site. An upgrade to software or components of an existing scanner does not constitute  
161 replacement of a PET scanner. An applicant proposing to replace an existing PET scanner(s) or PET  
162 scanner service shall demonstrate the following, as applicable to the proposed project.  
163

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

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

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

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

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

172 (c) The applicant agrees that the PET scanner(s) to be replaced will be removed from service on or  
173 before beginning operation of the replacement scanner(s).  
174

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

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

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

181 (c) The existing fixed PET scanner service has been in operation for at least 36 months as of the  
182 date of the application submitted to the Department.  
183

#### 184 **Section 5. Requirements to expand a PET scanner service** 185

186 Sec. 5. An applicant proposing to expand a PET scanner service shall demonstrate the following, as  
187 applicable to the proposed project. This section does not apply to dedicated research, dedicated  
188 pediatric, or positron emission mammography (PEM) scanners.  
189

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

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

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

198 (c) The additional PET scanner(s) shall be located at the same site.  
199

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

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

205 (b) 1,800 PET equivalents were performed per existing and approved scanner(s) in the most  
206 recent 12-month period verifiable by the Department for an applicant serving only host sites in rural or  
207 micropolitan statistical area counties.  
208

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

- 211 (a) The applicant is currently a host site being served by one or more mobile PET scanner  
212 services.
- 213 (b) The applicant has performed:
- 214 (i) An average of 1,900 pet equivalents for the host site and each of the existing and approved  
215 fixed scanners in the most recent 12-month period verifiable by the Department for a host site in a  
216 metropolitan statistical area county, or
- 217 (ii) An average of 1,700 PET equivalents for the host site and each of the existing and approved  
218 fixed scanners in the most recent 12-month period verifiable by the Department for a host site in a rural or  
219 micropolitan statistical area county.
- 220 (c) The applicant agrees to cease operation as a host site and not become a host site for at least  
221 12 months from the date the fixed scanner becomes operational.  
222

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

224

225 Sec. 6. Acquiring a PET scanner service and its scanner(s) means obtaining possession and control  
226 by contract, ownership, lease, or other comparable arrangement and renewal of lease for an existing  
227 fixed or mobile PET scanner. An applicant proposing to acquire a PET scanner service shall demonstrate  
228 the following, as applicable to the proposed project.  
229

230 (1) For the first application proposing to acquire an existing fixed, mobile, or host site PET scanner  
231 service, other than a renewal of lease, on or after November 21, 2011, the existing PET service and its  
232 scanner(s) shall not be required to be in compliance with the applicable volume requirements set forth in  
233 this section. The PET scanner service shall be operating at the applicable volumes set forth in the project  
234 delivery requirements in the second 12 months of operation of the service by the applicant and annually  
235 thereafter.  
236

237 (2) For any application proposing to acquire an existing PET scanner service, except the first  
238 application approved pursuant to subsection (1), an applicant shall be required to document that the PET  
239 scanner service to be acquired is operating in compliance with the volume requirements set forth in  
240 Section 11 of these standards applicable to an existing PET scanner service on the date the application is  
241 submitted to the Department.  
242

243 (3) An applicant proposing to acquire an existing fixed or mobile PET scanner service shall  
244 demonstrate that the existing fixed or mobile scanner(s) performed an average of 500 PET equivalents  
245 per scanner in the most recent 12-month period verifiable by the Department.  
246

247 (4) An applicant proposing to acquire an existing host site shall demonstrate that the existing host  
248 site has performed 50 PET equivalents in the most recent 12-month period verifiable by the Department.  
249

250 (5) An applicant proposing to renew a lease for an existing fixed or mobile PET scanner(s) shall  
251 demonstrate that the renewal of the lease is more cost effective than replacing the scanner(s).  
252

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

254

255 Sec. 7. An applicant proposing to add a fixed PET scanner to an existing PET scanner service for  
256 exclusive research use shall demonstrate the following:  
257

258 (1) The applicant agrees that the dedicated research PET scanner will be used primarily (70% or  
259 more of the scans) for research purposes only.  
260

261 (2) The dedicated research PET scanner shall operate under a protocol approved by the  
262 applicant's Institutional Review Board, as defined by Public Law 93-348 and regulated by Title 45 CFR  
263 46.

264  
265 (3) The applicant has access to a cyclotron for accelerating charged particles to high energies by  
266 means of electromagnetic fields.

267  
268 (4) The proposed site can have no more than three dedicated research fixed PET scanners  
269 approved under this Section.

270  
271 **Section 8. Requirements for a dedicated pediatric PET scanner**

272  
273 Sec. 8. An applicant proposing to initiate a PET scanner service, or add a fixed PET scanner to  
274 expand an existing PET scanner service, for dedicated pediatric PET use shall demonstrate the following:

275  
276 (1) The applicant agrees that the dedicated pediatric PET scanner will be used primarily (70% or  
277 more of the scans) for patients under 18 years of age.

278  
279 (2) The applicant shall demonstrate the existing site provided the following for the most recent  
280 calendar year or a continuous 12-month period at the time the application is submitted to the Department:

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

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

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

284  
285 (3) The applicant shall have an active medical staff at the time the application is submitted to the  
286 Department that includes physicians who are fellowship-trained in the following pediatric specialties:

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

288 (b) anesthesiology

289 (c) cardiology

290 (d) critical care

291 (e) gastroenterology

292 (f) hematology/oncology

293 (g) neurology

294 (h) neurosurgery

295 (i) orthopedic surgery

296 (j) pathology

297 (k) pulmonology

298 (l) surgery

299 (m) neonatology

300  
301 (4) The applicant shall have in operation the following pediatric specialty programs at the time the  
302 application is submitted to the Department:

303 (a) bone marrow transplant program

304 (b) sedation program

305 (c) open heart program

306  
307 (5) The applicant meets the requirements of Section 3(1) through 3(4) if the applicant is initiating a  
308 PET scanner service with a dedicated pediatric fixed PET scanner.

309  
310 (6) The proposed site can have no more than two dedicated pediatric fixed PET scanners  
311 approved under this section.

312  
313 **Section 9. Requirements for a positron emission mammography (PEM) scanner**

314  
315 Sec. 9. An applicant proposing to add a PEM scanner service to an existing PET scanner service  
316 shall demonstrate the following, as applicable to the proposed project.

317  
318 (1) An applicant proposing to add a fixed PEM scanner to an existing fixed PET scanner site shall  
319 demonstrate the following:

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

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

326 (c) The proposed site can have no more than one fixed PEM scanner approved under this section.  
327

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

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

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

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

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

339 (e) The proposed network can have no more than one mobile PEM scanner approved under this  
340 section.  
341

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

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

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

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

351 (d) The applicant provides a draft contract for PEM services between the host site and central  
352 service coordinator.  
353

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

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

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

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

361 (d) The applicant provides a draft contract for PEM services between the host site and central  
362 service coordinator.  
363

364 **Section 10. PILOT PROGRAM REQUIREMENTS FOR ALL APPLICANTS PROPOSING TO INITIATE,**  
365 **REPLACE, EXPAND OR ACQUIRE A COMPREHENSIVE FIXED PET REFERRAL SERVICE**

366  
367 **(1) AN APPLICANT PROPOSING TO INITIATE A COMPREHENSIVE FIXED PET REFERRAL**  
368 **SERVICE SHALL DEMONSTRATE ALL OF THE FOLLOWING:**

369 (a) THE APPLICANT SHALL PROVIDE A LETTER(S) OF SUPPORT FROM A HOSPITAL(S)  
370 AND/OR PHYSICIAN PRACTICE(S) WITH THE SPECIALTIES LISTED BELOW, INDICATING  
371 WILLINGNESS TO PROVIDE REFERRALS AND CONSULTING SERVICES TO THE APPLICANT:

372 (i) CARDIOLOGY

373 (ii) ONCOLOGY

374 (iii) RADIATION ONCOLOGY/THERAPY

375 (iv) NEUROLOGY

376 (b) THE APPLICANT SHALL HAVE A FIXED CYCLOTRON.

377 (c) THE APPLICANT SHALL HAVE A RADIOPHARMACY ONSITE THAT WILL COMBINE  
378 CYCLOTRON-PRODUCED RADIONUCLIDE TRACERS WITH PHARMACEUTICAL COMPONENTS  
379 FOR PURPOSES OF ONSITE PATIENT ADMINISTRATION.

380 (d) THE APPLICANT'S RADIOPHARMACY SHALL SUPPORT THE DEVELOPMENT OF  
381 RADIOPHARMACEUTICALS FOR USE IN DIAGNOSTIC AND THERANOSTIC APPLICATIONS.

382 (e) THE APPLICANT IS PROPOSING NO MORE THAN TWO FIXED PET SCANNERS.

383 (f) THE APPLICANT AGREES TO OPERATE THE COMPREHENSIVE FIXED PET REFERRAL  
384 SERVICE IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET  
385 FORTH IN SECTION 12 OF THESE STANDARDS INCLUDING THE FOLLOWING:

386 (i) THE APPLICANT SHALL BECOME ACCREDITED BY  
387 ACR, INTERSOCIETAL ACCREDITATION COMMISSION (IAC) OR ANY OTHER NATIONAL  
388 ACCREDITATION BODY ACCEPTABLE TO THE DEPARTMENT.

389 (ii) THE APPLICANT'S RADIOPHARMACY SHALL BE LICENSED BY THE MICHIGAN BOARD  
390 OF PHARMACY.

391  
392 (2) AN APPLICANT PROPOSING TO INITIATE A COMPREHENSIVE FIXED PET REFERRAL  
393 SERVICE SHALL NOT BE REQUIRED TO PROJECT PET DATA UNITS.

394  
395 (3) AN APPLICANT PROPOSING TO REPLACE A COMPREHENSIVE FIXED PET REFERRAL  
396 SERVICE SHALL DEMONSTRATE ONE OF THE FOLLOWING:

397 (a) THE APPLICANT MEETS THE REQUIREMENTS OF SECTION 4(1).

398 (b) THE APPLICANT IS PROPOSING TO REPLACE A COMPREHENSIVE FIXED PET  
399 REFERRAL SERVICE AND ITS EXISTING PET SCANNER UNIT(S) TO A NEW SITE AND MEETS THE  
400 FOLLOWING:

401 (i) THE PROPOSED SITE IS WITHIN THE PLANNING AREA.

402 (ii) THE EXISTING FIXED PET SCANNER(S) PERFORMED 500 PET EQUIVALENTS PER  
403 FIXED SCANNER IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE DEPARTMENT.

404 (iii) THE EXISTING COMPREHENSIVE FIXED PET REFERRAL SERVICE HAS BEEN IN  
405 OPERATION FOR AT LEAST 36 MONTHS AS OF THE DATE OF THE APPLICATION SUBMITTED TO  
406 THE DEPARTMENT.

407 (iv) THE FIXED PET SCANNER(S) WILL CONTINUE TO BE LOCATED IN THE SAME OR IN A  
408 CONTIGUOUS BUILDING AS A FIXED CYCLOTRON-EQUIPPED RADIOPHARMACY.

409  
410  
411 (4) AN APPLICANT PROPOSING TO EXPAND A COMPREHENSIVE FIXED PET REFERRAL  
412 SERVICE SHALL DEMONSTRATE THAT IT MEETS THE REQUIREMENTS OF SECTION 5.

413  
414 (5) AN APPLICANT PROPOSING TO ACQUIRE A COMPREHENSIVE FIXED PET REFERRAL  
415 SERVICE OR ITS SCANNER(S) SHALL DEMONSTRATE THAT IT MEETS THE REQUIREMENTS OF  
416 SECTION 6.

417  
418 (6) THE COMMISSION MAY DECIDE TO HAVE THE REQUIREMENTS OF THE PILOT  
419 PROGRAM DESCRIBED IN THIS SECTION BECOME A PERMANENT PART OF THE PET SCANNER  
420 SERVICES STANDARDS. IF THE COMMISSION DOES NOT TAKE ACTION TO MAKE THE PILOT  
421 PROGRAM A PERMANENT PART OF THE STANDARDS, THE PROVISIONS OF THIS SECTION, AS



PART OF A PILOT PROGRAM, WILL EXPIRE ON SEPTEMBER 30, 2027 AND BE OF NO FURTHER FORCE AND EFFECT AFTER SEPTEMBER 30, 2027. ANY APPLICANT SEEKING TO BE PART OF THE PILOT PROGRAM DESCRIBED IN THIS SECTION MUST SUBMIT ITS APPLICATION ON OR BEFORE SEPTEMBER 1, 2023. THESE PROVISIONS SHALL NOT BE APPLICABLE TO ANY APPLICATION WHICH HAS NOT BEEN SUBMITTED BY SEPTEMBER 1, 2023.

#### **SECTION 11. Requirement for Medicaid participation**

**Sec. 4011.** An applicant shall provide verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within (6) months from the offering of services if a CON is approved.

#### **Section 4112. Project delivery requirements and terms of approval for all applicants**

**Sec. 4112.** An applicant shall agree that, if approved, the PET scanner services shall be delivered in compliance with the following terms of approval.

(1) Compliance with these standards.

(2) Compliance with the following quality assurance requirements:

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

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

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

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

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

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

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

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

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

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

(a) The PET scanners shall be operating at an average of 500 PET equivalents per scanner during the second 12 months of operations, and annually thereafter. This requirement shall be waived during review of applications under sections 4(1) and 6(5), if applicable. In meeting these requirements, an

475 applicant shall not include any PET scans performed on a PET scanner used exclusively for research  
476 approved pursuant to Section 7, for a dedicated pediatric PET scanner approved pursuant to Section 8,  
477 or for a PEM scanner approved pursuant to Section 9.

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

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

487  
488 (5) Compliance with the following dedicated research PET scanner requirements, if applicable:

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

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

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

495  
496 (6) Compliance with the following dedicated pediatric PET scanner requirements, if applicable:

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

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

501  
502 (7) Compliance with the following PEM scanner requirements, if applicable:

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

505  
506 (8) Compliance with the following mobile PET scanner requirements, if applicable:

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

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

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

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

518  
519 (9) AN APPLICANT FOR A COMPREHENSIVE FIXED PET REFERRAL SERVICE APPROVED  
520 UNDER SECTION 10 SHALL AGREE THAT THE SERVICES SHALL BE DELIVERED IN COMPLIANCE  
521 WITH THE FOLLOWING TERMS:

522 (a) THE APPLICANT SHALL BECOME ACCREDITED BY ACR, IAC OR ANY OTHER NATIONAL  
523 ACCREDITATION BODY ACCEPTABLE TO THE DEPARTMENT WITHIN 24 MONTHS OF  
524 OPERATION AND SHALL MAINTAIN ACCREDITATION ON AN ONGOING BASIS.

525 (b) THE APPLICANT'S RADIOPHARMACY SHALL BE LICENSED BY THE MICHIGAN BOARD  
526 OF PHARMACY WITHIN 12 MONTHS OF OPERATION AND SHALL CONTINUE TO BE LICENSED ON  
527 AN ONGOING BASIS.

528 (c) THE APPLICANT SHALL HAVE EQUIPMENT AND SUPPLIES ONSITE TO HANDLE  
529 CLINICAL EMERGENCIES THAT MIGHT OCCUR IN THE UNIT. PET SERVICE STAFF WILL BE  
530 TRAINED IN CPR AND OTHER APPROPRIATE EMERGENCY INTERVENTIONS.

531 (d) THE APPLICANT SHALL ESTABLISH AND MAINTAIN: (i) A STANDING MEDICAL STAFF  
532 AND GOVERNING BODY (OR ITS EQUIVALENT) REQUIREMENT THAT PROVIDES FOR THE  
533 MEDICAL AND ADMINISTRATIVE CONTROL OF THE ORDERING AND UTILIZATION OF PET  
534 PATIENT PROCEDURES, AND (ii) A FORMAL PROGRAM OF UTILIZATION REVIEW AND QUALITY  
535 ASSURANCE.

536 (e) BY APRIL 30<sup>TH</sup> OF EACH YEAR, AN APPLICANT SHALL PROVIDE ANNUAL REPORTS TO  
537 THE DEPARTMENT REGARDING ALL DIAGNOSTIC SCANS PERFORMED USING RADIOISOTOPES  
538 OTHER THAN FDG IN THE PRECEDING CALENDAR YEAR. THIS REPORTING REQUIREMENT  
539 SHALL CONTINUE FOR A PERIOD OF 7 YEARS AND IS IN ADDITION TO THE REQUIREMENTS OF  
540 SECTION 12(4)(b). THESE DATA SHALL MINIMALLY INCLUDE PATIENT AND REFERRING  
541 PHYSICIAN ZIP CODES, NUMBER OF SCANS BY DIAGNOSIS AND/OR RADIOTRACER, NUMBER  
542 OF PEDIATRIC (<18) AND ADULT SCANS, AVERAGE EQUIPMENT TIME BY VISIT TYPE, AS  
543 AVAILABLE, AND NUMBER OF SCANS PERFORMED AS PART OF A RESEARCH STUDY.

544  
545 (10) The agreements and assurances required by this section shall be in the form of a certification  
546 agreed to by the applicant or its authorized agent.

## 547 548 **Section 12. Methodology for computing the projected PET data units**

549  
550 Sec. 12. An applicant being reviewed under Section 3 shall apply the methodology set forth in this  
551 section in computing the projected number of PET data units.

552  
553 (1) Identify the number of diagnosis-specific new cancer cases documented in accordance with the  
554 requirements of Section 13.

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

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

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

565  
566 (2) Identify the number of diagnosis-specific new cancer cases documented in accord with the  
567 requirements of section 13.

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

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

572  
573 (3) Multiply the number of diagnostic cardiac catheterization cases identified in accord with the  
574 requirements of Section 15 by 0.1, which is the estimated probability that a patient having a diagnostic  
575 cardiac catheterization will require a PET scan.

576  
577 (4) Multiply the number of intractable epilepsy cases (ICD-9-CM codes 345.01, 345.11, 345.41,  
578 345.51, 345.61, 345.71, 345.81, or 345.91, see Appendix D for ICD-10-CM Codes) identified in accord  
579 with the requirements of Section 16 by 1.0, which is the estimated probability that a patient having an  
580 intractable epilepsy procedure will require a PET scan. Multiply the number resulting from the calculation

581 in subsection (3) by 1.0, which is the estimated number of PET scans needed for each patient requiring a  
582 PET scan.

583  
584 (5) Sum the numbers resulting from the calculations in subsections (1) through (4) to determine the  
585 total number of projected PET data units.

586  
587 (6) Multiply the result calculated in subsection (5) above by a factor of 3.0 if the applicant is  
588 proposing to serve only planning area 6 to determine the total number of projected PET data units.

589  
590 (7) Multiply the result calculated in subsection (5) above by a factor of 2.0 if the applicant is  
591 proposing to serve only planning area 5 to determine the total number of projected PET data units.

592

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

594

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

597

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

599

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

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

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

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

618

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

621

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

630

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

632

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

643

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

645

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

648

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

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

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

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

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

670

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

673

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

682

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

684

685 Sec. 16. An applicant proposing to use intractable epilepsy cases shall demonstrate all of the  
686 following:  
687

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

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

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

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

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

707  
708 (2) No entity currently operating or approved to operate a scanner shall contribute intractable  
709 epilepsy case data.

710  
711 (3) The Department may not consider a withdrawal of intractable epilepsy case data during the  
712 120-day application review cycle following the date on which the Department review of the application  
713 commences or after a proposed decision to approve the application unless the application is denied,  
714 withdrawn, or expired. The withdrawal must be submitted to the Department in the form of a governing  
715 body resolution that contains the specific CON application number to which the data were originally  
716 committed, the legal applicant entity, the committing entity, the type of data, the date of the meeting in  
717 which the governing body authorized the withdrawal of the data, the governing body president's  
718 signature, and the date of the signature.

719  
720 **Section 17. Methodology for computing PET equivalents**  
721

722 Sec. 17. PET equivalents shall be calculated as follows:  
723

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

724

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

726

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

729

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

731

732       Sec. 19. Proposed projects reviewed under these standards shall not be subject to comparative  
733 review. These CON review standards supersede and replace the CON standards for PET scanner  
734 services approved by the CON Commission on ~~March JUNE 18 11, 2014 2015~~ and effective ~~June~~  
735 ~~SEPTEMBER 214, 20142015.~~

736

**APPENDIX A**

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Counties assigned to each health service area are as follows:

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



**APPENDIX B**

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

**PLANNING AREA 1**

**COUNTIES**

HSA 1	Livingston	Monroe	St. Clair
	Macomb	Oakland	Washtenaw
	Wayne		

**PLANNING AREA 2**

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

**PLANNING AREA 3**

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

**PLANNING AREA 4**

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

**PLANNING AREA 5**

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

**PLANNING AREA 6**

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

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Rural Michigan counties are as follows:

Alcona	Gogebic	Ogemaw
Alger	Huron	Ontonagon
Antrim	Iosco	Osceola
Arenac	Iron	Oscoda
Baraga	Lake	Otsego
Charlevoix	Luce	Presque Isle
Cheboygan	Mackinac	Roscommon
Clare	Manistee	Sanilac
Crawford	Montmorency	Schoolcraft
Emmet	Newaygo	Tuscola
Gladwin	Oceana	

Micropolitan statistical area Michigan counties are as follows:

Allegan	Hillsdale	Mason
Alpena	Houghton	Mecosta
Benzie	Ionia	Menominee
Branch	Isabella	Missaukee
Chippewa	Kalkaska	St. Joseph
Delta	Keweenaw	Shiawassee
Dickinson	Leelanau	Wexford
Grand Traverse	Lenawee	
Gratiot	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	Jackson	Muskegon
Bay	Kalamazoo	Oakland
Berrien	Kent	Ottawa
Calhoun	Lapeer	Saginaw
Cass	Livingston	St. Clair
Clinton	Macomb	Van Buren
Eaton	Midland	Washtenaw
Genesee	Monroe	Wayne
Ingham	Montcalm	

Source:

75 F.R., p. 37245 (June 28, 2010)  
Statistical Policy Office  
Office of Information and Regulatory Affairs  
United States Office of Management and Budget

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**APPENDIX D**

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

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

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**APPENDIX D continued**

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

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

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