

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. ~~(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 for all projects approved and Certificates of Need issued under Part 222 of the Code ~~that involve PET scanner services.~~

~~— (2) PET is a covered clinical service for purposes of PURSUANT TO Part 222 of the Code. A PET scanner previously approved pursuant to Section 10 of these standards and recognized by the Department as a dedicated research PET scanner listed in the Department Inventory of PET Scanners, and now seeking approval to operate pursuant to sections 3, 4, or 5, shall be considered as a person requesting CON approval to initiate or expand, as applicable, a PET scanner service.~~

~~— (3) PET SCANNER SERVICES ARE A COVERED CLINICAL SERVICE.~~ The Department shall use ~~sections 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 16, 17, 18, 19, 20, and 21, as applicable,~~ THESE STANDARDS in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

~~— (4) The Department shall use sections 14 and 15, as applicable, in applying AND Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.~~

~~— (5) The Department shall use Section 13, as applicable, in applying Section 22215(1)(b) of the Code, being Section 333.22215(1)(b) of the Michigan Compiled Laws.~~

Section 2. Definitions

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

~~(a) "Accelerator" means an apparatus, such as a linear accelerator or cyclotron, for accelerating charged particles to high energies by means of electromagnetic fields.~~

~~— (b) "Acquisition of an existing PET scanner" means obtaining possession or control of an existing PET scanner from an existing PET scanner service by contract, ownership, lease, or other comparable arrangement.~~

~~— (c) "Acquisition of an existing PET scanner service" means obtaining possession or control of an existing PET service and its unit(s) by contract, ownership, lease, or other comparable arrangement.~~

~~— (d) "Anatomical site" means the physical area that can be imaged by a single PET scan.~~

~~— (e) "Arterial sampling" means the insertion of an in-dwelling intra-arterial catheter for the withdrawal of arterial blood as part of a PET procedure.~~

~~— (f) "Bed position" means the anatomical site being imaged. A change in bed position occurs when a different anatomical site is imaged and the scan requires the physical relocation of the patient relative to the PET scanner.~~

~~— (g) "Central service coordinator" means the legal entity that has, or will have, operational responsibility for a mobile PET scanner service.~~

~~(h)~~ (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.

~~— (i) "Cyclotron" means an apparatus for accelerating charged particles to high energies by means~~

54 of electromagnetic fields.

55 ~~_____ (j) "Dedicated pediatric PET scanner" means a PET scanner approved pursuant to Section 11 of~~
56 ~~these standards, recognized by the Department as a dedicated pediatric PET scanner listed in the~~
57 ~~Department Inventory of PET Scanners, and is a PET scanner upon which at least 70% of the PET~~
58 ~~procedures are performed on patients under 18 years of age.~~

59 ~~_____ (k) "Dedicated research PET scanner" means a PET scanner approved pursuant to Section 10 of~~
60 ~~these standards and recognized by the Department as a dedicated research PET scanner listed in the~~
61 ~~Department Inventory of PET Scanners. The Department shall modify the Department Inventory of PET~~
62 ~~Scanners as applicable.~~

63 ~~(lC)~~ "Department" means the ~~state agency known as the~~ Michigan Department of Community
64 Health (MDCH).

65 ~~_____ (m) "Department inventory of PET scanners" or "Department Inventory" means the list, maintained~~
66 ~~by the Department on a continuous basis, of: (i) the PET scanners operating pursuant to a valid CON~~
67 ~~issued under Part 222 or former Part 221; (ii) PET scanners that are not yet operational but have a valid~~
68 ~~CON issued under Part 222; (iii) proposed PET scanners under appeal from a final Department decision~~
69 ~~or pending a hearing from a proposed decision issued under Part 222 of the Code; and (iv) proposed~~
70 ~~PET scanners that are part of a completed application under Part 222 of the Code.~~

71 ~~_____ (n) "Dynamic PET scan" means a PET scan that is closely timed to the administration of a~~
72 ~~radiopharmaceutical in order to capture the perfusion of the tracer.~~

73 ~~(oD)~~ "Existing PET scanner" means an ~~CON-approved and~~ operational PET scanner used to
74 provide PET services on the date an application is submitted to the Department.

75 ~~(pE)~~ "Existing PET scanner service" means an ~~CON-approved and~~ operational ~~PET scanner(s)~~
76 ~~SERVICE used to provide~~ providing PET ~~SCANNER~~ services at one site in the case of a fixed PET
77 service or at each host site in the case of a mobile PET service on the date an application is submitted to
78 the Department.

79 ~~_____ (q) "Expand a fixed PET scanner service" means increasing the number of fixed PET scanners at~~
80 ~~the same geographic location of an existing fixed PET scanner service.~~

81 ~~_____ (r) "Expand a mobile PET scanner service" means the addition of a mobile PET scanner that will~~
82 ~~be operated by a central service coordinator in the same planning area in which the CSC is approved~~
83 ~~primarily to operate one or more mobile PET scanners as of the date an application is submitted to the~~
84 ~~Department.~~

85 ~~_____ (s) "FDG" means 2-{fluorine-18} fluoro-2-deoxy-D-glucose radiopharmaceuticals.~~

86 ~~(tF)~~ "Health service area" or "HSA" means the groups of counties listed in ~~Section 22~~APPENDIX A.

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

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

90 ~~_____ (w) "Initiate a mobile PET host site" means the provision of PET services at a host site that has not~~
91 ~~received any approved mobile PET services within 12 months from the date an application is submitted to~~
92 ~~the Department. The term does not include the renewal of a lease for the mobile PET service(s).~~

93 ~~_____ (x) "Initiate a PET scanner service" means begin operation of a PET scanner service, either fixed~~
94 ~~or mobile, at a geographic location that does not offer (or has not offered within the last consecutive 12-~~
95 ~~month period) approved PET scanner services and is not listed on the Department Inventory of PET~~
96 ~~Scanners on the date on which an application is submitted to the Department.~~

97 ~~_____ (y) "Institutional review board" or "IRB" means an institutional review board as defined by Public~~
98 ~~Law 93-348 which is regulated by Title 45 CFR 46.~~

99 ~~(zI)~~ "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C.1396
100 to 1396g and 1396i to 1396u.

101 ~~_____ (aa) "Metropolitan statistical area county" means a county located in a metropolitan statistical area~~
102 ~~as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas"~~
103 ~~by the statistical policy office of the office of information and regulatory affairs of the United States office~~
104 ~~of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.~~

105 ~~(bbJ)~~ "Michigan Inpatient Data Base" or "MIDB" means the data base compiled by the Michigan
106 Health and Hospital Association or successor organization. The data base consists of inpatient

107 discharge records from all Michigan hospitals and Michigan residents discharged from hospitals in border
108 states for a specific calendar year.

109 ~~—(cc) "Micropolitan statistical area county" means a county located in a micropolitan statistical area
110 as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas"
111 by the statistical policy office of the office of information and regulatory affairs of the United States office
112 of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.~~

113 ~~(ddK) "Mobile PET scanner" means a PET scanner unit and transporting equipment operated by a
114 central service coordinator that serves two or more host sites.~~

115 ~~(eeL) "Mobile PET scanner network" means the route (i.e., all host sites) that the central service
116 coordinator is authorized to serve under CON. The mobile PET unit shall operate under a contractual
117 agreement for the provision of PET services on a regularly scheduled basis at each host site, with a
118 minimum of one visit per year.~~

119 ~~—(ff) "Out-state Michigan" means health service areas two (2) through eight (8).~~

120 ~~(ggM) "Patient visit" means a single session lasting no more than one day utilizing a PET scanner
121 during which 1 or more PET procedures are performed.~~

122 ~~(hhN) "Pediatric patient" means any patient less than 18 years of age.~~

123 ~~—(iiO) "PET data unit" means the result of the methodology as used in Section 1712.~~

124 ~~—(jjP) "PET equivalent" means the number calculated in accordance with Section 16 17 for a single
125 patient visit.~~

126 ~~(kkPQO) "PET procedure" means the acquisition of a single image or image sequence involving a single
127 injection of tracer.~~

128 ~~(llQRP) "PET scan" means one (1) or more PET procedures performed during a single patient visit.~~

129 ~~(mmRSQ) "PET scanner" means an FDA-approved full or partial ring scanner or coincidence system
130 that has a crystal at least 5/8-inch thick, techniques to minimize or correct for scatter and/or randoms, and
131 digital detectors and iterative reconstruction. Further, the term does include PET/CT scanner hybrids. If
132 the PET/CT scanner will be used for computed tomography (CT) scans only in conjunction with the PET
133 scan, then no separate CON is required for that CT use. The term does not include single-photon
134 emission computed tomography systems (SPECT), x-ray CT systems, magnetic resonance, ultrasound
135 computed tomographic systems, gamma cameras modified for either non-coincidence or coincidence
136 imaging, or similar technology.~~

137 ~~(nnSTR) "PET scanner services" or "PET services" means either the CON-approved utilization of a PET
138 unit(s) at one site in the case of a fixed PET service or at each host site in the case of a mobile PET
139 service.~~

140 ~~—(ooTU) "Planning area" means the health service area(s), as applicable, and identified in Section.~~

141 ~~—(pp) "Radionuclide generator" means the source of radioactive material, other than an accelerator or
142 nuclear reactor, used to produce radiopharmaceuticals.~~

143 ~~—(qq) "Radiopharmaceutical" means a radioactive pharmaceutical used for diagnostic or therapeutic
144 purposes.~~

145 ~~—(rr) "Relocate a fixed PET scanner" means a change in the location of a fixed PET scanner(s)
146 from the existing site to a different site within the relocation zone.~~

147 ~~—(ss) "Relocate an existing fixed PET scanner service" means a change in the location of a fixed
148 pet scanner service and its unit(s) from the existing site to a different site within the relocation zone.~~

149 ~~—(tt) "Relocation zone" means a proposed site that is within a 10-mile radius of the existing fixed
150 PET scanner service for a metropolitan statistical area county and a 25-mile radius of the existing fixed
151 PET scanner service for a rural or micropolitan statistical area county, based upon documentation
152 acceptable and verified by the Department.~~

153 ~~—(uu) "Replace a PET scanner" means an equipment change, other than an upgrade, involving a
154 PET scanner that results in that applicant operating the same number of PET scanners before and after
155 project completion.~~

156 ~~—(vv) "Rural county" means a county not located in a metropolitan statistical area or micropolitan
157 statistical areas as those terms are defined under the "standards for defining metropolitan and
158 micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of
159 the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as~~

- 160 shown in Appendix A.
- 161 (~~wwwUVS~~) "SPECT" means single photon emission computed tomography.
- 162 —(xx) "Static PET scan" means any PET scan that is not dynamic.
- 163 —(yy) "Tracer" means a radiopharmaceutical developed for use in PET scanner services which allows
- 164 the quantification and/or qualitative images of chemistry, metabolism, and/or perfusion in vivo.
- 165 —(zz) "Transmission scan" means transmission computed tomography using a sealed radioactive
- 166 photon source or x-ray tube photon source applied to the attenuation correction of the emission scan
- 167 data.
- 168 —(aaa) "Upgrade an existing PET scanner" means any equipment change that:
- 169 —(i) does not involve a change in, or replacement of, the scanner;
- 170 —(ii) does not result in an increase in the number of PET scanners;
- 171 —(iii) does not result in a change in the type of PET scanner (e.g., changing a mobile PET scanner to
- 172 a fixed PET scanner) or a change in manufacturer; and
- 173 —(iv) involves a capital expenditure of less than \$500,000 in any consecutive 24-month period.

174

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

176

177 **Section 3. Requirements ~~for approval for all fixed services and mobile host sites~~ TO INITIATE A**

178 **PET SCANNER SERVICE**

179

180 Sec. 3. ~~(1)~~ An applicant proposing to ~~provide~~ INITIATE PET scanner services shall ~~provide~~

181 DEMONSTRATE the following ~~services and medical specialties, AS APPLICABLE TO THE PROPOSED~~

182 PROJECT:

183

184 (1) THE APPLICANT SHALL DEMONSTRATE THE PROPOSED SITE PROVIDES THE

185 FOLLOWING SERVICES AND SPECIALTIES:

- 186 (a) nuclear medicine services AS DOCUMENTED BY A CERTIFICATE FROM THE US NUCLEAR
- 187 REGULATORY COMMISSION, ~~as documented on the certificate issued by the Department of~~
- 188 Environmental Quality,
- 189 (b) single photon emission computed tomography (SPECT) services,
- 190 (c) computed tomography (CT) scanning services,
- 191 (d) magnetic resonance imaging (MRI) services,
- 192 (e) cardiac catheterization services,
- 193 (f) open heart surgery,
- 194 (g) thoracic surgery,
- 195 (h) cardiology,
- 196 (i) oncology,
- 197 (j) radiation oncology,
- 198 (k) neurology,
- 199 (l) neurosurgery, and
- 200 (m) psychiatry.
- 201

202 (2) If the applicant PROPOSED SITE does not provide any of the services listed in this subsection

203 (1) at the same site at which the proposed PET scanner service will be located ON-SITE, the applicant

204 shall include in the application PROVIDE written contracts or agreements with a hospital(s) located within

205 the same planning area OR 25-MILES RADIUS OF THE PROPOSED SITE for the services not provided

206 at the proposed PET scanner service site.

207

208 (3) THE APPLICANT SHALL DEMONSTRATE THE PROPOSED SITE HAS AN ON-SITE

209 SOURCE OF RADIOPHARMACEUTICALS.

210

211 ~~(24)~~ If ~~a~~ THE proposed ~~PET scanner service~~ SITE does not ~~involve~~ PROVIDE an on-site source of

212 radiopharmaceuticals, ~~an~~ THE applicant ~~must~~ SHALL provide ~~in the application~~ a written contract or

213 agreement that demonstrates ~~that~~ a reliable supply of radiopharmaceuticals ~~will be available to the~~
214 ~~proposed PET scanner service.~~

215
216 (54) AN APPLICANT PROPOSING TO INITIATE A FIXED PET SCANNER SERVICE WITH ITS
217 FIRST PET SCANNER SHALL PROJECT 2,600 PET DATA UNITS OR SHALL DEMONSTRATE ALL
218 OF THE FOLLOWING:

219 (A) THE APPLICANT IS CURRENTLY A HOST SITE BEING SERVED BY ONE OR MORE
220 MOBILE PET SCANNER SERVICES.

221 (B) THE APPLICANT HAS PERFORMED:

222 (I) 1,700 PET EQUIVALENTS IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY
223 THE DEPARTMENT FOR A HOST SITE IN A METROPOLITAN STATISTICAL AREA COUNTY, OR

224 (II) 1,500 PET EQUIVALENTS IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY
225 THE DEPARTMENT FOR A HOST SITE IN A RURAL OR MICROPOLITAN STATISTICAL AREA
226 COUNTY.

227 (C) THE APPLICANT AGREES TO CEASE OPERATION AS A HOST SITE AND NOT BECOME A
228 HOST SITE FOR AT LEAST 12 MONTHS FROM THE DATE THE FIXED PET SCANNER BECOMES
229 OPERATIONAL.

230
231 (65) AN APPLICANT PROPOSING TO INITIATE A MOBILE PET SCANNER SERVICE WITH ITS
232 FIRST MOBILE PET SCANNER SHALL PROJECT 2,100 PET DATA UNITS.

233 (A) OF THE 2,100 PET DATA UNITS, THE APPLICANT SHALL PROJECT A MINIMUM OF 360
234 PET DATA UNITS WITHIN A 20-MILE RADIUS OF EACH PROPOSED HOST SITE FOR PLANNING
235 AREA 1, OR 240 PET DATA UNITS PER HOST SITE FOR ANY OTHER PLANNING AREA, FOR THE
236 PROPOSED SERVICE.

237 (B) THE APPLICATION FOR THE MOBILE PET SCANNER SERVICE IS ACCOMPANIED BY AT
238 LEAST TWO HOST SITE APPLICATIONS.

239 (C) EACH APPLICANT PROVIDES A ROUTE SCHEDULE FOR THE PROPOSED MOBILE PET
240 SCANNER SERVICE.

241 (D) THE APPLICANT PROVIDES A DRAFT CONTRACT FOR SERVICES BETWEEN THE
242 PROPOSED HOST SITE AND CENTRAL SERVICE COORDINATOR.

243
244 (76) AN APPLICANT PROPOSING TO INITIATE A HOST SITE ON A PROPOSED OR EXISTING
245 MOBILE PET SCANNER SERVICE SHALL DEMONSTRATE THE FOLLOWING:

246 (A) THE APPLICANT PROVIDES A PROPOSED ROUTE SCHEDULE.

247 (B) THE APPLICANT PROVIDES A DRAFT CONTRACT FOR SERVICES BETWEEN THE
248 PROPOSED HOST SITE AND CENTRAL SERVICE COORDINATOR.

249 (C) THE APPLICANT HAS NOT INITIATED FIXED PET SCANNER SERVICES UNDER
250 SUBSECTION 3(54) WITHIN THE MOST RECENT 12-MONTH PERIOD AS OF THE DATE THE
251 APPLICATION IS SUBMITTED TO THE DEPARTMENT.

252 (D) AN APPLICANT INITIATING A HOST SITE IN HSA 8 ON A MOBILE PET SCANNER
253 SERVICE THAT OPERATES PREDOMINANTLY OUTSIDE OF MICHIGAN SHALL DEMONSTRATE
254 240 PET DATA UNITS FROM PLANNING AREA 6.

255
256 (87) AN APPLICANT PROPOSING TO INITIATE PET SCANNER SERVICES AS AN EXISTING
257 HOST SITE ON A DIFFERENT MOBILE PET SCANNER SERVICE SHALL DEMONSTRATE THE
258 FOLLOWING:

259 (A) THE APPLICANT PROVIDES A PROPOSED ROUTE SCHEDULE.

260 (B) THE APPLICANT PROVIDES A DRAFT CONTRACT FOR SERVICES BETWEEN THE
261 PROPOSED HOST SITE AND CENTRAL SERVICE COORDINATOR.

262 (C) 50 PET EQUIVALENTS WERE PERFORMED IN THE MOST RECENT 12-MONTH PERIOD
263 VERIFIABLE BY THE DEPARTMENT FROM AN EXISTING MOBILE PET SCANNER SERVICE AT THE
264 FOR AN EXISTING HOST SITE.

266 **Section 4. Requirements for approval for applicants proposing to initiate TO REPLACE AN**
267 **EXISTING PET scanner-service(S) OR PET SCANNER SERVICE**

268
269 Sec. 4. REPLACING A PET SCANNER(S) MEANS A CHANGE IN THE SCANNER EQUIPMENT
270 OR RELOCATION OF THE SERVICE TO A NEW SITE. AN UPGRADE TO SOFTWARE OR
271 COMPONENTS OF AN EXISTING SCANNER DOES NOT CONSTITUTE REPLACEMENT OF A PET
272 SCANNER. AN APPLICANT PROPOSING TO REPLACE AN EXISTING PET SCANNER(S) OR PET
273 SCANNER SERVICE SHALL DEMONSTRATE THE FOLLOWING, AS APPLICABLE TO THE
274 PROPOSED PROJECT. (1) An applicant proposing to initiate a fixed PET scanner(S) service shall project
275 an operating level of at least 2,600 PET data units for each proposed PET scanner based on the
276 methodology used in Section 17.

277
278 (2) An applicant proposing to REPLACE a PET scanner(S) shall DEMONSTRATE EACH OF THE
279 FOLLOWING. An applicant proposing to initiate a mobile PET scanner service shall project 2,100 PET
280 data units for each proposed mobile PET scanner based on the methodology used in Section 17:

281 (a) Of the 2,100 PET data units, the applicant(s) shall project a minimum of 360 PET data units,
282 within the same planning area and a 20-mile radius of the proposed host site, for each proposed PET
283 scanner service site located in a planning area that does not include any rural or micropolitan statistical
284 area counties and a minimum of 240 PET data units, within the same planning area as the proposed host
285 site, for each PET scanner service site located in a planning area that includes any rural or micropolitan
286 statistical area counties. THE REPLACEMENT SCANNER(S) IS THE SAME TYPE (FIXED OR MOBILE)
287 AS THE SCANNER(S) TO BE REPLACED.

288 (b) The requirements of subsection (2) shall not apply to an applicant that proposes to add a
289 Michigan site as a host site if the applicant, the central service coordinator, demonstrates that the mobile
290 PET scanner service operates predominantly outside of Michigan and that all of the following
291 requirements are met THE SCANNER(S) TO BE REPLACED IS FULLY DEPRECIATED ACCORDING
292 TO GENERALLY ACCEPTED ACCOUNTING PRINCIPLES OR EITHER OF THE FOLLOWING:

293 (i) The proposed host site will be located in HSA 8 EXISTING SCANNER(S) POSES A THREAT
294 TO THE SAFETY OF THE PATIENTS.

295 (ii) The proposed host site in HSA 8 demonstrates a minimum of 240 PET data units based on the
296 methodology in Section 17 REPLACEMENT SCANNER(S) OFFERS TECHNOLOGICAL
297 IMPROVEMENTS THAT ENHANCE QUALITY OF CARE, INCREASE EFFICIENCY, AND REDUCE
298 OPERATING COSTS AND PATIENT CHARGES.

299 (3C) Initiation of a mobile PET host site does not include the provision of mobile PET services at a
300 host site if the applicant, whether the host site or the central service coordinator, demonstrates or
301 provides, as applicable, each of the following: THE APPLICANT AGREES THAT THE PET SCANNER(S)
302 TO BE REPLACED WILL BE REMOVED FROM SERVICE ON OR BEFORE BEGINNING OPERATION
303 OF THE REPLACEMENT SCANNER(S).

304
305 (a2) The host site has received mobile PET services from an existing approved mobile PET unit
306 within the most recent 12-month period as of the date the application is submitted to the Department. AN
307 APPLICANT PROPOSING TO REPLACE A FIXED PET SCANNER SERVICE TO A NEW SITE SHALL
308 DEMONSTRATE THE FOLLOWING:-:

309 (bA) The addition of a host site to a mobile PET scanner service will not increase the number of PET
310 units operated by the central service coordinator or by any other person, PROPOSED SITE IS WITHIN A
311 10-MILE RADIUS OF THE EXISTING SITE FOR A METROPOLITAN STATISTICAL AREA COUNTY OR
312 A 25-MILE RADIUS FOR A RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY.

313 (cB) The application is submitted to the Department prior to the provision of PET services on that
314 network EXISTING FIXED PET SCANNER(S) PERFORMED 500 PET EQUIVALENTS PER FIXED
315 SCANNER IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE DEPARTMENT.

316 (dC) A signed certification whereby the host site has agreed and assured that it will provide PET
317 services in accordance with the terms for approval set forth in Section 14 and 15. The applicant also
318 shall provide a current route schedule for the mobile PET scanner service THE EXISTING FIXED PET

319 SCANNER SERVICE HAS BEEN IN OPERATION FOR AT LEAST 36 MONTHS AS OF THE DATE OF
320 THE APPLICATION SUBMITTED TO THE DEPARTMENT.

321 ~~— (e) The central service coordinator requires, as a condition of any contract with each host site,~~
322 ~~compliance with the requirements of these standards by that host site, and the central service coordinator~~
323 ~~assures compliance, by that host site, as a condition of the CON issued to the central service coordinator.~~

324 ~~— (f) An applicant, whether a central service coordinator or a proposed host site, proposing to initiate~~
325 ~~a mobile PET host site to an existing mobile PET network or a mobile PET network that has been applied~~
326 ~~for under Section 5(3), shall not be required to demonstrate a minimum number of PET data units.~~

327
328 ~~— (4) An applicant that meets all of the following requirements shall not be required to be in~~
329 ~~compliance with subsection (1):~~

330 ~~— (a) The applicant is proposing to initiate a fixed PET scanner service.~~

331 ~~— (b) The applicant is currently a host site being served by one or more mobile PET scanners.~~

332 ~~— (c) The applicant has received, in aggregate, the following:~~

333 ~~— (i) At least 4,500 PET equivalents, for an applicant in a metropolitan statistical area county, during~~
334 ~~the most recent 12-month period for which the Department has verifiable data.~~

335 ~~— (ii) At least 4,000 PET equivalents, for an applicant in a rural or micropolitan statistical area~~
336 ~~county, during the most recent 12-month period for which the Department has verifiable data.~~

337 ~~— (d) The applicant shall install the fixed PET unit at the same site as the existing approved host site.~~

338 ~~— (e) The applicant shall cease operation as a host site and not become a host site for at least 12~~
339 ~~months from the date the fixed PET scanner, including any temporary scanner used during the transition~~
340 ~~from mobile to fixed, becomes operational.~~

341
342 **Section 5. Requirements ~~for approval for applicants proposing to expand a PET scanner service~~**

343
344 ~~Sec. 5. (1) An applicant proposing to increase EXPAND A the number of fixed PET scanner SERVICE~~
345 ~~(second, third, etc.) shall demonstrate the following, AS APPLICABLE TO THE PROPOSED PROJECT.:~~
346 ~~THIS SECTION DOES NOT APPLY TO DEDICATED RESEARCH, DEDICATED PEDIATRIC, OR~~
347 ~~POSITRON EMISSION MAMMOGRAPHY (PEM) SCANNERS.~~

348
349
350 ~~(a1) For aAn applicant in a metropolitan statistical area county, all of the applicant's approved fixed~~
351 ~~PET scanners have performed an average of at least 5,500 PET equivalents per PET scanner during the~~
352 ~~most recent 12-month period for which the Department has verifiable data. PROPOSING TO ADD A~~
353 ~~FIXED PET SCANNER(S) TO AN EXISTING FIXED PET SCANNER SERVICE SHALL DEMONSTRATE~~
354 ~~THE FOLLOWING.:~~

355 ~~(bA) For an applicant in a rural or micropolitan statistical area county, all of the applicant's approved~~
356 ~~fixed pet scanners have performed an average of at least 5,000 pet equivalents per pet scanner~~
357 ~~during 1,900 PET EQUIVALENTS WERE PERFORMED PER EXISTING AND APPROVED FIXED PET~~
358 ~~SCANNER(S) IN the most recent 12-month period for which the department has verifiable~~
359 ~~data. VERIFIABLE BY THE DEPARTMENT FOR AN APPLICANT IN A METROPOLITAN STATISTICAL~~
360 ~~AREA COUNTY, OR~~

361 ~~(B) 1,700 PET EQUIVALENTS WERE PERFORMED PER EXISTING AND APPROVED FIXED~~
362 ~~PET SCANNER(S) IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE DEPARTMENT~~
363 ~~FOR AN APPLICANT IN A RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY.~~

364 ~~(c) In the case of a fixed PET scanner service, the additional PET scanner shall be located at the~~
365 ~~same geographic location as the existing fixed PET scanner service unless the applicant meets the~~
366 ~~applicable requirements for relocation in accordance with Section 9. THE ADDITIONAL PET~~
367 ~~SCANNER(S) SHALL BE LOCATED AT THE SAME SITE.~~

368
369 ~~(2) An applicant proposing to increase ADD the number of A mobile PET scanner(s) TO AN~~
370 ~~EXISTING MOBILE PET SCANNER SERVICE (second, third, etc.) shall demonstrate the following:~~

371 ~~(a) 2,000 PET EQUIVALENTS WERE PERFORMED PER EXISTING AND APPROVED MOBILE~~

372 SCANNER(S)

373 ~~For an applicant serving at least one existing host site in a metropolitan statistical area county, all of the~~
374 ~~applicant's approved mobile PET scanners on a mobile route have performed an average of at least~~
375 ~~5,000 PET equivalents per PET scanner during IN the most recent 12-month period VERIFIABLE BY for~~
376 ~~which the Department has verifiable data. FOR AN APPLICANT SERVING AT LEAST ONE EXISTING~~
377 ~~HOST SITE IN A METROPOLITAN STATISTICAL AREA COUNTY, OR~~

378 ~~(b) 1,800 PET EQUIVALENTS WERE PERFORMED PER EXISTING AND APPROVED~~
379 ~~SCANNER(S). For an applicant serving only host sites in rural or micropolitan statistical area counties, all~~
380 ~~of the applicant's approved mobile PET scanners on a mobile route have performed an average of at~~
381 ~~least 4,500 PET equivalents per PET scanner during IN the most recent 12-month period VERIFIABLE~~
382 ~~for which BY the Department has verifiable data. FOR AN APPLICANT SERVING ONLY HOST SITES IN~~
383 ~~RURAL OR MICROPOLITAN STATISTICAL AREA COUNTIES.~~

384
385 ~~(3) An applicant PROPOSING TO ADD A FIXED PET SCANNER TO AN EXISTING FIXED PET~~
386 ~~SCANNER SERVICE that meets ALSO RECEIVES MOBILE PET SCANNER SERVICES SHALL~~
387 ~~DEMONSTRATE all of the following requirements shall not be required to be in compliance with~~
388 ~~subsection (1):~~

389 ~~(a) The applicant is proposing CURRENTLY A HOST SITE BEING SERVED BY ONE OR MORE~~
390 ~~to initiate a mobile PET scanner services.~~

391 ~~(b) The applicant is currently a fixed PET scanner service HAS PERFORMED:~~

392 ~~(c) The applicant has demonstrated the following: AN AVERAGE OF 1,900 PET EQUIVALENTS~~
393 ~~FOR THE HOST SITE AND EACH OF THE EXISTING AND APPROVED FIXED SCANNER IN THE~~
394 ~~MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE DEPARTMENT FOR A HOST SITE IN A~~
395 ~~METROPOLITAN STATISTICAL AREA COUNTY, OR~~

396 ~~(i) For a An applicant in a metropolitan statistical area county, all of the applicant's approved fixed~~
397 ~~AVERAGE OF 1,700 PET scanners EQUIVALENTS have performed an average of at least 5,500 PET~~
398 ~~equivalents FOR THE HOST SITE AND EACH OF THE EXISTING AND APPROVED FIXED per PET~~
399 ~~scanners scanners during IN the most recent 12-month period for which VERIFIABLE BY the Department~~
400 ~~has verifiable data FOR A HOST SITE IN A RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY.~~

401 ~~_____ (ii) For an applicant in a rural or micropolitan statistical area county, all of the applicant's approved~~
402 ~~fixed PET scanners have performed an average of at least 5,000 PET equivalents per PET scanner~~
403 ~~during the most recent 12-month period for which the Department has verifiable data. _____~~

404 ~~_____ (d) At least two (2) separate CON applications have been submitted simultaneously as host sites~~
405 ~~for the proposed mobile PET service, subject to Section 4(3).~~

406 ~~_____ (e) A proposed regular route schedule, the procedures for handling emergency situations, and~~
407 ~~copies of all proposed contracts related to the mobile PET service have been included in the CON~~
408 ~~application.~~

409 ~~_____ (f) The requirements of Section 3 have been met.~~

410 ~~_____ (g) The applicant agrees to comply with sections (13) and (14).~~

411 ~~_____ (h) The mobile unit must operate within the same planning area and comply with Section 4(2)(a).~~

412 ~~(C) THE APPLICANT AGREES TO CEASE OPERATION AS A HOST SITE AND NOT BECOME A~~
413 ~~HOST SITE FOR AT LEAST 12 MONTHS FROM THE DATE THE FIXED SCANNER BECOMES~~
414 ~~OPERATIONAL.~~

415
416
417 **Section 6. Requirements for approval for applicants proposing to replace ACQUIRE a PET**
418 **scanner SERVICE OR SCANNER(S)**

419
420 ~~Sec. 6. (1) An applicant proposing to replace an existing fixed ACQUIRING A PET SCANNER~~
421 ~~SERVICE AND ITS scanner(s) MEANS OBTAINING POSSESSION AND CONTROL BY CONTRACT,~~
422 ~~OWNERSHIP, LEASE, OR OTHER COMPARABLE ARRANGEMENT AND RENEWAL OF LEASE FOR~~
423 ~~AN EXISTING shall demonstrate that all of the applicant's approved and operating fixed OR MOBILE~~
424 ~~PET scanners. AN APPLICANT PROPOSING TO ACQUIRE A have performed an average of at least~~

425 ~~4,500 PET SCANNER SERVICE equivalents SHALL DEMONSTRATE THE FOLLOWING, AS~~
426 ~~APPLICABLE TO THE PROPOSED PROJECT per PET scanner during the most recent 12-month period~~
427 ~~for which the Department has verifiable data.~~

428
429 ~~(21) FOR THE FIRST An applicant APPLICATION proposing to replace ACQUIRE an existing~~
430 ~~FIXED, mobile, OR HOST SITE PET scanner(s) SERVICE, OTHER THAN A RENEWAL OF LEASE,~~
431 ~~shall demonstrate that all of the applicant's approved and operating mobile PET scanners on OR AFTER~~
432 ~~<INSERT EFFECTIVE DATE OF STANDARDS>, THE EXISTING-a mobile route have performed an~~
433 ~~average of at least 3,000 PET equivalents per PET scanner SERVICE AND ITS SCANNER(S) SHALL~~
434 ~~NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE APPLICABLE VOLUME REQUIREMENTS~~
435 ~~SET FORTH IN THIS SECTION during the most recent 12-month period for which the Department has~~
436 ~~verifiable data.~~

437
438 ~~(32) An exemption APPLICANT to subsections (1) and (2) may be made by the Department, if an~~
439 ~~applicant demonstrates to the satisfaction of the Department, the following: PROPOSING TO ACQUIRE~~
440 ~~AN EXISTING FIXED OR MOBILE PET SCANNER SERVICE SHALL DEMONSTRATE THAT THE~~
441 ~~EXISTING FIXED OR MOBILE SCANNER(S) PERFORMED AN AVERAGE OF 500 PET~~
442 ~~EQUIVALENTS PER SCANNER IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE~~
443 ~~DEPARTMENT.~~

444
445 ~~(a3) The existing PET scanner is technologically incapable of performing the applicable minimum~~
446 ~~number of PET equivalents. An applicant proposing a TO replacement ACQUIRE AN EXISTING HOST~~
447 ~~SITE under this subsection shall provide documentation DEMONSTRATE, satisfactory to THAT the~~
448 ~~Department, from a person or an organization with recognized professional expertise regarding that type~~
449 ~~of equipment, other than the applicant or a representative of a manufacturer or vendor of that type of~~
450 ~~equipment, indicating the number of PET equivalents the existing HOST SITE HAS equipment is~~
451 ~~technologically capable of performing PERFORMED: 50 PET EQUIVALENTS The applicant also shall~~
452 ~~provide documentation, satisfactory to the Department, that the number of PET equivalents performed~~
453 ~~during IN the most recent 12-month period, for which VERIFIABLE BY the Department has verifiable~~
454 ~~data, was the number the equipment is technologically capable of performing.~~

455
456 ~~(4) An applicant proposing to RENEW A LEASE FOR AN EXISTING FIXED OR MOBILE replace a~~
457 ~~PET scanner(s), whether fixed or mobile, shall demonstrate THAT THE RENEWAL OF THE LEASE IS~~
458 ~~MORE COST EFFECTIVE THAN REPLACING THE SCANNER(S).~~

459 ~~— (a) the equipment to be replaced is fully depreciated according to generally accepted accounting~~
460 ~~principles or~~

461 ~~— (b) either of the following:~~

462 ~~— (i) the existing equipment clearly poses a threat to the safety of the public and the applicant's staff~~
463 ~~as determined by the Department or other qualified agency or individual (physicist, US Department of~~
464 ~~Energy, applicant's radiation safety committee, etc.) or~~

465 ~~— (ii) the proposed replacement PET scanner(s) offers technological improvements that enhance~~
466 ~~quality of care, increase efficiency, and reduce operating costs and patient charges.~~

467
468 ~~— (5) An applicant that meets all of the following requirements shall not be required to be in~~
469 ~~compliance with subsections (1), (2), (3) and (4):~~

470 ~~— (a) The existing PET scanner became operational before January 1, 2005 and is not PET/CT~~
471 ~~scanner hybrid.~~

472 ~~— (b) The proposed PET scanner is a PET/CT scanner hybrid.~~

473
474 ~~— (6) In the case of a fixed PET scanner, the proposed PET scanner will be located at the same site~~
475 ~~as the applicant's existing fixed PET scanner to be replaced. If the proposed scanner will not be located~~
476 ~~at the same site, the applicant must meet the requirements to relocate a PET scanner at the proposed~~
477 ~~site, in accordance with Section 9.~~

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Section 7. Requirements for approval for applicants proposing to acquire an existing DEDICATED RESEARCH FIXED PET scanner

Sec. 7. An applicant proposing to ~~acquire~~ ADD an existing FIXED PET scanner, ~~whether fixed or mobile, scanner~~ TO AN EXISTING PET SCANNER SERVICE FOR EXCLUSIVE RESEARCH USE shall demonstrate ~~that it meets all of the following~~ THE FOLLOWING:

(1) THE APPLICANT AGREES THAT THE DEDICATED RESEARCH PET SCANNER WILL BE USED PRIMARILY (70% OR MORE OF THE SCANS) FOR RESEARCH PURPOSES ONLY.

(a2) The project is limited solely to the acquisition of an existing DEDICATED RESEARCH PET scanner SHALL OPERATE UNDER A PROTOCOL APPROVED BY THE APPLICANT'S INSTITUTIONAL REVIEW BOARD, AS DEFINED BY PUBLIC LAW 93-348 AND REGULATED BY TITLE 45 CFR 46.

(b3) The project APPLICANT HAS ACCESS TO A CYCLOTRON FOR ACCELERATING CHARGED PARTICLES TO HIGH ENERGIES BY MEANS will not change the number of PET scanners listed on the Department Inventory of PET Scanners ELECTROMAGNETIC FIELDS.

(e4) The project PROPOSED SITE CAN HAVE NO MORE THAN THREE DEDICATED RESEARCH FIXED will not result in the replacement of the PET scanners scanners APPROVED UNDER THIS to be acquired unless the applicant demonstrates that the requirements of Section 6 also have been met.

(d) The PET scanner to be acquired is listed on the Department Inventory of PET Scanners on the date the application is submitted to the Department.

(e) The applicant agrees to operate the PET scanner in accordance with all applicable project delivery requirements set forth in Section 14 of these standards.

Section 8. Requirements for approval for applicants proposing to acquire an existing A DEDICATED PEDIATRIC PET scanner service

Sec. 8. An applicant proposing to ~~acquire~~ INITIATE an existing A PET scanner service, ~~whether OR ADD A fixed~~ PET SCANNER TO EXPAND AN EXISTING PET SCANNER SERVICE, FOR DEDICATED PEDIATRIC PET USE ~~or mobile,~~ shall demonstrate that it meets all of the DEMONSTRATE THE following:

(a1) The project APPLICANT AGREES THAT THE DEDICATED PEDIATRIC is limited solely to the acquisition of an existing PET scanner servicescanner WILL BE USED PRIMARILY (70% OR MORE OF THE SCANS) FOR PATIENTS UNDER 18 YEARS OF AGE.

(b2) The project APPLICANT SHALL DEMONSTRATE will not change the number EXISTING SITE of Pet scanners PROVIDED listed on the FOLLOWING FOR THE MOST RECENT CALENDAR YEAR OR A CONTINUOUS 12-MONTH PERIOD AT THE TIME THE APPLICATION IS SUBMITTED TO THE Department Inventory of PET Scanners.:

(eA) AT LEAST 7,000 PEDIATRIC (< 18 YEARS OLD) DISCHARGES, EXCLUDING NORMAL NEWBORNS, The project will not result in the replacement of the PET scanners to be acquired unless the applicant demonstrates that the requirements of Section 6 also have been met.

(eB) AT LEAST 5,000 PEDIATRIC (< 18 YEARS OLD) SURGERIES, All PET scanners to be acquired are listed on the Department Inventory of PET Scanners on the date the application is submitted to the Department. AND

531 ~~(eC) AT LEAST 50 NEW PEDIATRIC CANCER CASES ON ITS CANCER REGISTRY~~The applicant
532 ~~agrees to operate the PET scanner service in accordance with all applicable project delivery~~
533 ~~requirements set forth in Section 14.~~

534
535 (3) THE APPLICANT SHALL HAVE AN ACTIVE MEDICAL STAFF AT THE TIME THE
536 APPLICATION IS SUBMITTED TO THE DEPARTMENT THAT INCLUDES PHYSICIANS WHO ARE
537 FELLOWSHIP-TRAINED IN THE FOLLOWING PEDIATRIC SPECIALTIES:

538 (A) RADIOLOGY (AT LEAST TWO STAFF MEMBERS)

539 (B) ANESTHESIOLOGY

540 (C) CARDIOLOGY

541 (D) CRITICAL CARE

542 (E) GASTROENTEROLOGY

543 (F) HEMATOLOGY/ONCOLOGY

544 (G) NEUROLOGY

545 (H) NEUROSURGERY

546 (I) ORTHOPEDIC SURGERY

547 (J) PATHOLOGY

548 (K) PULMONOLOGY

549 (L) SURGERY

550 (M) NEONATOLOGY

551
552 (4) THE APPLICANT SHALL HAVE IN OPERATION THE FOLLOWING PEDIATRIC SPECIALTY
553 PROGRAMS AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT:

554
555 (A) BONE MARROW TRANSPLANT PROGRAM

556 (B) SEDATION PROGRAM

557 (C) OPEN HEART PROGRAM

558
559 (5) THE APPLICANT MEETS THE REQUIREMENTS OF SECTION 3(1) THROUGH 3(4) IF THE
560 APPLICANT IS INITIATING A PET SCANNER SERVICE WITH A DEDICATED PEDIATRIC FIXED PET
561 SCANNER.

562
563 (6) THE PROPOSED SITE CAN HAVE NO MORE THAN TWO DEDICATED PEDIATRIC FIXED
564 PET SCANNERS APPROVED UNDER THIS SECTION.

565
566 **Section 9. Requirements for ~~approval for applicants proposing to relocate an existing PET A~~**
567 **~~POSITRON EMISSION MAMMOGRAPHY (PEM) scanner service or its unit(s)~~**

568
569 Sec. 9. AN APPLICANT PROPOSING TO ADD A PEM SCANNER SERVICE TO AN EXISTING
570 PET SCANNER SERVICE SHALL DEMONSTRATE THE FOLLOWING, AS APPLICABLE TO THE
571 PROPOSED PROJECT:

572
573 (1) AN APPLICANT PROPOSING TO ADD A FIXED PEM SCANNER TO AN EXISTING FIXED
574 PET SCANNER SITE SHALL DEMONSTRATE THE FOLLOWING:

575 (A) THE APPLICANT IS CERTIFIED THROUGH THE AMERICAN COLLEGE OF RADIOLOGY
576 (ACR) AS A BREAST IMAGING CENTER OF EXCELLENCE (BICOE) AT THE TIME THE
577 APPLICATION IS SUBMITTED TO THE DEPARTMENT.

578 (B) THE APPLICANT HAS PERFORMED 1,000 PET EQUIVALENTS PER SCANNER AT THE
579 SITE IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE DEPARTMENT, OR THE
580 APPLICANT OPERATES A COMPREHENSIVE CANCER CENTER RECOGNIZED BY THE NATIONAL
581 CANCER INSTITUTE.

582 (C) THE PROPOSED SITE CAN HAVE NO MORE THAN ONE FIXED PEM SCANNER
583 APPROVED UNDER THIS SECTION.

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(2) AN APPLICANT PROPOSING TO ADD A MOBILE PEM SCANNER TO AN EXISTING MOBILE PET SCANNER SERVICE SHALL DEMONSTRATES THE FOLLOWING:

(A) THE CENTRAL SERVICE COORDINATOR APPLICATION FOR A MOBILE PEM SCANNER SHALL BE ACCOMPANIED BY AT LEAST FIVE (5) COMPANION HOST SITE APPLICATIONS FOR INITIATION OF MOBILE PEM SCANNER SERVICES. THE PROPOSED HOST SITES HAVE NOT RECEIVED MOBILE PEM SCANNER SERVICES WITHIN THE MOST RECENT 12-MONTH PERIOD.

(B) THE APPLICANT HAS PERFORMED AN AVERAGE OF 500 PET EQUIVALENTS PER SCANNER ON THE EXISTING MOBILE PET NETWORK IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE DEPARTMENT.

(C) THE APPLICANT PROVIDES A ROUTE SCHEDULE FOR THE PROPOSED MOBILE PEM SCANNER SERVICE.

(D) THE APPLICANT PROVIDES A DRAFT CONTRACT FOR PEM SERVICES BETWEEN THE PROPOSED HOST SITES AND CENTRAL SERVICE COORDINATOR.

(E) THE PROPOSED NETWORK CAN HAVE NO MORE THAN ONE MOBILE PEM SCANNER APPROVED UNDER THIS SECTION.

(3) AN APPLICANT, WHETHER AN EXISTING FIXED PET SCANNER SITE OR HOST SITE, PROPOSING TO INITIATE MOBILE PEM SCANNER SERVICES AS A HOST SITE SHALL DEMONSTRATE THE FOLLOWING-:

(A) THE APPLICANT IS CERTIFIED THROUGH THE ACR AS A BICOE SITE AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(B) THE APPLICANT HAS PERFORMED 100 PET EQUIVALENTS IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE DEPARTMENT, OR THE APPLICANT OPERATES A COMPREHENSIVE CANCER CENTER RECOGNIZED BY THE NATIONAL CANCER INSTITUTE.

(C) THE APPLICANT PROVIDES A PROPOSED ROUTE SCHEDULE FOR THE MOBILE PEM SCANNER SERVICE.

(D) THE APPLICANT PROVIDES A DRAFT CONTRACT FOR PEM SERVICES BETWEEN THE HOST SITE AND CENTRAL SERVICE COORDINATOR.

(4) AN APPLICANT PROPOSING TO ADD AN EXISTING PEM SCANNER HOST SITE TO AN EXISTING MOBILE PEM SCANNER SERVICE SHALL DEMONSTRATE THE FOLLOWING:

(A) THE HOST SITE HAS PERFORMED MOBILE PEM SCANNER SERVICE WITHIN THE MOST RECENT 12-MONTH PERIOD AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(B) THE PROPOSED SITE IS CERTIFIED THROUGH THE ACR AS A BICOE SITE AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(C) THE APPLICANT PROVIDES A PROPOSED ROUTE SCHEDULE FOR THE MOBILE PEM SCANNER SERVICE.

(D) THE APPLICANT PROVIDES A DRAFT CONTRACT FOR PEM SERVICES BETWEEN THE HOST SITE AND CENTRAL SERVICE COORDINATOR.

~~(1) An applicant proposing to relocate an existing fixed PET service and all its existing unit(s) shall demonstrate that it meets all of the following:~~

~~_____ (a) The service and all its existing units to be relocated are fixed PET scanners._____~~

~~_____ (b) The existing fixed PET service to be relocated has been in operation for at least 36 months as of the date of the application submitted to the Department.~~

~~_____ (c) The proposed new site of the existing PET service to be relocated is in the relocation zone.~~

~~_____ (d) The proposed project will not result in an increase in the number of PET scanner(s) operated by the applicant at the proposed site unless the applicant demonstrates that the requirements of Section 5, as applicable, have also been met.~~

~~_____ (e) The proposed project will not result in the replacement of the PET scanner(s) of the service to be relocated unless the applicant demonstrates that the requirements of Section 6, as applicable, have also been met.~~

637 ~~_____ (f) The applicant agrees to operate the PET service and all its units in accordance with all~~
638 ~~applicable project delivery requirements set forth in Section 15 of these standards.~~

639
640 ~~_____ (2) An applicant proposing to relocate a PET scanner of an existing PET service shall demonstrate~~
641 ~~that it meets all of the following:~~

642 ~~_____ (a) The PET scanner to be relocated is a fixed PET scanner.~~

643 ~~_____ (b) The existing fixed PET service from which the PET scanner is to be relocated has been in~~
644 ~~operation for at least 36 months as of the date of the application submitted to the Department.~~

645 ~~_____ (c) The proposed new site for the PET scanner to be relocated is in the relocation zone.~~

646 ~~_____ (d) The proposed project will not result in the replacement of the PET scanner(s) to be relocated~~
647 ~~unless the applicant demonstrates that the requirements of Section 6, as applicable, have also been met.~~

648 ~~_____ (e) The applicant agrees to operate the PET scanner at the proposed site in accordance with all~~
649 ~~applicable project delivery requirements set forth in Section 15.~~

650
651 **Section 10. Requirements for approval for applicants proposing a dedicated research fixed PET**
652 **scanner**MEDICAID PARTICIPATION

653
654 ~~Sec. 10. (1) An applicant proposing to operate a fixed PET scanner (whether new or replacement) to be~~
655 ~~used exclusively for research shall demonstrate each of the following~~PROVIDE VERIFICATION OF
656 MEDICAID PARTICIPATION. AN APPLICANT THAT IS A NEW PROVIDER NOT CURRENTLY
657 ENROLLED IN MEDICAID SHALL CERTIFY THAT PROOF OF MEDICAID PARTICIPATION WILL BE
658 PROVIDED TO THE DEPARTMENT WITHIN (6) MONTHS FROM THE OFFERING OF SERVICES IF A
659 CON IS APPROVED.;

660
661 **Section 11. PROJECT DELIVERY Requirements for approval for applicants proposing to establish**
662 **a dedicated pediatric PET scanner**AND TERMS OF APPROVAL FOR ALL APPLICANTS

663
664 ~~Sec. 11. (1) An applicant proposing to establish a dedicated pediatric PET scanner(s) shall~~ AGREE
665 THAT, IF APPROVED, demonstrate all of the followingPET SCANNER SERVICES SHALL BE
666 DELIVERED IN COMPLIANCE WITH THE FOLLOWING TERMS OF APPROVAL.;

667
668 ~~_____ (a1) The applicant shall experience at least 7,000 pediatric (< 18 years old) discharges, excluding~~
669 ~~normal newborns, in the most recent year of operation~~COMPLIANCE WITH THESE STANDARDS.

670
671 ~~_____ (b2) The applicant shall experience at least 5,000 pediatric (< 18 years old) surgeries in the most~~
672 ~~recent year of operation~~COMPLIANCE WITH THE FOLLOWING QUALITY ASSURANCE
673 REQUIREMENTS.;

674 ~~(c) The applicant shall experience at least 50 new pediatric cancer cases on its cancer registry in~~
675 ~~the most recent year of operation~~A PET SCANNER SERVICE SHALL BE STAFFED SO THAT
676 SCREENING OF REQUESTS FOR AND INTERPRETATION OF PET PROCEDURES WILL BE
677 CARRIED OUT BY A PHYSICIAN(S) WITH APPROPRIATE TRAINING AND FAMILIARITY WITH THE
678 APPROPRIATE DIAGNOSTIC USE AND INTERPRETATION OF CROSS-SECTIONAL IMAGES OF
679 THE ANATOMICAL REGION(S) TO BE EXAMINED. FOR PURPOSES OF EVALUATING THIS
680 SUBSECTION, THE DEPARTMENT SHALL CONSIDER IT PRIMA FACIE EVIDENCE AS TO THE
681 TRAINING OF THE PHYSICIAN(S) IF THE PHYSICIAN IS BOARD CERTIFIED OR BOARD QUALIFIED
682 IN NUCLEAR MEDICINE OR NUCLEAR RADIOLOGY. HOWEVER, AN APPLICANT MAY SUBMIT,
683 AND THE DEPARTMENT MAY ACCEPT, OTHER EVIDENCE THAT THE PHYSICIAN(S) IS QUALIFIED
684 TO OPERATE THE PET SERVICE/SCANNER. THE PHYSICIAN(S) MUST BE ON-SITE OR
685 AVAILABLE THROUGH TELECOMMUNICATION CAPABILITIES TO PARTICIPATE IN THE
686 SCREENING OF PATIENTS FOR PET PROCEDURES AND TO PROVIDE OTHER CONSULTATION
687 SERVICES.

688 ~~(d) The applicant shall have an active medical staff at the time the application is submitted to the~~
689 ~~Department that~~PET SCANNER SERVICE SHALL includes, but is not limited to, physicians who are

690 ~~fellows~~ PERSONNEL, EMPLOYED DIRECTLY OR ON A
691 CONTRACTUAL BASIS: A TECHNOLOGIST WITH TRAINING IN PET SCANNING AND A PHYSICIST.
692 THE PHYSICIST MUST BE BOARD CERTIFIED OR ELIGIBLE FOR CERTIFICATION BY THE
693 AMERICAN BOARD OF RADIOLOGY OR AN EQUIVALENT ORGANIZATION.

- 694 ~~(i) pediatric radiology (at least two staff members)~~
- 695 ~~(ii) pediatric anesthesiology~~
- 696 ~~(iii) pediatric cardiology~~
- 697 ~~(iv) pediatric critical care~~
- 698 ~~(v) pediatric gastroenterology~~
- 699 ~~(vi) pediatric hematology/oncology~~
- 700 ~~(vii) pediatric neurology~~
- 701 ~~(viii) pediatric neurosurgery~~
- 702 ~~(ix) pediatric orthopedic surgery~~
- 703 ~~(x) pediatric pathology~~
- 704 ~~(xi) pediatric pulmonology~~
- 705 ~~(xii) pediatric surgery~~
- 706 ~~(xiii) neonatology~~

707 ~~(eC) The applicant shall have in operation the following pediatric specialty programs at the time the~~
708 application is submitted to PET SCANNER SERVICE SHALL HAVE A PHYSICIAN ON-SITE OR
709 IMMEDIATELY AVAILABLE TO THE PET SCANNER SERVICE AT ALL TIMES WHEN PATIENTS ARE
710 UNDERGOING PET PROCEDURES ~~the Department:~~

- 711 ~~(i) pediatric bone marrow transplant program~~
- 712 ~~(ii) established pediatric sedation program~~
- 713 ~~(iii) pediatric open heart program~~

714 (D) THE APPLICANT MAINTAINS THE SERVICES AND SPECIALTIES AS SET FORTH IN
715 SECTION 3(1) THROUGH 3(4).

716
717 ~~(23) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the~~
718 requirements of Section 4 or Section 5 of these standards but must meet Section 6. COMPLIANCE WITH
719 THE FOLLOWING ACCESS TO CARE REQUIREMENTS:

720 ~~(3A) The dedicated pediatric PET scanner SERVICE shall be excluded.~~ ACCEPT REFERRALS FOR
721 PET SCANNER SERVICES from the adult count for ALL APPROPRIATELY LICENSED
722 PRACTITIONERS ~~the facility.~~

723 (B) THE PET SCANNER SERVICE SHALL PARTICIPATE IN MEDICAID AT LEAST 12
724 CONSECUTIVE MONTHS WITHIN THE FIRST TWO YEARS OF OPERATION AND CONTINUE TO
725 PARTICIPATE ANNUALLY THEREAFTER.

726 (C) THE PET SCANNER SERVICE SHALL NOT DENY PET SCANNER SERVICES TO ANY
727 INDIVIDUAL BASED ON ABILITY TO PAY OR SOURCE OF PAYMENT.

728 (D) THE OPERATION OF AND REFERRAL OF PATIENTS TO THE PET SCANNER SERVICE
729 SHALL BE IN CONFORMANCE WITH 1978 PA 368, SEC. 16221, AS AMENDED BY 1986 PA 319; MCL
730 333.16221; MSA 14.15 (16221).

731
732 (4) COMPLIANCE WITH THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:

733 (A) THE PET SCANNERS SHALL BE OPERATING AT AN AVERAGE OF 500 PET
734 EQUIVALENTS PER SCANNER DURING THE SECOND 12 MONTHS OF OPERATIONS, AND
735 ANNUALLY THEREAFTER. THIS REQUIREMENT SHALL BE WAIVED DURING REVIEW OF
736 APPLICATIONS UNDER SECTIONS 4(1) AND 6(4), IF APPLICABLE. IN MEETING THESE
737 REQUIREMENTS, AN APPLICANT SHALL NOT INCLUDE ANY PET SCANS PERFORMED ON A PET
738 SCANNER USED EXCLUSIVELY FOR RESEARCH APPROVED PURSUANT TO SECTION 7, FOR A
739 DEDICATED PEDIATRIC PET SCANNER APPROVED PURSUANT TO SECTION 8, OR FOR A PEM
740 SCANNER APPROVED PURSUANT TO SECTION 9.

741 (B) THE PET SCANNER SERVICE SHALL PARTICIPATE IN A DATA COLLECTION SYSTEM
742 ESTABLISHED AND ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE. THE DATA MAY

743 INCLUDE, BUT ARE NOT LIMITED TO, CLINICAL SCAN DATA, ANNUAL BUDGET AND COST
744 INFORMATION, OPERATING SCHEDULES, THROUGH-PUT SCHEDULES, DEMOGRAPHIC AND
745 DIAGNOSTIC INFORMATION, AND THE VOLUME OF CARE PROVIDED TO PATIENTS FROM ALL
746 PAYOR SOURCES. THE APPLICANT SHALL PROVIDE THE REQUIRED DATA ON A SEPARATE
747 BASIS FOR EACH SEPARATE AND DISTINCT SITE, PET SCANNER, OR PET SCANNER SERVICE
748 AS REQUIRED BY THE DEPARTMENT, IN A FORMAT ESTABLISHED BY THE DEPARTMENT. THE
749 DEPARTMENT MAY ELECT TO VERIFY THE DATA THROUGH ON-SITE REVIEW OF APPROPRIATE
750 RECORDS.

751 (C) THE PET SCANNER SERVICE SHALL PROVIDE THE DEPARTMENT WITH TIMELY
752 NOTICE OF THE PROPOSED PROJECT IMPLEMENTATION CONSISTENT WITH APPLICABLE
753 STATUTE AND PROMULGATED RULES.

754
755 (5) COMPLIANCE WITH THE FOLLOWING DEDICATED RESEARCH PET SCANNER
756 REQUIREMENTS, IF APPLICABLE:

757 (A) THE CAPITAL AND OPERATING COSTS RELATING TO THE DEDICATED RESEARCH PET
758 SCANNER SHALL BE CHARGED ONLY TO A SPECIFIC RESEARCH ACCOUNT(S) AND NOT TO
759 ANY PATIENT OR THIRD- PARTY PAYOR.

760 (B) THE DEDICATED RESEARCH PET SCANNER SHALL NOT BE USED FOR ANY
761 PURPOSES OTHER THAN AS APPROVED BY THE INSTITUTIONAL REVIEW BOARD.

762 (C) THE DEDICATED RESEARCH PET SCANNER WILL BE USED PRIMARILY (70% OR MORE
763 OF THE SCANS) FOR RESEARCH PURPOSES ONLY.

764
765 (6) COMPLIANCE WITH THE FOLLOWING DEDICATED PEDIATRIC PET SCANNER
766 REQUIREMENTS, IF APPLICABLE:

767 (A) THE DEDICATED PEDIATRIC PET SCANNER WILL BE USED PRIMARILY (70% OR MORE
768 OF THE SCANS) FOR PATIENTS UNDER 18 YEARS OF AGE.

769 (B) SHALL MAINTAIN ACTIVE MEDICAL STAFF IN THE APPLICABLE PEDIATRIC
770 SPECIALTIES AND PEDIATRIC SPECIALTY PROGRAMS AS SET FORTH IN THE SECTION.

771
772 (7) COMPLIANCE WITH THE FOLLOWING PEM SCANNER REQUIREMENTS, IF APPLICABLE:

773 (A) THE PEM SCANNER SERVICE MUST MAINTAIN ACR ACCREDITATION AS A BICOE SITE
774 VERIFIABLE BY THE DEPARTMENT.

775
776 (8) COMPLIANCE WITH THE FOLLOWING MOBILE PET SCANNER REQUIREMENTS, IF
777 APPLICABLE:

778 (A) THE CENTRAL SERVICE COORDINATOR FOR A MOBILE PET SCANNER SERVICE
779 SHALL NOTIFY THE DEPARTMENT 30 DAYS PRIOR TO DROPPING AN EXISTING HOST SITE.

780 (B) EACH HOST SITE MUST HAVE AT LEAST ONE PHYSICIAN WHO IS BOARD CERTIFIED
781 OR BOARD ELIGIBLE IN NUCLEAR MEDICINE OR NUCLEAR RADIOLOGY ON ITS MEDICAL STAFF.
782 THE PHYSICIAN(S) SHALL BE RESPONSIBLE FOR ESTABLISHING PATIENT EXAMINATION AND
783 INFUSION PROTOCOL, AND PROVIDING FOR THE INTERPRETATION OF SCANS PERFORMED.

784 (C) EACH HOST SITE SHALL PROVIDE A PROPERLY PREPARED PARKING PAD FOR THE
785 MOBILE PET SCANNER UNIT, A WAITING AREA FOR PATIENTS, AND A MEANS FOR PATIENTS
786 TO ENTER THE VEHICLE WITHOUT GOING OUTSIDE (SUCH AS AN ENCLOSED CANOPY OR AN
787 ENCLOSED CORRIDOR).

788 (D) A MOBILE PET SCANNER SERVICE SHALL OPERATE UNDER A CONTRACTUAL
789 AGREEMENT THAT INCLUDES THE PROVISION OF PET SERVICES AT EACH HOST SITE ON A
790 REGULARLY SCHEDULED BASIS.

791
792 (9) THE AGREEMENTS AND ASSURANCES REQUIRED BY THIS SECTION SHALL BE IN THE
793 FORM OF A CERTIFICATION AGREED TO BY THE APPLICANT OR ITS AUTHORIZED AGENT.

794
795 **Section 12. ~~Additional requirements~~METHODOLOGY for ~~mobile~~COMPUTING THE PROJECTED**

796 | **PET service**DATA UNITS

797
798 | Sec. 12. ~~(1) An applicant proposing to begin operation of a mobile PET service shall demonstrate all~~
799 ~~of the following~~BEING REVIEWED UNDER SECTION 3 SHALL APPLY THE METHODOLOGY SET
800 FORTH IN THIS SECTION IN COMPUTING THE PROJECTED NUMBER OF PET DATA UNITS:

801
802 | (a1) A separate CON application has been submitted by the central service coordinator and each
803 proposed host siteIDENTIFY THE NUMBER OF DIAGNOSIS-SPECIFIC NEW CANCER CASES
804 DOCUMENTED IN ACCORDANCE WITH THE REQUIREMENTS OF SECTION 13.

805 | ~~(bA) A proposed regular route schedule, the procedures for handling emergency situations, and~~
806 ~~copies of all proposed contracts related to the mobile PET service have been included in the CON~~
807 ~~application~~COMBINE THE NUMBER OF CANCER CASES FOR LUNG (SITE CODES C340-C349),
808 ESOPHAGUS (SITE CODES C150-C159), COLORECTAL (SITE CODES C180-C209), LYMPHOMA
809 (MORPHOLOGY CODES (9590-9729), MELANOMA (MORPHOLOGY CODES 8720-8790), AND HEAD
810 & NECK [SITE CODES C000-C148, C300-C329, C410, C411, C470 OR C490 EXCLUDING C440-C444
811 (SKIN OF HEAD AND NECK), AND ADDITIONAL CODES APPROVED BY NATIONAL COVERAGE
812 DETERMINATION]. USE THE NAME "COMBINED" FOR THIS GROUPING.

813 | ~~(eB) The requirements of sections 3, 4, 5, and 6, as applicable, have been met.~~ MULTIPLY THE
814 NUMBER RESULTING FROM THE CALCULATION IN "COMBINED" CANCER CASES IDENTIFIED IN
815 SUBSECTION (1)(B) BY 0.8, WHICH IS THE ESTIMATED PROBABILITY THAT A "COMBINED"
816 CANCER CASE WILL REQUIRE A PET SCAN.

817 | (C) MULTIPLY THE NUMBER RESULTING FROM THE CALCULATION IN SUBSECTION (1)(C)
818 BY 2.5, WHICH IS THE ESTIMATED NUMBER OF PET SCANS NEEDED FOR EACH PATIENT
819 REQUIRING A PET SCAN.

820
821 | ~~(2) An applicant proposing to become a host site on an existing mobile PET scanner service shall~~
822 ~~demonstrate that it meets all of the following:~~ IDENTIFY THE NUMBER OF DIAGNOSIS-SPECIFIC NEW
823 CANCER CASES DOCUMENTED IN ACCORD WITH THE REQUIREMENTS OF SECTION 13.

824 | ~~(a) Approval of the application will not result in an increase in the number of mobile PET scanners~~
825 ~~listed on the "Department Inventory of PET Scanners" unless the requirements of Section 5 have been~~
826 ~~met.~~ MULTIPLY THE NUMBER OF BREAST CANCER CASES (SITE CODES C500-C509) BY 0.25,
827 WHICH IS THE ESTIMATED PROBABILITY THAT A BREAST CANCER CASE WILL REQUIRE A PET
828 SCAN.

829 | ~~(b) A proposed regular route schedule, the procedures for handling emergency situations, and~~
830 ~~copies of all proposed contracts related to the mobile PET scanner have been included in the CON~~
831 ~~application.~~ MULTIPLY THE NUMBER RESULTING FROM THE CALCULATION IN SUBSECTION (2)(B)
832 BY 1.0, WHICH IS THE ESTIMATED NUMBER OF PET SCANS NEEDED FOR EACH PATIENT
833 REQUIRING A PET SCAN.

834
835 | (3) MULTIPLY THE NUMBER OF DIAGNOSTIC CARDIAC CATHETERIZATION CASES
836 IDENTIFIED IN ACCORD WITH THE REQUIREMENTS OF SECTION 15 BY 0.1, WHICH IS THE
837 ESTIMATED PROBABILITY THAT A PATIENT HAVING A DIAGNOSTIC CARDIAC
838 CATHETERIZATION WILL REQUIRE A PET SCAN.

839
840 | (4) MULTIPLY THE NUMBER OF INTRACTABLE EPILEPSY CASES (ICD-9-CM CODES 345.01,
841 345.11, 345.41, 345.51, 345.61, 345.71, 345.81, OR 345.91) IDENTIFIED IN ACCORD WITH THE
842 REQUIREMENTS OF SECTION 16 BY 1.0, WHICH IS THE ESTIMATED PROBABILITY THAT A
843 PATIENT HAVING AN INTRACTABLE EPILEPSY PROCEDURE WILL REQUIRE A PET SCAN.
844 MULTIPLY THE NUMBER RESULTING FROM THE CALCULATION IN SUBSECTION (3) BY 1.0,
845 WHICH IS THE ESTIMATED NUMBER OF PET SCANS NEEDED FOR EACH PATIENT REQUIRING A
846 PET SCAN.

847
848 | (5) SUM THE NUMBERS RESULTING FROM THE CALCULATIONS IN SUBSECTIONS (1)

849 THROUGH (4) TO DETERMINE THE TOTAL NUMBER OF PROJECTED PET DATA UNITS.

850
851 (6) MULTIPLY THE RESULT CALCULATED IN SUBSECTION (5) ABOVE BY A FACTOR OF 3.0
852 IF THE APPLICANT IS PROPOSING TO SERVE ONLY PLANNING AREA 6 TO DETERMINE THE
853 TOTAL NUMBER OF PROJECTED PET DATA UNITS.

854
855 (7) MULTIPLY THE RESULT CALCULATED IN SUBSECTION (5) ABOVE BY A FACTOR OF 2.0
856 IF THE APPLICANT IS PROPOSING TO SERVE ONLY PLANNING AREA 5 TO DETERMINE THE
857 TOTAL NUMBER OF PROJECTED PET DATA UNITS.

858
859 **Section 13. ~~Requirements for approval for all applicants~~COMMITMENT OF DIAGNOSIS-SPECIFIC**
860 **NEW CANCER CASES**

861
862 ~~Sec. 13. An applicant shall provide verification of Medicaid participation at the time the application is~~
863 ~~submitted to the Department. If the required documentation is not submitted with the application on the~~
864 ~~designated application date, the application will be deemed filed on the first applicable designated~~
865 ~~application date after all required documentation is received by the Department.~~AN APPLICANT
866 PROPOSING TO USE DIAGNOSIS-SPECIFIC NEW CANCER CASES SHALL DEMONSTRATE ALL OF
867 THE FOLLOWING:

868
869 (1) ONLY THOSE CANCER DIAGNOSES IDENTIFIED IN SECTION 12(1) AND 12(2) SHALL BE
870 INCLUDED.

871
872 (2) EACH ENTITY CONTRIBUTING DIAGNOSIS SPECIFIC NEW CANCER CASE DATA
873 PROVIDES, AS PART OF THE APPLICATION AT THE TIME IT IS SUBMITTED TO THE
874 DEPARTMENT, A SIGNED GOVERNING BODY RESOLUTION THAT IDENTIFIES THE NUMBER OF
875 DIAGNOSIS-SPECIFIC CANCER CASES BEING COMMITTED TO THE APPLICATION AND THAT
876 STATES NO CURRENT OR FUTURE DIAGNOSIS-SPECIFIC NEW CANCER CASE DATA WILL BE
877 USED IN SUPPORT OF ANY OTHER APPLICATION FOR A PET UNIT FOR A PERIOD OF FIVE (5)
878 YEARS FROM THE DATE OF START OF OPERATIONS OF THE APPROVED PET SCANNER
879 SERVICE FOR WHICH DATA ARE BEING COMMITTED. IF THE REQUIRED DOCUMENTATION FOR
880 THIS SUBSECTION IS NOT SUBMITTED WITH THE APPLICATION ON THE DESIGNATED
881 APPLICATION DATE, THE APPLICATION WILL BE DEEMED FILED ON THE FIRST APPLICABLE
882 DESIGNATED APPLICATION DATE AFTER ALL REQUIRED DOCUMENTATION IS RECEIVED BY
883 THE DEPARTMENT.

884 (A) FOR FIXED PET SCANNER SERVICES, THE GEOGRAPHIC LOCATION OF EACH ENTITY
885 CONTRIBUTING DIAGNOSIS-SPECIFIC NEW CANCER CASE DATA IS IN THE SAME PLANNING
886 AREA AS THE PROPOSED PET SERVICE.

887 (B) FOR MOBILE PET SCANNER SERVICES, THE GEOGRAPHIC LOCATION OF EACH
888 ENTITY CONTRIBUTING DIAGNOSIS-SPECIFIC NEW CANCER CASE DATA IN THE PLANNING
889 AREA(S) FOR WHICH THE PROPOSED PET SERVICE CONTAINS A PROPOSED HOST SITE OR
890 WITHIN A 75-MILE RADIUS OF THE PROPOSED HOST SITE FOR RURAL AND MICROPOLITAN
891 STATISTICAL AREA COUNTIES OR 25-MILE RADIUS FOR METROPOLITAN STATISTICAL AREA
892 COUNTIES.

893 (C) NO ENTITY CONTRIBUTING DIAGNOSIS-SPECIFIC NEW CANCER CASE DATA HAS
894 PREVIOUSLY COMMITTED OR IS COMMITTING DATA TO ANOTHER SERVICE THAT IS LESS
895 THAN FIVE (5) YEARS FROM THE START OF OPERATIONS OF THAT SERVICE.

896
897 (3) NO ENTITY CURRENTLY OPERATING OR APPROVED TO OPERATE A PET SCANNER
898 SERVICE SHALL CONTRIBUTE DIAGNOSIS-SPECIFIC NEW CANCER CASES.

899
900 (4) THE DEPARTMENT MAY NOT CONSIDER A WITHDRAWAL OF DIAGNOSIS-SPECIFIC
901 NEW CANCER CASE DATA DURING THE 120-DAY APPLICATION REVIEW CYCLE FOLLOWING

902 THE DATE ON WHICH THE DEPARTMENT REVIEW OF THE APPLICATION COMMENCES OR
903 AFTER A PROPOSED DECISION TO APPROVE THE APPLICATION HAS BEEN ISSUED UNLESS
904 THE APPLICATION IS DENIED, WITHDRAWN, OR EXPIRED. THE WITHDRAWAL MUST BE
905 SUBMITTED TO THE DEPARTMENT IN THE FORM OF A GOVERNING BODY RESOLUTION THAT
906 CONTAINS THE SPECIFIC CON APPLICATION NUMBER TO WHICH THE DATA WERE ORIGINALLY
907 COMMITTED, THE LEGAL APPLICANT ENTITY, THE COMMITTING ENTITY, THE TYPE OF DATA,
908 THE DATE OF THE MEETING IN WHICH THE GOVERNING BODY AUTHORIZED THE WITHDRAWAL
909 OF THE DATA, THE GOVERNING BODY PRESIDENT'S SIGNATURE, AND THE DATE OF THE
910 SIGNATURE.

911
912 **Section -14. ~~Project delivery requirements and terms of approval for all applicants~~**
913 **DOCUMENTATION OF DIAGNOSIS-SPECIFIC NEW CANCER CASE DATA**
914

915 Sec. 14. AN APPLICANT REQUIRED TO DOCUMENT VOLUMES OF DIAGNOSIS-SPECIFIC
916 NEW CANCER CASES SHALL SUBMIT, AS PART OF ITS APPLICATION AT THE TIME IT IS
917 SUBMITTED TO THE DEPARTMENT, DOCUMENTATION FROM THE DIVISION FOR VITAL
918 RECORDS AND HEALTH STATISTICS VERIFYING THE NUMBER OF DIAGNOSIS-SPECIFIC NEW
919 CANCER CASES PROVIDED IN SUPPORT OF THE APPLICATION FOR THE MOST RECENT
920 CALENDAR YEAR FOR WHICH VERIFIABLE DATA ARE AVAILABLE FROM THE STATE
921 REGISTRAR. IF THE REQUIRED DOCUMENTATION FOR THIS SUBSECTION IS NOT SUBMITTED
922 WITH THE APPLICATION ON THE DESIGNATED APPLICATION DATE, THE APPLICATION WILL BE
923 DEEMED FILED ON THE FIRST APPLICABLE DESIGNATED APPLICATION DATE AFTER ALL
924 REQUIRED DOCUMENTATION IS RECEIVED BY THE DEPARTMENT. DIAGNOSIS-SPECIFIC NEW
925 CANCER CASE DATA SUPPORTING AN APPLICATION UNDER THESE STANDARDS SHALL BE
926 SUBMITTED TO THE DIVISION FOR VITAL RECORDS AND HEALTH STATISTICS USING A FORMAT
927 AND MEDIA SPECIFIED IN INSTRUCTIONS FROM THE DEPARTMENT OF COMMUNITY HEALTH.

928 ~~—(1) An applicant shall agree that, if approved, the services provided by the PET service shall be~~
929 ~~delivered in compliance with the following terms of CON approval:~~

930 ~~— (a) Compliance with these standards.~~

931 ~~— (b) Compliance with applicable safety and operating standards.~~

932 ~~— (c) Compliance with the following quality assurance standards:~~

933 ~~— (i) The approved PET scanner shall be operating at the applicable required volumes specified in~~
934 ~~these standards. In meeting this requirement, an applicant shall not include any patient visits conducted~~
935 ~~by dedicated research PET scanners.~~

936 ~~— (ii) An applicant shall establish and maintain (A) a standing medical staff and governing body (or~~
937 ~~its equivalent) requirement that provides for the medical and administrative control of the ordering and~~
938 ~~utilization of PET patient visits and (B) a formal program of utilization review and quality assurance.~~
939 ~~These responsibilities may be assigned to an existing body of the applicant, as appropriate.~~

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

949 ~~— (iv) An applicant shall establish a PET service team. A PET service team shall be responsible for~~
950 ~~(A) developing criteria for procedure performance, (B) developing protocols for procedure performance,~~
951 ~~(C) developing a clinical data base for utilization review and quality assurance purposes, (D) transmitting~~
952 ~~requested data to the Department, (E) screening of patients to assure appropriate utilization of the PET~~
953 ~~scanner, (F) taking and interpreting scans, and (G) coordinating PET activity at a PET host site(s) for a~~
954 ~~mobile pet service(s)/scanner(s).~~

955 ~~— (v) At a minimum, the PET service team shall include the following personnel, employed directly by~~
956 ~~the applicant or on a contractual basis: (A) a team leader, (B) technologists with training in PET~~
957 ~~scanning, (C) radiation safety personnel, and (D) a physicist(s). The physicist(s) must be board certified~~
958 ~~or eligible for certification by the American Board of Radiology or an equivalent organization. Other~~
959 ~~personnel that may be appropriate members of the PET service team, depending on the type of operation~~
960 ~~and PET procedures performed, include but are not limited to nurses, computer technicians, radio-~~
961 ~~chemists, radio-chemistry technicians, radio-pharmacists, and instrument maintenance technicians. If the~~
962 ~~team leader is not a physician, the PET service team also shall include a physician with appropriate~~
963 ~~training and familiarity with the appropriate diagnostic use and interpretation of cross-sectional images of~~
964 ~~the anatomical region(s) to be examined.~~
965 ~~— (vi) The applicant shall have, within the PET service, equipment and supplies to handle clinical~~
966 ~~emergencies that might occur within the PET service, with PET staff trained in CPR and other appropriate~~
967 ~~emergency interventions, and a physician on-site or immediately available to the PET service at all times~~
968 ~~when patients are undergoing PET procedures.~~
969 ~~— (vii) An applicant shall participate in Medicaid at least 12 consecutive months within the first two~~
970 ~~years of operation and continue to participate annually thereafter.~~
971 ~~— (viii) Fixed and mobile PET scanner units shall be operating at a minimum average annual level of~~
972 ~~utilization during the second twelve months of operation, and annually thereafter, of 1,500 PET~~
973 ~~equivalents per unit.~~
974 ~~— (d) Compliance with the following requirements:~~
975 ~~— (i) The applicant shall accept referrals for PET scanner services from all appropriately licensed~~
976 ~~practitioners.~~
977 ~~— (ii) The applicant, to assure that the PET scanner services will be utilized by all segments of the~~
978 ~~Michigan population, shall (A) not deny PET scanner services to any individual based on ability to pay or~~
979 ~~source of payment, (B) provide PET scanning services to any individual based on the clinical indications~~
980 ~~of need for the service, and (C) maintain information by payor and non-paying sources to indicate the~~
981 ~~volume of care from each source provided annually.~~
982 ~~— Compliance with selective contracting requirements shall not be construed as a violation of this~~
983 ~~term.~~
984 ~~— (iii) The applicant shall participate in a data collection network established and administered by the~~
985 ~~Department or its designee. The data may include, but are not limited to annual budget and cost~~
986 ~~information, operating schedules, through-put schedules, demographic and diagnostic information, the~~
987 ~~volume of care provided to patients from all payor sources, and other data requested by the Department~~
988 ~~or its designee. The applicant shall provide the required data on a separate basis for each separate and~~
989 ~~distinct site, PET scanner, or PET service as required by the Department, in a format established by the~~
990 ~~Department, and in a mutually agreed upon media. The Department may elect to verify the data through~~
991 ~~on-site review of appropriate records. If the applicant intends to include research PET equivalents~~
992 ~~conducted by a PET scanner other than a dedicated research PET scanner in its utilization statistics, the~~
993 ~~applicant shall submit to the Department a copy of the research protocol with evidence of approval by the~~
994 ~~Institutional Review Board. The applicant shall submit this at the time the applicant intends to include~~
995 ~~research procedures in its utilization statistics. The applicant shall separately report to the Department~~
996 ~~any PET equivalents conducted by a dedicated research PET scanner.~~
997 ~~— (iv) PET equipment to be replaced shall be removed from service on or before beginning operation~~
998 ~~of the replacement equipment, including the use of temporary scanners as part of the replacement~~
999 ~~project.~~
1000 ~~— (v) The applicant shall provide the Department with a notice stating the first date on which the PET~~
1001 ~~scanner became operational, and such notice shall be submitted to the Department consistent with~~
1002 ~~applicable statute and promulgated rules.~~
1003
1004 ~~— (2) An applicant for a dedicated research PET scanner under Section 10 shall agree that the~~
1005 ~~services provided by the PET scanner approved pursuant to Section 10 shall be delivered in compliance~~
1006 ~~with the following terms of CON approval:~~
1007 ~~— (a) The capital and operating costs relating to the dedicated research PET scanner approved~~

1008 pursuant to Section 8 shall be charged only to a specific research account(s) and not to any patient or
1009 third-party payer.

1010 (b) The dedicated research PET scanner approved pursuant to Section 10 shall not be used for
1011 any purposes other than as approved by the Institutional Review Board unless the applicant has obtained
1012 CON approval for the PET scanner pursuant to Part 222 and these standards, other than Section 10.

1013
1014 (3) The operation of and referral of patients to the PET service shall be in conformance with 1978
1015 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

1016
1017 (4) The agreements and assurances required by this section shall be in the form of a certification
1018 authorized by the governing body of the applicant or its authorized agent.

1019
1020 **Section 15. ~~Project delivery requirements and additional terms of approval for applicants~~**
1021 **involving mobile PET services COMMITMENT AND DOCUMENTATION OF DIAGNOSTIC CARDIAC**
1022 **CATHETERIZATION DATA**

1023
1024 Sec. 15. AN APPLICANT PROPOSING TO USE DIAGNOSTIC CARDIAC CATHETERIZATION
1025 DATA SHALL DEMONSTRATE ALL OF THE FOLLOWING:

1026
1027 (1) EACH ENTITY CONTRIBUTING DIAGNOSTIC CARDIAC CATHETERIZATION DATA
1028 PROVIDES, AS PART OF THE APPLICATION AT THE TIME IT IS SUBMITTED TO THE
1029 DEPARTMENT, A SIGNED GOVERNING BODY RESOLUTION THAT IDENTIFIES THE NUMBER OF
1030 DIAGNOSTIC CARDIAC CATHETERIZATION CASES (SESSIONS) COMMITTED TO THE
1031 APPLICATION AND THAT STATES NO CURRENT OR FUTURE DIAGNOSTIC CARDIAC
1032 CATHETERIZATION DATA WILL BE USED IN SUPPORT OF ANY OTHER APPLICATION FOR A PET
1033 UNIT FOR THE DURATION OF THE PET SERVICE FOR WHICH DATA ARE BEING COMMITTED
1034 FOR A PERIOD OF FIVE (5) YEARS FROM THE DATE OF START OF OPERATIONS OF THE
1035 APPROVED PET SERVICE FOR WHICH DATA ARE BEING COMMITTED. IF THE REQUIRED
1036 DOCUMENTATION FOR THIS SUBSECTION IS NOT SUBMITTED WITH THE APPLICATION ON THE
1037 DESIGNATED APPLICATION DATE, THE APPLICATION WILL BE DEEMED FILED ON THE FIRST
1038 APPLICABLE DESIGNATED APPLICATION DATE AFTER ALL REQUIRED DOCUMENTATION IS
1039 RECEIVED BY THE DEPARTMENT.

1040 (A) FOR FIXED PET SCANNER SERVICES, THE GEOGRAPHIC LOCATION OF EACH ENTITY
1041 CONTRIBUTING DIAGNOSTIC CARDIAC CATHETERIZATION DATA IS IN THE SAME PLANNING
1042 AREA AS THE PROPOSED PET UNIT/SERVICE.

1043 (B) FOR MOBILE PET SCANNER SERVICES, THE GEOGRAPHIC LOCATION OF EACH
1044 ENTITY CONTRIBUTING DIAGNOSTIC CARDIAC CATHETERIZATION CASE DATA IN THE
1045 PLANNING AREA(S) FOR WHICH THE PROPOSED PET SERVICE CONTAINS A PROPOSED HOST
1046 SITE OR WITHIN A 75-MILE RADIUS OF THE PROPOSED HOST SITE FOR RURAL AND
1047 MICROPOLITAN STATISTICAL AREA COUNTIES OR 25-MILE RADIUS FOR METROPOLITAN
1048 STATISTICAL AREA COUNTIES.

1049 (C) NO ENTITY CONTRIBUTING DIAGNOSTIC CARDIAC CATHETERIZATION DATA HAS
1050 PREVIOUSLY COMMITTED OR IS COMMITTING DATA TO ANOTHER SERVICE THAT IS LESS
1051 THAN FIVE (5) YEARS FROM THE START OF OPERATIONS OF THAT SERVICE.

1052 (D) THE DIAGNOSTIC CARDIAC CATHETERIZATION CASE DATA IS FROM THE MOST
1053 RECENTLY COMPLETED REPORT(S) OF THE ANNUAL SURVEY PRODUCED BY THE
1054 DEPARTMENT, AND THE CONTRIBUTING ENTITY HAS CON APPROVAL TO PROVIDE
1055 DIAGNOSTIC CARDIAC CATHETERIZATION SERVICES.

1056
1057 (2) NO ENTITY CURRENTLY OPERATING OR APPROVED TO OPERATE A PET SCANNER
1058 SERVICE SHALL CONTRIBUTE DIAGNOSTIC CARDIAC CATHETERIZATION CASE DATA.

1059
1060 (3) THE DEPARTMENT MAY NOT CONSIDER A WITHDRAWAL OF DIAGNOSTIC CARDIAC

1061 CATHETERIZATION CASE DATA DURING THE 120-DAY APPLICATION REVIEW CYCLE
1062 FOLLOWING THE DATE ON WHICH THE DEPARTMENT REVIEW OF THE APPLICATION
1063 COMMENCES OR AFTER A PROPOSED DECISION TO APPROVE THE APPLICATION HAS BEEN
1064 DENIED UNLESS THE APPLICATION IS DENIED, WITHDRAWN, OR EXPIRED. THE WITHDRAWAL
1065 MUST BE SUBMITTED TO THE DEPARTMENT IN THE FORM OF A GOVERNING BODY
1066 RESOLUTION THAT CONTAINS THE SPECIFIC CON APPLICATION NUMBER TO WHICH THE DATA
1067 WERE ORIGINALLY COMMITTED, THE LEGAL APPLICANT ENTITY, THE COMMITTING ENTITY,
1068 THE TYPE OF DATA, THE DATE OF THE MEETING IN WHICH THE GOVERNING BODY
1069 AUTHORIZED THE WITHDRAWAL OF THE DATA, THE GOVERNING BODY PRESIDENT'S
1070 SIGNATURE, AND THE DATE OF THE SIGNATURE.

1071
1072 ~~(1) In addition to the provisions of Section 14, an applicant for a mobile PET services shall agree that the~~
1073 ~~services provided by the mobile PET scanner(s) shall be delivered in compliance with the following terms~~
1074 ~~of CON approval:~~

1075 ~~— (a) The central service coordinator for a mobile PET service, with an approved CON, shall notify~~
1076 ~~the administrative unit of the Department of Community Health responsible for administering the CON~~
1077 ~~program 30 days prior to dropping an existing host site.~~

1078 ~~— (b) Each host site must have at least one physician who is board certified or board eligible in~~
1079 ~~nuclear medicine or nuclear radiology on its medical staff. The physician(s) shall be responsible for (i)~~
1080 ~~establishing patient examination and infusion protocol and (ii) providing for the interpretation of scans~~
1081 ~~performed by the mobile PET service/scanner.~~

1082 ~~— (c) Each mobile PET scanner service shall have an operations committee with members~~
1083 ~~representing each host site, the central service coordinator, and the medical director. This committee~~
1084 ~~shall oversee the effective and efficient use of the PET scanner, establish the regular route schedule,~~
1085 ~~identify the process by which changes are to be made to the schedule, develop procedures for handling~~
1086 ~~emergency situations, and review the ongoing operations of the mobile PET scanner service on at least a~~
1087 ~~quarterly basis.~~

1088 ~~— (d) The central service coordinator shall arrange for emergency repair services to be available 24~~
1089 ~~hours each day for the mobile PET scanner equipment as well as the vehicle transporting the equipment.~~
1090 ~~In addition, to preserve image quality and minimize PET scanner downtime, calibration checks shall be~~
1091 ~~performed on the PET scanner unit at least once each work day or in accordance with the manufacturer's~~
1092 ~~requirements. Routine maintenance services shall be provided on a regularly scheduled basis, at least~~
1093 ~~once a week or in accordance with the manufacturer's requirements, during hours not normally used for~~
1094 ~~patient procedures.~~

1095 ~~— (e) Each host site shall provide a properly prepared parking pad, for the mobile PET scanner unit,~~
1096 ~~of sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for~~
1097 ~~patients to enter the vehicle without going outside (such as an enclosed canopy or an enclosed corridor).~~
1098 ~~Each host site also must provide the capability for processing the film and maintaining the confidentiality~~
1099 ~~of patient records. A communication system must be provided between the mobile vehicle and each host~~
1100 ~~site to provide for immediate notification of emergency medical situations.~~

1101 ~~— (f) A mobile PET scanner service shall operate under a contractual agreement that includes the~~
1102 ~~provision of PET services at each host site on a regularly scheduled basis.~~

1103 ~~— (g) The volume of utilization at each host site shall be reported to the Department by the central~~
1104 ~~service coordinator under the terms of Section 14(1)(d)(iii).~~

1105
1106 ~~— (2) The agreements and assurances required by this section shall be in the form of a certification~~
1107 ~~authorized by the owner or the governing body of the applicant or its authorized agent.~~

1108
1109 **Section 16. Determination of PET equivalents**
1110 **COMMITMENT AND DOCUMENTATION OF**
1111 **INTRACTABLE EPILEPSY DATA**

1112 Sec. 16. AN APPLICANT PROPOSING TO USE INTRACTABLE EPILEPSY CASES SHALL
1113 DEMONSTRATE ALL OF THE FOLLOWING:

1114
1115 (1) EACH ENTITY CONTRIBUTING INTRACTABLE EPILEPSY DATA PROVIDES, AS PART OF
1116 THE APPLICATION AT THE TIME IT IS SUBMITTED TO THE DEPARTMENT, A SIGNED GOVERNING
1117 BODY RESOLUTION THAT IDENTIFIES THE NUMBER OF INTRACTABLE EPILEPSY CASES
1118 COMMITTED TO THE APPLICATION AND THAT STATES NO CURRENT OR FUTURE INTRACTABLE
1119 EPILEPSY CASE DATA WILL BE USED IN SUPPORT OF ANY OTHER APPLICATION FOR A PET
1120 UNIT FOR THE DURATION OF THE PET SERVICE FOR WHICH THE DATA ARE BEING COMMITTED
1121 FOR A PERIOD OF FIVE (5) YEARS FROM THE DATE OF START OF OPERATIONS OF THE
1122 APPROVED PET SERVICE FOR WHICH DATA ARE BEING COMMITTED. IF THE REQUIRED
1123 DOCUMENTATION FOR THIS SUBSECTION IS NOT SUBMITTED WITH THE APPLICATION ON THE
1124 DESIGNATED APPLICATION DATE, THE APPLICATION WILL BE DEEMED FILED ON THE FIRST
1125 APPLICABLE DESIGNATED APPLICATION DATE AFTER ALL REQUIRED DOCUMENTATION IS
1126 RECEIVED BY THE DEPARTMENT.

1127 (A) FOR FIXED PET SCANNER SERVICES, THE GEOGRAPHIC LOCATION OF EACH ENTITY
1128 CONTRIBUTING INTRACTABLE EPILEPSY CASE DATA IS IN THE SAME PLANNING AREA AS THE
1129 PROPOSED PET UNIT/SERVICE.

1130 (B) FOR MOBILE PET SCANNER SERVICES, THE GEOGRAPHIC LOCATION OF EACH
1131 ENTITY CONTRIBUTING INTRACTABLE EPILEPSY CASE DATA IN THE PLANNING AREA(S) FOR
1132 WHICH THE PROPOSED PET SCANNER SERVICE CONTAINS A PROPOSED HOST SITE OR
1133 WITHIN A 75-MILE RADIUS OF THE PROPOSED HOST SITE FOR RURAL AND MICROPOLITAN
1134 STATISTICAL AREA COUNTIES OR 25-MILE RADIUS FOR METROPOLITAN STATISTICAL AREA
1135 COUNTIES.

1136 (C) NO ENTITY CONTRIBUTING INTRACTABLE EPILEPSY CASE DATA HAS PREVIOUSLY
1137 COMMITTED OR IS COMMITTING DATA TO ANOTHER SERVICE THAT IS LESS THAN FIVE (5)
1138 YEARS FROM THE START OF OPERATIONS OF THAT SERVICE.

1139 (D) THE INTRACTABLE EPILEPSY CASE DATA IS FROM THE MOST RECENT MICHIGAN
1140 INPATIENT DATA BASE (MIDB) AVAILABLE TO THE DEPARTMENT.

1141
1142 (2) NO ENTITY CURRENTLY OPERATING OR APPROVED TO OPERATE A SCANNER SHALL
1143 CONTRIBUTE INTRACTABLE EPILEPSY CASE DATA.

1144
1145 (3) THE DEPARTMENT MAY NOT CONSIDER A WITHDRAWAL OF INTRACTABLE EPILEPSY
1146 CASE DATA DURING THE 120-DAY APPLICATION REVIEW CYCLE FOLLOWING THE DATE ON
1147 WHICH THE DEPARTMENT REVIEW OF THE APPLICATION COMMENCES OR AFTER A
1148 PROPOSED DECISION TO APPROVE THE APPLICATION UNLESS THE APPLICATION IS DENIED,
1149 WITHDRAWN, OR EXPIRED. THE WITHDRAWAL MUST BE SUBMITTED TO THE DEPARTMENT IN
1150 THE FORM OF A GOVERNING BODY RESOLUTION THAT CONTAINS THE SPECIFIC CON
1151 APPLICATION NUMBER TO WHICH THE DATA WERE ORIGINALLY COMMITTED, THE LEGAL
1152 APPLICANT ENTITY, THE COMMITTING ENTITY, THE TYPE OF DATA, THE DATE OF THE
1153 MEETING IN WHICH THE GOVERNING BODY AUTHORIZED THE WITHDRAWAL OF THE DATA,
1154 THE GOVERNING BODY PRESIDENT'S SIGNATURE, AND THE DATE OF THE SIGNATURE.

1155
1156
1157 ~~For purposes of these standards, PET equivalents shall be calculated as follows:~~

1158 ~~(a) Each actual patient visit performed during the time period specified in the applicable section(s)~~
1159 ~~of these standards shall be assigned a number of PET equivalents based on the sum of the applicable~~
1160 ~~values set forth in subsections (i) through (vii).~~

1161 ~~(i) A single patient visit _____ 1.0~~

1162 ~~(ii) Number of chemically different tracers~~
1163 ~~used during a single patient visit.~~

1164 ~~1 tracers = 0~~

1165 ~~>2 tracers = 0.8~~

1166 ~~(iii) Number of tracer injections performed~~

- ~~1167 during a single patient visit.~~
- ~~1168 1 tracer injection = 0~~
- ~~1169 2 tracer injections = 0.3~~
- ~~1170 ≥3 tracer injections = 0.6~~
- ~~1171 (iv) Dynamic scan(s) performed during a single patient visit = 0.5~~
- ~~1172 patient visit.~~
- ~~1173 (v) Number of bed positions used during a single patient visit.~~
- ~~1174 1 bed position = 0~~
- ~~1175 ≥2 bed positions = 0.2 for each additional position~~
- ~~1176 (vi) Arterial sampling performed during a single patient visit = 0.5~~
- ~~1177 patient visit.~~
- ~~1178 (vii) Transmission scan = .1 per bed position~~
- ~~1180 **Total PET Equivalents for a Single Patient Visit**~~
- ~~1181 (b) For each pediatric patient visit, the PET equivalent(s) determined pursuant to subdivision (a) shall be multiplied as follows:~~
- ~~1182 patient ≤ 5 years of age multiply by 4.0~~
- ~~1183 patient >5≤10 years of age multiply by 3.0~~
- ~~1184 patient >10≤17 years of age multiply by 2.0~~
- ~~1185 (c) For each radiation therapy patient visit, the PET equivalent(s) determined pursuant to subdivision (a) shall be multiplied by 1.5.~~
- ~~1186 (d) The PET equivalents for each patient visit determined pursuant to subdivisions (a), (b) and (c) shall be summed to determine the total PET equivalents for the time period specified in the applicable section(s) of these standards.~~

SECTION 17. METHODOLOGY FOR COMPUTING PET EQUIVALENTS

~~1192 Sec. 17. For purposes of these standards, PET equivalents shall be calculated as follows:~~

TABLE1 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.	

**Section 4718. Methodology for computing the projected number of PET data units
DEPARTMENT INVENTORY OF PET SCANNERS**

~~1199 Sec. 4718. THE DEPARTMENT SHALL MAINTAIN AND PUBLICLY POST ON ITS WEB SITE A LIST OF PET SCANNER SERVICES ANNUALLY.~~

~~1200 —The applicant being reviewed under Section 4 shall apply the methodology set forth in this section in computing the projected number of PET data units.~~

~~1204 —(1)(a) Identify the number of diagnosis specific new cancer cases documented in accord with the requirements of Section 18.~~

~~1206 —(b) Combine the number of cancer cases for lung (site codes C340-C349), esophagus (site codes~~

1207 C150-C159), colorectal (site codes C180-C209), lymphoma (morphology codes 9590-9729), melanoma
1208 (morphology codes 8720-8790), and head & neck [site codes C000-C148, C300-C329, C410, C411,
1209 C470 OR C490 excluding C440-C444 (skin of head and neck), and additional codes approved by
1210 National Coverage Determination]. Use the name "combined" for this grouping.
1211 — (c) Multiply the number resulting from the calculation in "combined" cancer cases identified in
1212 subsection (1)(b) by 0.8, which is the estimated probability that a "combined" cancer case will require a
1213 PET scan.
1214 — (d) Multiply the number resulting from the calculation in subsection (1)(c) by 2.5, which is the
1215 estimated number of PET scans needed for each patient requiring a PET scan.
1216
1217 — (2)(a) Identify the number of diagnosis specific new cancer cases documented in accord with the
1218 requirements of Section 18.
1219 — (b) Multiply the number of breast cancer cases (site codes C500-C509) by 0.25, which is the
1220 estimated probability that a breast cancer case will require a PET scan.
1221 — (c) Multiply the number resulting from the calculation in subsection (2)(b) by 1.0, which is the
1222 estimated number of PET scans needed for each patient requiring a PET scan.
1223
1224 — (3)(a) Multiply the number of diagnostic cardiac catheterization cases identified in accord with the
1225 requirements of Section 20 by 0.1, which is the estimated probability that a patient having a diagnostic
1226 cardiac catheterization will require a PET scan.
1227 — (b) Multiply the number resulting from the calculation in subsection (3)(a) by 1.0, which is the
1228 estimated number of PET scans needed for each patient requiring a PET scan.
1229
1230 (4)(a)(b) Multiply the number resulting from the calculation in subsection (4)(a) by 1.0, which is the
1231 estimated number of PET scans needed for each patient requiring a PET scan.
1232
1233 — (5) Sum the numbers resulting from the calculations in subsections (1) through (4) to determine the
1234 total number of projected PET data units.
1235
1236 — (6) Multiply the result calculated in subsection (5) above by a factor of 3.0 if the applicant is
1237 proposing to serve only Planning Area 6 to determine the total number of projected PET data units.
1238
1239 — (7) Multiply the result calculated in subsection (5) above by a factor of 2.0 if the applicant is
1240 proposing to serve only Planning Area 5 to determine the total number of projected PET data units.
1241

1242
1243 **Section 1819. Commitment of diagnosis specific new cancer cases COMPARATIVE REVIEWS;**
1244 **EFFECT ON PRIOR PLANNING POLICIES**

1245
1246 Sec. 1819. PROPOSED PROJECTS REVIEWED UNDER THESE STANDARDS SHALL NOT BE
1247 SUBJECT TO COMPARATIVE REVIEW. THESE CON REVIEW STANDARDS SUPERSEDE AND
1248 REPLACE THE CON STANDARDS FOR PET SCANNER SERVICES APPROVED BY THE CON
1249 COMMISSION ON DECEMBER 12, 2006 AND EFFECTIVE MARCH 8, 2007.
1250

1251 ~~(1) An applicant proposing to use diagnosis specific new cancer cases shall demonstrate all of the~~
1252 ~~following:~~
1253 ~~— (a) Only those cancer diagnoses identified in Section 17(1) and 17(2) shall be included.~~
1254 ~~— (b) Each entity contributing diagnosis specific new cancer case data provides, as part of the~~
1255 ~~application at the time it is submitted to the Department, a signed governing body resolution that identifies~~
1256 ~~the number of diagnosis specific cancer cases being committed to the application and that states no~~
1257 ~~current or future diagnosis specific new cancer case data will be used in support of any other application~~
1258 ~~for a PET unit for a period of five (5) years from the date of start of operations of the approved PET~~
1259 ~~service for which data are being committed. If the required documentation for this subsection is not~~

1260 submitted with the application on the designated application date, the application will be deemed filed on
1261 the first applicable designated application date after all required documentation is received by the
1262 Department.

1263 ~~—(c) For fixed PET scanner services, the geographic location of each entity contributing diagnosis
1264 specific new cancer case data is in the same planning area as the proposed PET service.~~

1265 ~~—(d) For mobile PET scanner services, the geographic location of each entity contributing diagnosis
1266 specific new cancer case data in the planning area(s) for which the proposed PET service contains a
1267 proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical
1268 area counties or 25-mile radius for metropolitan statistical area counties.~~

1269 ~~—(e) No entity contributing diagnosis specific new cancer case data has previously committed or is
1270 committing data to another service that is less than five (5) years from the start of operations of that
1271 service and is listed on the "Department Inventory of Pet Scanners."~~

1272
1273 ~~—(2) No entity currently operating or approved to operate a scanner, whether fixed or mobile, listed
1274 on the "Department Inventory of PET Scanners" shall contribute diagnosis specific new cancer cases.~~

1275
1276 ~~—(3)(a) The Department may not consider a withdrawal of diagnosis specific new cancer case data
1277 during the 120-day application review cycle following the date on which the Department review of the
1278 application commences or after a proposed decision to approve the application has been issued unless
1279 the application is denied, withdrawn, or expired.~~

1280 ~~—(b) The withdrawal must be submitted to the Department in the form of a governing body resolution
1281 that contains the specific CON application number to which the data were originally committed, the legal
1282 applicant entity, the committing entity, the type of data, the date of the meeting in which the governing
1283 body authorized the withdrawal of the data, the governing body president's signature, and the date of the
1284 signature.~~

1285 **Section 19. Documentation of diagnosis specific new cancer case data**

1286 ~~—Sec. 19. (1) An applicant required to document volumes of diagnosis specific new cancer cases
1287 shall submit, as part of its application at the time it is submitted to the Department, documentation from
1288 the Division for Vital Records and Health Statistics verifying the number of diagnosis specific new cancer
1289 cases provided in support of the application for the most recent calendar year for which verifiable data are
1290 available from the State Registrar. If the required documentation for this subsection is not submitted with
1291 the application on the designated application date, the application will be deemed filed on the first
1292 applicable designated application date after all required documentation is received by the Department.~~

1293
1294 ~~—(2) Diagnosis specific new cancer case data supporting an application under these standards shall
1295 be submitted to the Division for Vital Records and Health Statistics using a format and media specified in
1296 instructions from the Department of Community Health.~~

1297 **Section 20. Commitment and documentation of diagnostic cardiac catheterization data**

1298
1299
1300 ~~—Sec. 20. (1) An applicant proposing to use diagnostic cardiac catheterization data shall demonstrate
1301 all of the following:~~

1302 ~~—(a) Each entity contributing diagnostic cardiac catheterization data [pursuant to Section 17(3)(a)]
1303 provides, as part of the application at the time it is submitted to the Department, a signed governing body
1304 resolution that identifies the number of diagnostic cardiac catheterization cases (sessions) committed to
1305 the application and that states no current or future diagnostic cardiac catheterization data will be used in
1306 support of any other application for a PET unit for the duration of the PET service for which data are
1307 being committed for a period of five (5) years from the date of start of operations of the approved PET
1308 service for which data are being committed. If the required documentation for this subsection is not
1309 submitted with the application on the designated application date, the application will be deemed filed on
1310 the first applicable designated application date after all required documentation is received by the
1311
1312~~

1313 Department.
1314 — (b) For fixed PET scanner services, the geographic location of each entity contributing diagnostic
1315 cardiac catheterization data is in the same planning area as the proposed PET unit/service.
1316 — (c) For mobile PET scanner services, the geographic location of each entity contributing diagnosis
1317 specific new cancer case data in the planning area(s) for which the proposed PET service contains a
1318 proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical
1319 area counties or 25-mile radius for metropolitan statistical area counties.
1320 — (d) No entity contributing diagnostic cardiac catheterization data has previously committed or is
1321 committing data to another service that is less than five (5) years from the start of operations of that
1322 service and is listed on the "Department Inventory of Pet Scanners."
1323 — (e) The diagnostic cardiac catheterization case data is from the most recently completed report(s)
1324 of the "Annual Hospital Statistical Questionnaire" produced by the Department, and the contributing entity
1325 has CON Approval to provide diagnostic cardiac catheterization services.
1326
1327 — (2) No entity currently operating or approved to operate a PET scanner, whether fixed or mobile,
1328 listed on the "Department Inventory of PET Scanners" shall contribute diagnostic cardiac catheterization
1329 case data.
1330
1331 — (3)(a) The Department may not consider a withdrawal of diagnostic cardiac catheterization case data
1332 during the 120-day application review cycle following the date on which the Department review of the
1333 application commences or after a proposed decision to approve the application has been denied unless
1334 the application is denied, withdrawn, or expired.
1335 — (b) The withdrawal must be submitted to the Department in the form of a governing body resolution
1336 that contains the specific CON application number to which the data were originally committed, the legal
1337 applicant entity, the committing entity, the type of data, the date of the meeting in which the governing
1338 body authorized the withdrawal of the data, the governing body president's signature, and the date of the
1339 signature.
1340
1341 **Section 21. Commitment and documentation of intractable epilepsy data**
1342
1343 — Sec. 21. (1) An applicant proposing to use intractable epilepsy cases shall demonstrate all of the
1344 following:
1345 — (a) Each entity contributing intractable epilepsy data [pursuant to Section 17(4)(a)] provides, as
1346 part of the application at the time it is submitted to the Department, a signed governing body resolution
1347 that identifies the number of intractable epilepsy cases committed to the application and that states no
1348 current or future intractable epilepsy case data will be used in support of any other application for a PET
1349 unit for the duration of the PET service for which the data are being committed for a period of five (5)
1350 years from the date of start of operations of the approved PET service for which data are being
1351 committed. If the required documentation for this subsection is not submitted with the application on the
1352 designated application date, the application will be deemed filed on the first applicable designated
1353 application date after all required documentation is received by the Department.
1354 — (b) For fixed PET scanner services, the geographic location of each entity contributing intractable
1355 epilepsy case data is in the same planning area as the proposed PET unit/service.
1356 — (c) For mobile PET scanner services, the geographic location of each entity contributing diagnosis
1357 specific new cancer case data in the planning area(s) for which the proposed PET service contains a
1358 proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical
1359 area counties or 25-mile radius for metropolitan statistical area counties.
1360 — (d) No entity contributing intractable epilepsy case data has previously committed or is committing
1361 data to another service that is less than five (5) years from the start of operations of that service and is
1362 listed on the "Department Inventory of Pet Scanners."
1363 — (e) The intractable epilepsy case data is from the most recent Michigan Inpatient Data Base
1364 (MIDB) available to the Department.
1365

1366 ~~—— (2) No entity currently operating or approved to operate a scanner, whether fixed or mobile, listed~~
1367 ~~on the "Department Inventory of Pet Scanners" shall contribute intractable epilepsy case data.~~

1368
1369 ~~—— (3)(a) The Department may not consider a withdrawal of intractable epilepsy case data during the~~
1370 ~~120-day application review cycle following the date on which the Department review of the application~~
1371 ~~commences or after a proposed decision to approve the application unless the application is denied,~~
1372 ~~withdrawn, or expired.~~

1373 ~~—— (b) The withdrawal must be submitted to the Department in the form of a governing body resolution~~
1374 ~~that contains the specific CON application number to which the data were originally committed, the legal~~
1375 ~~applicant entity, the committing entity, the type of data, the date of the meeting in which the governing~~
1376 ~~body authorized the withdrawal of the data, the governing body president's signature, and the date of the~~
1377 ~~signature.~~

1379

1380 | ~~Sec. 22.~~ Counties assigned to each health service area are as follows:

1381

1382

HEALTH SERVICE AREA

COUNTIES

1383

1384

1

Livingston

Monroe

St. Clair

1385

Macomb

Oakland

Washtenaw

1386

Wayne

1387

1388

2

Clinton

Hillsdale

Jackson

1389

Eaton

Ingham

Lenawee

1390

1391

3

Barry

Calhoun

St. Joseph

1392

Berrien

Cass

Van Buren

1393

Branch

Kalamazoo

1394

1395

4

Allegan

Mason

Newaygo

1396

Ionia

Mecosta

Oceana

1397

Kent

Montcalm

Osceola

1398

Lake

Muskegon

Ottawa

1399

1400

5

Genesee

Lapeer

Shiawassee

1401

1402

6

Arenac

Huron

Roscommon

1403

Bay

Iosco

Saginaw

1404

Clare

Isabella

Sanilac

1405

Gladwin

Midland

Tuscola

1406

Gratiot

Ogemaw

1407

1408

7

Alcona

Crawford

Missaukee

1409

Alpena

Emmet

Montmorency

1410

Antrim

Gd Traverse

Oscoda

1411

Benzie

Kalkaska

Otsego

1412

Charlevoix

Leelanau

Presque Isle

1413

Cheboygan

Manistee

Wexford

1414

1415

8

Alger

Gogebic

Mackinac

1416

Baraga

Houghton

Marquette

1417

Chippewa

Iron

Menominee

1418

Delta

Keweenaw

Ontonagon

1419

Dickinson

Luce

Schoolcraft

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Section 23. Planning Areas

APPENDIX B

Sec. 23. COUNTIES BY Health service areas assigned to each planning area are as follows:

PLANNING AREA 1

COUNTIES

HSA 1

Livingston
Macomb
Wayne

Monroe
Oakland

St. Clair
Washtenaw

PLANNING AREA 2

HSA 2

Clinton
Eaton

Hillsdale
Ingham

Jackson
Lenawee

HSA 3

Barry
Berrien
Branch

Calhoun
Cass
Kalamazoo

St. Joseph
Van Buren

PLANNING AREA 3

HSA 4

Allegan
Ionia
Kent
Lake

Mason
Mecosta
Montcalm
Muskegon

Newaygo
Oceana
Osceola
Ottawa

PLANNING AREA 4

HSA 5

Genesee
Arenac

Lapeer
Huron

Shiawassee
Roscommon

HSA 6

Bay
Clare
Gladwin
Gratiot

Iosco
Isabella
Midland
Ogemaw

Saginaw
Sanilac
Tuscola

PLANNING AREA 5

HSA 7

Alcona
Alpena
Antrim
Benzie
Charlevoix
Cheboygan

Crawford
Emmet
Gd Traverse
Kalkaska
Leelanau
Manistee

Missaukee
Montmorency
Oscoda
Otsego
Presque Isle
Wexford

PLANNING AREA 6

HSA 8

Alger
Baraga
Chippewa
Delta
Dickinson

Gogebic
Houghton
Iron
Keweenaw
Luce

Mackinac
Marquette
Menominee
Ontonagon
Schoolcraft

CON REVIEW STANDARDS
FOR PET SCANNER SERVICES

Rural Michigan counties are as follows:

1481	Alcona	Hillsdale	Ogemaw
1482	Alger	Huron	Ontonagon
1483	Antrim	Iosco	Osceola
1484	Arenac	Iron	Oscoda
1485	Baraga	Lake	Otsego
1486	Charlevoix	Luce	Presque Isle
1487	Cheboygan	Mackinac	Roscommon
1488	Clare	Manistee	Sanilac
1489	Crawford	Mason	Schoolcraft
1490	Emmet	Montcalm	Tuscola
1491	Gladwin	Montmorency	
1492	Gogebic	Oceana	

Micropolitan statistical area Michigan counties are as follows:

1496	Allegan	Gratiot	Mecosta
1497	Alpena	Houghton	Menominee
1498	Benzie	Isabella	Midland
1499	Branch	Kalkaska	Missaukee
1500	Chippewa	Keweenaw	St. Joseph
1501	Delta	Leelanau	Shiawassee
1502	Dickinson	Lenawee	Wexford
1503	Grand Traverse	Marquette	

Metropolitan statistical area Michigan counties are as follows:

1507	Barry	Ionia	Newaygo
1508	Bay	Jackson	Oakland
1509	Berrien	Kalamazoo	Ottawa
1510	Calhoun	Kent	Saginaw
1511	Cass	Lapeer	St. Clair
1512	Clinton	Livingston	Van Buren
1513	Eaton	Macomb	Washtenaw
1514	Genesee	Monroe	Wayne
1515	Ingham	Muskegon	

Source:

1519 65 F.R., p. 82238 (December 27, 2000)
 1520 Statistical Policy Office
 1521 Office of Information and Regulatory Affairs
 1522 United States Office of Management and Budget
 1523