

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 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 a ~~N~~ ~~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 a ~~N~~ ~~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 4712.~~
124 ~~—(jjP) "PET equivalent" means the number calculated in accordance with Section 46-17 for a single~~
125 ~~patient visit.~~
126 ~~(kkPQ) "PET procedure" means the acquisition of a single image or image sequence involving a single~~
127 ~~injection of tracer.~~
128 ~~(llQR) "PET scan" means one (1) or more PET procedures performed during a single patient visit.~~
129 ~~(mmRS) "PET scanner" means an FDA-approved full or partial ring scanner or coincidence system that~~
130 ~~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 ~~(nnST) "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 GROUPS OF health service area(s), as applicable, and identified~~
141 ~~LISTED in Section 23 APPENDIX B.~~
142 ~~—(pp) "Radionuclide generator" means the source of radioactive material, other than an accelerator or~~
143 ~~nuclear reactor, used to produce radiopharmaceuticals.~~
144 ~~—(qq) "Radiopharmaceutical" means a radioactive pharmaceutical used for diagnostic or therapeutic~~
145 ~~purposes.~~
146 ~~—(rr) "Relocate a fixed PET scanner" means a change in the location of a fixed PET scanner(s)~~
147 ~~from the existing site to a different site within the relocation zone.~~
148 ~~—(ss) "Relocate an existing fixed PET scanner service" means a change in the location of a fixed~~
149 ~~pet scanner service and its unit(s) from the existing site to a different site within the relocation zone.~~
150 ~~—(tt) "Relocation zone" means a proposed site that is within a 10-mile radius of the existing fixed~~
151 ~~PET scanner service for a metropolitan statistical area county and a 25-mile radius of the existing fixed~~
152 ~~PET scanner service for a rural or micropolitan statistical area county, based upon documentation~~
153 ~~acceptable and verified by the Department.~~
154 ~~—(uu) "Replace a PET scanner" means an equipment change, other than an upgrade, involving a~~
155 ~~PET scanner that results in that applicant operating the same number of PET scanners before and after~~
156 ~~project completion.~~
157 ~~—(vv) "Rural county" means a county not located in a metropolitan statistical area or micropolitan~~
158 ~~statistical areas as those terms are defined under the "standards for defining metropolitan and~~
159 ~~micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of~~
160 ~~the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as~~
161 ~~shown in Appendix A.~~
162 ~~(wwUV) "SPECT" means single photon emission computed tomography.~~

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

175
176 (2) The definitions in Part 222 shall apply to these standards.
177

178 **Section 3. Requirements ~~for approval for all fixed services and mobile host sites~~ TO INITIATE A** 179 **PET SCANNER SERVICE** 180

181 Sec. 3. ~~(1)~~ An applicant proposing to ~~provide~~ INITIATE PET scanner services shall ~~provide~~
182 DEMONSTRATE the following ~~services and medical specialties, AS APPLICABLE TO THE PROPOSED~~
183 PROJECT:
184

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

186 FOLLOWING SERVICES AND SPECIALTIES:

- 187 ~~(a)~~ nuclear medicine services AS DOCUMENTED BY A CERTIFICATE FROM THE US NUCLEAR
188 REGULATORY COMMISSION, ~~as documented on the certificate issued by the Department of~~
189 Environmental Quality,
190 (b) single photon emission computed tomography (SPECT) services,
191 (c) computed tomography (CT) scanning services,
192 (d) magnetic resonance imaging (MRI) services,
193 (e) cardiac catheterization services,
194 (f) open heart surgery,
195 (g) thoracic surgery,
196 (h) cardiology,
197 (i) oncology,
198 (j) radiation oncology,
199 (k) neurology,
200 (l) neurosurgery, and
201 (m) psychiatry.
202

203 ~~(2)~~ If the ~~applicant~~ PROPOSED SITE does not provide any of the services listed in ~~this~~ subsection
204 ~~(1) at the same site at which the proposed PET scanner service will be located~~ ON-SITE, the applicant
205 shall ~~include in the application~~ PROVIDE written contracts or agreements with a hospital(s) located within
206 the same planning area OR 25-MILES RADIUS OF THE PROPOSED SITE for the services not provided
207 at the proposed ~~PET scanner service~~ site.
208

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

210 SOURCE OF RADIOPHARMACEUTICALS.

211

212 ~~(24)~~ If ~~a~~ THE proposed ~~PET scanner service~~ SITE does not ~~involve~~ PROVIDE an on-site source of
213 radiopharmaceuticals, ~~an~~ THE applicant ~~must~~ SHALL provide ~~in the application~~ a written contract or
214 agreement that demonstrates ~~that~~ a reliable supply of radiopharmaceuticals ~~will be available to the~~
215 proposed PET scanner service.
216

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

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

222 (B) THE APPLICANT HAS RECEIVED:

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

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

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

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

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

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

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

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

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

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

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

250 (C) THE APPLICANT HAS NOT INITIATED FIXED PET SCANNER SERVICES UNDER
251 SUBSECTION 3(5) WITHIN THE MOST RECENT 12-MONTH PERIOD AS OF THE DATE THE
252 APPLICATION IS SUBMITTED TO THE DEPARTMENT.

253 (D) AN APPLICANT INITIATING A HOST SITE IN HSA 8 ON A MOBILE PET SCANNER
254 SERVICE THAT OPERATES PREDOMINANTLY OUTSIDE OF MICHIGAN SHALL DEMONSTRATE
255 240 PET DATA UNITS FROM PLANNING AREA 6.

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

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

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

263 (C) 50 PET EQUIVALENTS WERE PERFORMED IN THE MOST RECENT 12-MONTH PERIOD
264 VERIFIABLE BY THE DEPARTMENT FROM AN EXISTING MOBILE PET SCANNER SERVICE FOR
265 AN EXISTING HOST SITE PROPOSING TO INITIATE SERVICES ON A DIFFERENT MOBILE PET
266 SCANNER SERVICE.

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

271 Sec. 4. REPLACING A PET SCANNER(S) MEANS A CHANGE IN THE SCANNER EQUIPMENT
272 OR RELOCATION OF THE SERVICE TO A NEW SITE. AN UPGRADE TO SOFTWARE OR
273 COMPONENTS/PARTS OF AN EXISTING SCANNER DOES NOT CONSTITUTE REPLACEMENT OF
274 A PET SCANNER. (1) An applicant proposing to initiate a fixed PET scanner(S) service shall project an
275 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, AS APPLICABLE TO THE PROPOSED PROJECT. An applicant proposing to initiate a
280 mobile PET scanner service shall project 2,100 PET data units for each proposed mobile PET scanner
281 based on the methodology used in Section 17:

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

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

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

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

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

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

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

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

317 (dC) A signed certification whereby the host site has agreed and assured that it will provide PET
318 services in accordance with the terms for approval set forth in Section 14 and 15. The applicant also
319 shall provide a current route schedule for the mobile PET scanner service. THE EXISTING FIXED PET
320 SCANNER SERVICE HAS BEEN IN OPERATION FOR AT LEAST 36 MONTHS AS OF THE DATE OF
321 THE APPLICATION SUBMITTED TO THE DEPARTMENT.

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

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

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

331 ~~_____ (a) The applicant is proposing to initiate a fixed PET scanner service.~~

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

333 ~~_____ (c) The applicant has received, in aggregate, the following:~~

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

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

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

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

342 343 **Section 5. Requirements ~~for approval for applicants proposing to expand a PET scanner service~~**

344
345 ~~Sec. 5. (1) An applicant proposing to increase EXPAND A the number of fixed PET scanner~~
346 ~~SERVICE (second, third, etc.) shall demonstrate EACH OF the following, AS APPLICABLE TO THE~~
347 ~~PROPOSED PROJECT.:~~

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

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

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

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

367
368 ~~(2) An applicant proposing to increase ADD the number of A mobile PET scanner(s) TO AN~~
369 ~~EXISTING MOBILE PET SCANNER SERVICE (second, third, etc.) shall demonstrate the following:~~

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

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

377 ~~(b) 1,800 PET EQUIVALENTS WERE PERFORMED PER EXISTING AND APPROVED~~
378 ~~SCANNER(S) For an applicant serving only host sites in rural or micropolitan statistical area counties, all~~

379 of the applicant's approved mobile PET scanners on a mobile route have performed an average of at
380 least 4,500 PET equivalents per PET scanner during ~~IN~~ the most recent 12-month period VERIFIABLE
381 for which BY the Department has verifiable data. FOR AN APPLICANT SERVING ONLY HOST SITES IN
382 RURAL OR MICROPOLITAN STATISTICAL AREA COUNTIES.

383
384 (3) An applicant PROPOSING TO ADD A FIXED PET SCANNER TO AN EXISTING FIXED PET
385 SCANNER SERVICE that ~~meets ALSO RECEIVES MOBILE PET SCANNER SERVICES SHALL~~
386 DEMONSTRATE all of the following requirements shall not be required to be in compliance with
387 subsection (1):

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

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

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

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

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

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

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

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

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

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

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

414
415 (4) THIS SECTION DOES NOT APPLY TO DEDICATED RESEARCH, DEDICATED PEDIATRIC,
416 OR POSITRON EMISSION MAMMOGRAPHY (PEM) SCANNERS.

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

420
421 Sec. 6. (1) ~~An applicant proposing to replace an existing fixed ACQUIRING A PET SCANNER~~
422 SERVICE AND ITS scanner(s) MEANS OBTAINING POSSESSION AND CONTROL BY CONTRACT,
423 OWNERSHIP, LEASE, OR OTHER COMPARABLE ARRANGEMENT AND RENEWAL OF LEASE FOR
424 AN EXISTING shall demonstrate that all of the applicant's approved and operating fixed OR MOBILE
425 PET scanners. AN APPLICANT PROPOSING TO ACQUIRE A have performed an average of at least
426 4,500 PET SCANNER SERVICE equivalents SHALL DEMONSTRATE EACH OF THE FOLLOWING, AS
427 APPLICABLE TO THE PROPOSED PROJECT per PET scanner during the most recent 12-month period
428 for which the Department has verifiable data.

429
430 (2) FOR THE FIRST An applicant APPLICATION proposing to ~~replace ACQUIRE~~ an existing
431 FIXED, mobile, OR HOST SITE PET scanner(s) SERVICE, OTHER THAN A RENEWAL OF LEASE,
432 shall demonstrate that all of the applicant's approved and operating mobile PET scanners on OR AFTER

433 ~~<INSERT EFFECTIVE DATE OF STANDARDS>, THE EXISTING-a mobile route have performed an~~
434 ~~average of at least 3,000 PET equivalents per PET scannerSERVICE AND ITS SCANNER(S) SHALL~~
435 ~~NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE APPLICABLE VOLUME REQUIREMENTS~~
436 ~~SET FORTH IN THIS SECTION-during the most recent 12-month period for which the Department has~~
437 ~~verifiable data.~~

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

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

456
457 ~~(4) An applicant proposing to RENEW A LEASE FOR AN EXISTING FIXED OR MOBILE replace a~~
458 ~~PET scanner(s) , whether fixed or mobile, shall demonstrate THAT THE LEASE IS COST EFFECTIVE~~
459 ~~AND THE EXISTING EQUIPMENT DOES NOT POSE A THREAT TO THE SAFETY OF THE PATIENT.~~

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

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

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

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

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

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

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

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

479
480 **Section 7. Requirements for approval for applicants proposing to acquire an existingA**
481 **DEDICATED RESEARCH FIXED PET scanner**

482
483 ~~Sec. 7. An applicant proposing to acquire-ADD an existing-FIXED PET scanner, whether fixed or~~
484 ~~mobile,scanner TO AN EXISTING PET SCANNER SERVICE FOR EXCLUSIVE RESEARCH USE shall~~
485 ~~demonstrate that it meets all of the following EACH OF THE FOLLOWING:~~

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

489
490 ~~(a2) The project is limited solely to the acquisition of an existing~~ DEDICATED RESEARCH PET
491 scanner SHALL OPERATE UNDER A PROTOCOL APPROVED BY THE APPLICANT'S
492 INSTITUTIONAL REVIEW BOARD, AS DEFINED BY PUBLIC LAW 93-348 AND REGULATED BY
493 TITLE 45 CFR 46.

494
495 ~~(b3) The project~~ APPLICANT HAS ACCESS TO A CYCLOTRON FOR ACCELERATING
496 CHARGED PARTICLES TO HIGH ENERGIES BY MEANS will not change the number of PET scanners
497 ~~listed on the Department Inventory of~~ PET Scanners ELECTROMAGNETIC FIELDS.

498
499 ~~(e4) The project~~ PROPOSED SITE CAN HAVE NO MORE THAN THREE DEDICATED
500 RESEARCH FIXED will not result in the replacement of the PET scanners scanners APPROVED UNDER
501 THIS to be acquired unless the applicant demonstrates that the requirements of Section 6 also have been
502 met.

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

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

507
508 **Section 8. Requirements for ~~approval for applicants proposing to acquire an existing A~~**
509 **DEDICATED PEDIATRIC PET scanner ~~service~~**

510
511 Sec. 8. An applicant proposing to ~~acquire~~ INITIATE an existing A PET scanner service, ~~whether OR~~
512 ADD A fixed PET SCANNER TO EXPAND AN EXISTING PET SCANNER SERVICE, FOR DEDICATED
513 PEDIATRIC PET USE, or mobile, shall NOT NEED TO MEET demonstrate that it meets all of the
514 REQUIREMENTS OF SECTION 5 IF THE APPLICANT DEMONSTRATES EACH OF THE following:

515
516 ~~(a1) The project~~ APPLICANT AGREES THAT THE DEDICATED PEDIATRIC is limited solely to the
517 ~~acquisition of an existing~~ PET scanner service scanner WILL BE USED PRIMARILY (70% OR MORE OF
518 THE SCANS) FOR PATIENTS UNDER 18 YEARS OF AGE.

519
520 ~~(b2) The project~~ APPLICANT SHALL DEMONSTRATE will not change the number EXISTING SITE
521 ~~of THE Pet~~ PET scanners SERVICE PROVIDED listed on the FOLLOWING FOR THE MOST RECENT
522 CALENDAR YEAR OR A CONTINUOUS 12-MONTH PERIOD AT THE TIME THE APPLICATION IS
523 SUBMITTED TO THE Department Inventory of PET Scanners:;

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

527
528 ~~_____ (eB) AT LEAST 5,000 PEDIATRIC (< 18 YEARS OLD) SURGERIES, All PET scanners to be~~
529 ~~acquired are listed on the Department Inventory of PET Scanners on the date the application is submitted~~
530 ~~to the Department.~~ AND

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

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

539 _____ (A) RADIOLOGY (AT LEAST TWO STAFF MEMBERS)

540 _____ (B) ANESTHESIOLOGY

- 541 (C) CARDIOLOGY
- 542 (D) CRITICAL CARE
- 543 (E) GASTROENTEROLOGY
- 544 (F) HEMATOLOGY/ONCOLOGY
- 545 (G) NEUROLOGY
- 546 (H) NEUROSURGERY
- 547 (I) ORTHOPEDIC SURGERY
- 548 (J) PATHOLOGY
- 549 (K) PULMONOLOGY
- 550 (L) SURGERY
- 551 (M) NEONATOLOGY

552

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

- 555
- 556 (A) BONE MARROW TRANSPLANT PROGRAM
- 557 (B) SEDATION PROGRAM
- 558 (C) OPEN HEART PROGRAM

559

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

563

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

566

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

569

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

573

574 (1) AN APPLICANT PROPOSING TO ADD A FIXED PEM SCANNER TO AN EXISTING FIXED
575 PET SCANNER SITE SHALL NOT NEED TO MEET THE REQUIREMENTS OF SECTION 5 IF THE
576 APPLICANT DEMONSTRATES THE FOLLOWING:

577 (A) **THE APPLICANT OR THE PROPOSED SITE** IS CERTIFIED THROUGH THE AMERICAN
578 COLLEGE OF RADIOLOGY (ACR) AS A BREAST IMAGING CENTER OF EXCELLENCE (BICOE) AT
579 THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT.

580 (B) THE APPLICANT HAS PERFORMED 1,000 PET EQUIVALENTS PER SCANNER AT THE
581 SITE IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE DEPARTMENT.

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

584

585 (2) AN APPLICANT PROPOSING TO ADD A MOBILE PEM SCANNER TO AN EXISTING
586 MOBILE PET SCANNER SERVICE SHALL NOT NEED TO MEET THE REQUIREMENTS OF SECTION
587 5 IF THE APPLICANT DEMONSTRATES THE FOLLOWING:

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

592 (B) EACH APPLICANT PROVIDES A ROUTE SCHEDULE FOR THE PROPOSED MOBILE PEM
593 SCANNER SERVICE.

594 (C) THE APPLICANT PROVIDES A DRAFT CONTRACT FOR PEM SERVICES BETWEEN THE

595 PROPOSED HOST SITES AND CENTRAL SERVICE COORDINATOR.

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

598
599 (3) AN APPLICANT, WHETHER AN EXISTING FIXED PET SCANNER SITE OR HOST SITE,
600 PROPOSING TO INITIATE MOBILE PEM SCANNER SERVICES AS HOST SITE SHALL
601 DEMONSTRATE THE FOLLOWING AS APPLICABLE TO THE PROPOSED PROJECT:

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

604 (B) FOR AN EXISTING FIXED PET SCANNER SITE, THE APPLICANT HAS PERFORMED 1,000
605 PET EQUIVALENTS PER SERVICE IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY
606 THE DEPARTMENT, AND FOR AN EXISTING PET SCANNER HOST SITE, THE APPLICANT HAS
607 PERFORMED 100 PET EQUIVALENTS IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY
608 THE DEPARTMENT.

609
610 (4) AN APPLICANT PROPOSING TO ADD AN EXISTING PEM SCANNER HOST SITE TO AN
611 EXISTING MOBILE PEM SCANNER SERVICE SHALL DEMONSTRATE THE FOLLOWING:

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

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

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

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

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

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

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

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

627 ~~— (d) The proposed project will not result in an increase in the number of PET scanner(s) operated~~
628 ~~by the applicant at the proposed site unless the applicant demonstrates that the requirements of Section~~
629 ~~5, as applicable, have also been met.~~

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

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

635
636 ~~— (2) An applicant proposing to relocate a PET scanner of an existing PET service shall demonstrate~~
637 ~~that it meets all of the following:~~

638 ~~— (a) The PET scanner to be relocated is a fixed PET scanner.~~

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

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

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

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

646
647 **Section 10. Requirements for approval for applicants proposing a dedicated research fixed PET**
648 **scanner**MEDICAID PARTICIPATION

649
650 Sec. 10. ~~(1) An applicant proposing to operate a fixed PET scanner (whether new or replacement)~~
651 ~~to be used exclusively for research shall demonstrate each of the following~~ PROVIDE VERIFICATION OF
652 MEDICAID PARTICIPATION. AN APPLICANT THAT IS A NEW PROVIDER NOT CURRENTLY
653 ENROLLED IN MEDICAID SHALL CERTIFY THAT PROOF OF MEDICAID PARTICIPATION WILL BE
654 PROVIDED TO THE DEPARTMENT WITHIN (6) MONTHS FROM THE OFFERING OF SERVICES IF A
655 CON IS APPROVED.:
656 ~~— (a) The PET scanner shall operate under a protocol approved by the applicant's Institutional~~
657 ~~Review Board.~~
658 ~~— (b) The applicant agrees to operate the PET scanner in accordance with the terms of approval in~~
659 ~~Section 14(1)(a), (b), (c)(vi), (d)(iii), (iv) and (v); 14(2); 14(3); and 14(4).~~
660 ~~— (c) The applicant has access to a cyclotron.~~
661
662 ~~— (2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the~~
663 ~~requirements and terms of sections 3, 4, 5, 6, 7, 8, 9 and 14(1)(c)(i), (ii), (iii), (iv), (v), (d)(i), and (d)(ii) of~~
664 ~~these standards.~~

665
666 **Section 11. PROJECT DELIVERY Requirements for approval for applicants proposing to establish**
667 **a dedicated pediatric PET scanner AND TERMS OF APPROVAL FOR ALL APPLICANTS**
668

669 Sec. 11. ~~(1) An applicant proposing to establish a dedicated pediatric PET scanner(s) shall~~ AGREE
670 THAT, IF APPROVED, demonstrate all of the following PET SCANNER SERVICES SHALL BE
671 DELIVERED IN COMPLIANCE WITH THE FOLLOWING TERMS OF APPROVAL.:
672

673 ~~— (a1) The applicant shall experience at least 7,000 pediatric (< 18 years old) discharges, excluding~~
674 ~~normal newborns, in the most recent year of operation~~ COMPLIANCE WITH THESE STANDARDS.
675

676 ~~— (b2) The applicant shall experience at least 5,000 pediatric (< 18 years old) surgeries in the most~~
677 ~~recent year of operation~~ COMPLIANCE WITH THE FOLLOWING QUALITY ASSURANCE
678 REQUIREMENTS.:

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

693 ~~(dB) The applicant shall have an active medical staff at the time the application is submitted to the~~
694 ~~Department that~~ PET SCANNER SERVICE SHALL include, but is not limited to, physicians who are
695 ~~fellowship-trained in the following pediatric specialties~~ PERSONNEL, EMPLOYED DIRECTLY OR ON A
696 CONTRACTUAL BASIS: A TECHNOLOGIST WITH TRAINING IN PET SCANNING AND A PHYSICIST.
697 THE PHYSICIST MUST BE BOARD CERTIFIED OR ELIGIBLE FOR CERTIFICATION BY THE
698 AMERICAN BOARD OF RADIOLOGY OR AN EQUIVALENT ORGANIZATION.

- 699 ~~(i) pediatric radiology (at least two staff members)~~
700 ~~— (ii) pediatric anesthesiology~~
701 ~~— (iii) pediatric cardiology~~
702 ~~— (iv) pediatric critical care~~

- 703 ~~— (v) pediatric gastroenterology~~
- 704 ~~— (vi) pediatric hematology/oncology~~
- 705 ~~— (vii) pediatric neurology~~
- 706 ~~— (viii) pediatric neurosurgery~~
- 707 ~~— (ix) pediatric orthopedic surgery~~
- 708 ~~— (x) pediatric pathology~~
- 709 ~~— (xi) pediatric pulmonology~~
- 710 ~~— (xii) pediatric surgery~~
- 711 ~~— (xiii) neonatology~~

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

- 716 ~~(i) pediatric bone marrow transplant program~~
- 717 ~~(ii) established pediatric sedation program~~
- 718 ~~(iii) pediatric open heart program~~

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

721
722 ~~(23) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the~~
723 ~~requirements of Section 4 or Section 5 of these standards but must meet Section 6.~~ COMPLIANCE WITH
724 THE FOLLOWING ACCESS TO CARE REQUIREMENTS:

725 ~~(3A) The dedicated pediatric PET scanner SERVICE shall be excluded~~ ACCEPT REFERRALS FOR
726 PET SCANNER SERVICES from the adult count for ALL APPROPRIATELY LICENSED
727 PRACTITIONERS ~~the facility.~~

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

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

733 (D) THE OPERATION OF AND REFERRAL OF PATIENTS TO THE PET SCANNER SERVICE
734 SHALL BE IN CONFORMANCE WITH 1978 PA 368, SEC. 16221, AS AMENDED BY 1986 PA 319; MCL
735 333.16221; MSA 14.15 (16221).

736
737 (4) COMPLIANCE WITH THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:

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

746 (B) THE PET SCANNER SERVICE SHALL PARTICIPATE IN A DATA COLLECTION SYSTEM
747 ESTABLISHED AND ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE. THE DATA MAY
748 INCLUDE, BUT ARE NOT LIMITED TO, CLINICAL SCAN DATA, ANNUAL BUDGET AND COST
749 INFORMATION, OPERATING SCHEDULES, THROUGH-PUT SCHEDULES, DEMOGRAPHIC AND
750 DIAGNOSTIC INFORMATION, AND THE VOLUME OF CARE PROVIDED TO PATIENTS FROM ALL
751 PAYOR SOURCES. THE APPLICANT SHALL PROVIDE THE REQUIRED DATA ON A SEPARATE
752 BASIS FOR EACH SEPARATE AND DISTINCT SITE, PET SCANNER, OR PET SCANNER SERVICE
753 AS REQUIRED BY THE DEPARTMENT, IN A FORMAT ESTABLISHED BY THE DEPARTMENT. THE
754 DEPARTMENT MAY ELECT TO VERIFY THE DATA THROUGH ON-SITE REVIEW OF APPROPRIATE
755 RECORDS.

756 (C) THE PET SCANNER SERVICE SHALL PROVIDE THE DEPARTMENT WITH TIMELY

757 NOTICE OF THE PROPOSED PROJECT IMPLEMENTATION CONSISTENT WITH APPLICABLE
758 STATUTE AND PROMULGATED RULES.

759
760 (5) COMPLIANCE WITH THE FOLLOWING DEDICATED RESEARCH PET SCANNER
761 REQUIREMENTS, IF APPLICABLE:

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

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

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

769
770 (6) COMPLIANCE WITH THE FOLLOWING DEDICATED PEDIATRIC PET SCANNER
771 REQUIREMENTS, IF APPLICABLE:

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

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

776
777 (7) COMPLIANCE WITH THE FOLLOWING PEM SCANNER REQUIREMENTS, IF APPLICABLE:

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

780
781 (8) COMPLIANCE WITH THE FOLLOWING MOBILE PET SCANNER REQUIREMENTS, IF
782 APPLICABLE:

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

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

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

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

796
797 (9) THE AGREEMENTS AND ASSURANCES REQUIRED BY THIS SECTION SHALL BE IN THE
798 FORM OF A CERTIFICATION AGREED TO BY THE APPLICANT OR ITS AUTHORIZED AGENT.

799
800 **Section 12. ~~Additional requirements~~METHODOLOGY for ~~mobile~~COMPUTING THE PROJECTED**
801 **PET serviceDATA UNITS**

802
803 ~~Sec. 12. (1)-An applicant proposing to begin operation of a mobile PET service shall demonstrate all~~
804 ~~of the following~~BEING REVIEWED UNDER SECTION 3 SHALL APPLY THE METHODOLOGY SET
805 FORTH IN THIS SECTION IN COMPUTING THE PROJECTED NUMBER OF PET DATA UNITS:

806
807 ~~(a1) A separate CON application has been submitted by the central service coordinator and each~~
808 ~~proposed host site~~IDENTIFY THE NUMBER OF DIAGNOSIS-SPECIFIC NEW CANCER CASES
809 DOCUMENTED IN ACCORDANCE WITH THE REQUIREMENTS OF SECTION 13.

810 ~~(bA) A proposed regular route schedule, the procedures for handling emergency situations, and~~

811 ~~copies of all proposed contracts related to the mobile PET service have been included in the CON~~
812 ~~application.~~ COMBINE THE NUMBER OF CANCER CASES FOR LUNG (SITE CODES C340-C349),
813 ESOPHAGUS (SITE CODES C150-C159), COLORECTAL (SITE CODES C180-C209), LYMPHOMA
814 (MORPHOLOGY CODES (9590-9729), MELANOMA (MORPHOLOGY CODES 8720-8790), AND HEAD
815 & NECK [SITE CODES C000-C148, C300-C329, C410, C411, C470 OR C490 EXCLUDING C440-C444
816 (SKIN OF HEAD AND NECK), AND ADDITIONAL CODES APPROVED BY NATIONAL COVERAGE
817 DETERMINATION]. USE THE NAME "COMBINED" FOR THIS GROUPING.

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

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

825
826 (2) An applicant proposing to become a host site on an existing mobile PET scanner service shall
827 demonstrate that it meets all of the following: IDENTIFY THE NUMBER OF DIAGNOSIS-SPECIFIC NEW
828 CANCER CASES DOCUMENTED IN ACCORD WITH THE REQUIREMENTS OF SECTION 13.

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

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

839
840 (3) MULTIPLY THE NUMBER OF DIAGNOSTIC CARDIAC CATHETERIZATION CASES
841 IDENTIFIED IN ACCORD WITH THE REQUIREMENTS OF SECTION 15 BY 0.1, WHICH IS THE
842 ESTIMATED PROBABILITY THAT A PATIENT HAVING A DIAGNOSTIC CARDIAC
843 CATHETERIZATION WILL REQUIRE A PET SCAN.

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

852
853 (5) SUM THE NUMBERS RESULTING FROM THE CALCULATIONS IN SUBSECTIONS (1)
854 THROUGH (4) TO DETERMINE THE TOTAL NUMBER OF PROJECTED PET DATA UNITS.

855
856 (6) MULTIPLY THE RESULT CALCULATED IN SUBSECTION (5) ABOVE BY A FACTOR OF 3.0
857 IF THE APPLICANT IS PROPOSING TO SERVE ONLY PLANNING AREA 6 TO DETERMINE THE
858 TOTAL NUMBER OF PROJECTED PET DATA UNITS.

859
860 (7) MULTIPLY THE RESULT CALCULATED IN SUBSECTION (5) ABOVE BY A FACTOR OF 2.0
861 IF THE APPLICANT IS PROPOSING TO SERVE ONLY PLANNING AREA 5 TO DETERMINE THE
862 TOTAL NUMBER OF PROJECTED PET DATA UNITS.

863
864 **Section 13. Requirements for approval for all applicants** COMMITMENT OF DIAGNOSIS-SPECIFIC

865 **NEW CANCER CASES**

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

873
874 **(1) ONLY THOSE CANCER DIAGNOSES IDENTIFIED IN SECTION 12(1) AND 12(2) SHALL BE**
875 **INCLUDED.**

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

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

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

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

901
902 **(3) NO ENTITY CURRENTLY OPERATING OR APPROVED TO OPERATE A PET SCANNER**
903 **SERVICE SHALL CONTRIBUTE DIAGNOSIS-SPECIFIC NEW CANCER CASES.**

904
905 **(4) THE DEPARTMENT MAY NOT CONSIDER A WITHDRAWAL OF DIAGNOSIS-SPECIFIC**
906 **NEW CANCER CASE DATA DURING THE 120-DAY APPLICATION REVIEW CYCLE FOLLOWING**
907 **THE DATE ON WHICH THE DEPARTMENT REVIEW OF THE APPLICATION COMMENCES OR**
908 **AFTER A PROPOSED DECISION TO APPROVE THE APPLICATION HAS BEEN ISSUED UNLESS**
909 **THE APPLICATION IS DENIED, WITHDRAWN, OR EXPIRED. THE WITHDRAWAL MUST BE**
910 **SUBMITTED TO THE DEPARTMENT IN THE FORM OF A GOVERNING BODY RESOLUTION THAT**
911 **CONTAINS THE SPECIFIC CON APPLICATION NUMBER TO WHICH THE DATA WERE ORIGINALLY**
912 **COMMITTED, THE LEGAL APPLICANT ENTITY, THE COMMITTING ENTITY, THE TYPE OF DATA,**
913 **THE DATE OF THE MEETING IN WHICH THE GOVERNING BODY AUTHORIZED THE WITHDRAWAL**
914 **OF THE DATA, THE GOVERNING BODY PRESIDENT'S SIGNATURE, AND THE DATE OF THE**
915 **SIGNATURE.**

917 **Section -14. Project delivery requirements and terms of approval for all applicants**
918 **DOCUMENTATION OF DIAGNOSIS-SPECIFIC NEW CANCER CASE DATA**
919

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

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

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

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

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

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

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

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

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

960 ~~— (v) At a minimum, the PET service team shall include the following personnel, employed directly by~~
961 ~~the applicant or on a contractual basis: (A) a team leader, (B) technologists with training in PET~~
962 ~~scanning, (C) radiation safety personnel, and (D) a physicist(s). The physicist(s) must be board certified~~
963 ~~or eligible for certification by the American Board of Radiology or an equivalent organization. Other~~
964 ~~personnel that may be appropriate members of the PET service team, depending on the type of operation~~
965 ~~and PET procedures performed, include but are not limited to nurses, computer technicians, radio-~~
966 ~~chemists, radio-chemistry technicians, radio-pharmacists, and instrument maintenance technicians. If the~~
967 ~~team leader is not a physician, the PET service team also shall include a physician with appropriate~~
968 ~~training and familiarity with the appropriate diagnostic use and interpretation of cross-sectional images of~~
969 ~~the anatomical region(s) to be examined.~~

970 ~~— (vi) The applicant shall have, within the PET service, equipment and supplies to handle clinical~~

971 ~~emergencies that might occur within the PET service, with PET staff trained in CPR and other appropriate~~
972 ~~emergency interventions, and a physician on-site or immediately available to the PET service at all times~~
973 ~~when patients are undergoing PET procedures.~~
974 ~~— (vii) An applicant shall participate in Medicaid at least 12 consecutive months within the first two~~
975 ~~years of operation and continue to participate annually thereafter.~~
976 ~~— (viii) Fixed and mobile PET scanner units shall be operating at a minimum average annual level of~~
977 ~~utilization during the second twelve months of operation, and annually thereafter, of 1,500 PET~~
978 ~~equivalents per unit.~~
979 ~~— (d) Compliance with the following requirements:~~
980 ~~— (i) The applicant shall accept referrals for PET scanner services from all appropriately licensed~~
981 ~~practitioners.~~
982 ~~— (ii) The applicant, to assure that the PET scanner services will be utilized by all segments of the~~
983 ~~Michigan population, shall (A) not deny PET scanner services to any individual based on ability to pay or~~
984 ~~source of payment, (B) provide PET scanning services to any individual based on the clinical indications~~
985 ~~of need for the service, and (C) maintain information by payor and non-paying sources to indicate the~~
986 ~~volume of care from each source provided annually.~~
987 ~~— Compliance with selective contracting requirements shall not be construed as a violation of this~~
988 ~~term.~~
989 ~~— (iii) The applicant shall participate in a data collection network established and administered by the~~
990 ~~Department or its designee. The data may include, but are not limited to annual budget and cost~~
991 ~~information, operating schedules, through-put schedules, demographic and diagnostic information, the~~
992 ~~volume of care provided to patients from all payor sources, and other data requested by the Department~~
993 ~~or its designee. The applicant shall provide the required data on a separate basis for each separate and~~
994 ~~distinct site, PET scanner, or PET service as required by the Department, in a format established by the~~
995 ~~Department, and in a mutually agreed upon media. The Department may elect to verify the data through~~
996 ~~on-site review of appropriate records. If the applicant intends to include research PET equivalents~~
997 ~~conducted by a PET scanner other than a dedicated research PET scanner in its utilization statistics, the~~
998 ~~applicant shall submit to the Department a copy of the research protocol with evidence of approval by the~~
999 ~~Institutional Review Board. The applicant shall submit this at the time the applicant intends to include~~
1000 ~~research procedures in its utilization statistics. The applicant shall separately report to the Department~~
1001 ~~any PET equivalents conducted by a dedicated research PET scanner.~~
1002 ~~— (iv) PET equipment to be replaced shall be removed from service on or before beginning operation~~
1003 ~~of the replacement equipment, including the use of temporary scanners as part of the replacement~~
1004 ~~project.~~
1005 ~~— (v) The applicant shall provide the Department with a notice stating the first date on which the PET~~
1006 ~~scanner became operational, and such notice shall be submitted to the Department consistent with~~
1007 ~~applicable statute and promulgated rules.~~
1008
1009 ~~— (2) An applicant for a dedicated research PET scanner under Section 10 shall agree that the~~
1010 ~~services provided by the PET scanner approved pursuant to Section 10 shall be delivered in compliance~~
1011 ~~with the following terms of CON approval:~~
1012 ~~— (a) The capital and operating costs relating to the dedicated research PET scanner approved~~
1013 ~~pursuant to Section 8 shall be charged only to a specific research account(s) and not to any patient or~~
1014 ~~third-party payor.~~
1015 ~~— (b) The dedicated research PET scanner approved pursuant to Section 10 shall not be used for~~
1016 ~~any purposes other than as approved by the Institutional Review Board unless the applicant has obtained~~
1017 ~~CON approval for the PET scanner pursuant to Part 222 and these standards, other than Section 10.~~
1018
1019 ~~— (3) The operation of and referral of patients to the PET service shall be in conformance with 1978~~
1020 ~~PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).~~
1021
1022 ~~— (4) The agreements and assurances required by this section shall be in the form of a certification~~
1023 ~~authorized by the governing body of the applicant or its authorized agent.~~
1024

1025 **Section 15. ~~Project delivery requirements and additional terms of approval for applicants~~**
1026 **~~involving mobile PET services~~COMMITMENT AND DOCUMENTATION OF DIAGNOSTIC CARDIAC**
1027 **CATHETERIZATION DATA**
1028

1029 Sec. 15. AN APPLICANT PROPOSING TO USE DIAGNOSTIC CARDIAC CATHETERIZATION
1030 DATA SHALL DEMONSTRATE ALL OF THE FOLLOWING:
1031

1032 (1) EACH ENTITY CONTRIBUTING DIAGNOSTIC CARDIAC CATHETERIZATION DATA
1033 PROVIDES, AS PART OF THE APPLICATION AT THE TIME IT IS SUBMITTED TO THE
1034 DEPARTMENT, A SIGNED GOVERNING BODY RESOLUTION THAT IDENTIFIES THE NUMBER OF
1035 DIAGNOSTIC CARDIAC CATHETERIZATION CASES (SESSIONS) COMMITTED TO THE
1036 APPLICATION AND THAT STATES NO CURRENT OR FUTURE DIAGNOSTIC CARDIAC
1037 CATHETERIZATION DATA WILL BE USED IN SUPPORT OF ANY OTHER APPLICATION FOR A PET
1038 UNIT FOR THE DURATION OF THE PET SERVICE FOR WHICH DATA ARE BEING COMMITTED
1039 FOR A PERIOD OF FIVE (5) YEARS FROM THE DATE OF START OF OPERATIONS OF THE
1040 APPROVED PET SERVICE FOR WHICH DATA ARE BEING COMMITTED. IF THE REQUIRED
1041 DOCUMENTATION FOR THIS SUBSECTION IS NOT SUBMITTED WITH THE APPLICATION ON THE
1042 DESIGNATED APPLICATION DATE, THE APPLICATION WILL BE DEEMED FILED ON THE FIRST
1043 APPLICABLE DESIGNATED APPLICATION DATE AFTER ALL REQUIRED DOCUMENTATION IS
1044 RECEIVED BY THE DEPARTMENT.

1045 (A) FOR FIXED PET SCANNER SERVICES, THE GEOGRAPHIC LOCATION OF EACH ENTITY
1046 CONTRIBUTING DIAGNOSTIC CARDIAC CATHETERIZATION DATA IS IN THE SAME PLANNING
1047 AREA AS THE PROPOSED PET UNIT/SERVICE.

1048 (B) FOR MOBILE PET SCANNER SERVICES, THE GEOGRAPHIC LOCATION OF EACH
1049 ENTITY CONTRIBUTING DIAGNOSTIC CARDIAC CATHETERIZATION CASE DATA IN THE
1050 PLANNING AREA(S) FOR WHICH THE PROPOSED PET SERVICE CONTAINS A PROPOSED HOST
1051 SITE OR WITHIN A 75-MILE RADIUS OF THE PROPOSED HOST SITE FOR RURAL AND
1052 MICROPOLITAN STATISTICAL AREA COUNTIES OR 25-MILE RADIUS FOR METROPOLITAN
1053 STATISTICAL AREA COUNTIES.

1054 (C) NO ENTITY CONTRIBUTING DIAGNOSTIC CARDIAC CATHETERIZATION DATA HAS
1055 PREVIOUSLY COMMITTED OR IS COMMITTING DATA TO ANOTHER SERVICE THAT IS LESS
1056 THAN FIVE (5) YEARS FROM THE START OF OPERATIONS OF THAT SERVICE.

1057 (D) THE DIAGNOSTIC CARDIAC CATHETERIZATION CASE DATA IS FROM THE MOST
1058 RECENTLY COMPLETED REPORT(S) OF THE ANNUAL SURVEY PRODUCED BY THE
1059 DEPARTMENT, AND THE CONTRIBUTING ENTITY HAS CON APPROVAL TO PROVIDE
1060 DIAGNOSTIC CARDIAC CATHETERIZATION SERVICES.

1061
1062 (2) NO ENTITY CURRENTLY OPERATING OR APPROVED TO OPERATE A PET SCANNER
1063 SERVICE SHALL CONTRIBUTE DIAGNOSTIC CARDIAC CATHETERIZATION CASE DATA.
1064

1065 (3) THE DEPARTMENT MAY NOT CONSIDER A WITHDRAWAL OF DIAGNOSTIC CARDIAC
1066 CATHETERIZATION CASE DATA DURING THE 120-DAY APPLICATION REVIEW CYCLE
1067 FOLLOWING THE DATE ON WHICH THE DEPARTMENT REVIEW OF THE APPLICATION
1068 COMMENCES OR AFTER A PROPOSED DECISION TO APPROVE THE APPLICATION HAS BEEN
1069 DENIED UNLESS THE APPLICATION IS DENIED, WITHDRAWN, OR EXPIRED. THE WITHDRAWAL
1070 MUST BE SUBMITTED TO THE DEPARTMENT IN THE FORM OF A GOVERNING BODY
1071 RESOLUTION THAT CONTAINS THE SPECIFIC CON APPLICATION NUMBER TO WHICH THE DATA
1072 WERE ORIGINALLY COMMITTED, THE LEGAL APPLICANT ENTITY, THE COMMITTING ENTITY,
1073 THE TYPE OF DATA, THE DATE OF THE MEETING IN WHICH THE GOVERNING BODY
1074 AUTHORIZED THE WITHDRAWAL OF THE DATA, THE GOVERNING BODY PRESIDENT'S
1075 SIGNATURE, AND THE DATE OF THE SIGNATURE.
1076

1077 ~~(1) In addition to the provisions of Section 14, an applicant for a mobile PET services shall agree that the~~
1078 ~~services provided by the mobile PET scanner(s) shall be delivered in compliance with the following terms~~

1079 of CON approval:
1080 — (a) The central service coordinator for a mobile PET service, with an approved CON, shall notify
1081 the administrative unit of the Department of Community Health responsible for administering the CON
1082 program 30 days prior to dropping an existing host site.
1083 — (b) Each host site must have at least one physician who is board certified or board eligible in
1084 nuclear medicine or nuclear radiology on its medical staff. The physician(s) shall be responsible for (i)
1085 establishing patient examination and infusion protocol and (ii) providing for the interpretation of scans
1086 performed by the mobile PET service/scanner.
1087 — (c) Each mobile PET scanner service shall have an operations committee with members
1088 representing each host site, the central service coordinator, and the medical director. This committee
1089 shall oversee the effective and efficient use of the PET scanner, establish the regular route schedule,
1090 identify the process by which changes are to be made to the schedule, develop procedures for handling
1091 emergency situations, and review the ongoing operations of the mobile PET scanner service on at least a
1092 quarterly basis.
1093 — (d) The central service coordinator shall arrange for emergency repair services to be available 24
1094 hours each day for the mobile PET scanner equipment as well as the vehicle transporting the equipment.
1095 In addition, to preserve image quality and minimize PET scanner downtime, calibration checks shall be
1096 performed on the PET scanner unit at least once each work day or in accordance with the manufacturer's
1097 requirements. Routine maintenance services shall be provided on a regularly scheduled basis, at least
1098 once a week or in accordance with the manufacturer's requirements, during hours not normally used for
1099 patient procedures.
1100 — (e) Each host site shall provide a properly prepared parking pad, for the mobile PET scanner unit,
1101 of sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for
1102 patients to enter the vehicle without going outside (such as an enclosed canopy or an enclosed corridor).
1103 Each host site also must provide the capability for processing the film and maintaining the confidentiality
1104 of patient records. A communication system must be provided between the mobile vehicle and each host
1105 site to provide for immediate notification of emergency medical situations.
1106 — (f) A mobile PET scanner service shall operate under a contractual agreement that includes the
1107 provision of PET services at each host site on a regularly scheduled basis.
1108 — (g) The volume of utilization at each host site shall be reported to the Department by the central
1109 service coordinator under the terms of Section 14(1)(d)(iii).
1110
1111 — (2) The agreements and assurances required by this section shall be in the form of a certification
1112 authorized by the owner or the governing body of the applicant or its authorized agent.
1113

1114 **Section 16. Determination of PET equivalents COMMITMENT AND DOCUMENTATION OF**
1115 **INTRACTABLE EPILEPSY DATA**

1116
1117 Sec. 16. AN APPLICANT PROPOSING TO USE INTRACTABLE EPILEPSY CASES SHALL
1118 DEMONSTRATE ALL OF THE FOLLOWING:

1119
1120 (1) EACH ENTITY CONTRIBUTING INTRACTABLE EPILEPSY DATA PROVIDES, AS PART OF
1121 THE APPLICATION AT THE TIME IT IS SUBMITTED TO THE DEPARTMENT, A SIGNED GOVERNING
1122 BODY RESOLUTION THAT IDENTIFIES THE NUMBER OF INTRACTABLE EPILEPSY CASES
1123 COMMITTED TO THE APPLICATION AND THAT STATES NO CURRENT OR FUTURE INTRACTABLE
1124 EPILEPSY CASE DATA WILL BE USED IN SUPPORT OF ANY OTHER APPLICATION FOR A PET
1125 UNIT FOR THE DURATION OF THE PET SERVICE FOR WHICH THE DATA ARE BEING COMMITTED
1126 FOR A PERIOD OF FIVE (5) YEARS FROM THE DATE OF START OF OPERATIONS OF THE
1127 APPROVED PET SERVICE FOR WHICH DATA ARE BEING COMMITTED. IF THE REQUIRED
1128 DOCUMENTATION FOR THIS SUBSECTION IS NOT SUBMITTED WITH THE APPLICATION ON THE
1129 DESIGNATED APPLICATION DATE, THE APPLICATION WILL BE DEEMED FILED ON THE FIRST
1130 APPLICABLE DESIGNATED APPLICATION DATE AFTER ALL REQUIRED DOCUMENTATION IS
1131 RECEIVED BY THE DEPARTMENT.

1132 (A) FOR FIXED PET SCANNER SERVICES, THE GEOGRAPHIC LOCATION OF EACH ENTITY

1133 CONTRIBUTING INTRACTABLE EPILEPSY CASE DATA IS IN THE SAME PLANNING AREA AS THE
1134 PROPOSED PET UNIT/SERVICE.

1135 (B) FOR MOBILE PET SCANNER SERVICES, THE GEOGRAPHIC LOCATION OF EACH
1136 ENTITY CONTRIBUTING INTRACTABLE EPILEPSY CASE DATA IN THE PLANNING AREA(S) FOR
1137 WHICH THE PROPOSED PET SCANNER SERVICE CONTAINS A PROPOSED HOST SITE OR
1138 WITHIN A 75-MILE RADIUS OF THE PROPOSED HOST SITE FOR RURAL AND MICROPOLITAN
1139 STATISTICAL AREA COUNTIES OR 25-MILE RADIUS FOR METROPOLITAN STATISTICAL AREA
1140 COUNTIES.

1141 (C) NO ENTITY CONTRIBUTING INTRACTABLE EPILEPSY CASE DATA HAS PREVIOUSLY
1142 COMMITTED OR IS COMMITTING DATA TO ANOTHER SERVICE THAT IS LESS THAN FIVE (5)
1143 YEARS FROM THE START OF OPERATIONS OF THAT SERVICE.

1144 (D) THE INTRACTABLE EPILEPSY CASE DATA IS FROM THE MOST RECENT MICHIGAN
1145 INPATIENT DATA BASE (MIDB) AVAILABLE TO THE DEPARTMENT.

1146
1147 (2) NO ENTITY CURRENTLY OPERATING OR APPROVED TO OPERATE A SCANNER SHALL
1148 CONTRIBUTE INTRACTABLE EPILEPSY CASE DATA.

1149
1150 (3) THE DEPARTMENT MAY NOT CONSIDER A WITHDRAWAL OF INTRACTABLE EPILEPSY
1151 CASE DATA DURING THE 120-DAY APPLICATION REVIEW CYCLE FOLLOWING THE DATE ON
1152 WHICH THE DEPARTMENT REVIEW OF THE APPLICATION COMMENCES OR AFTER A
1153 PROPOSED DECISION TO APPROVE THE APPLICATION UNLESS THE APPLICATION IS DENIED,
1154 WITHDRAWN, OR EXPIRED. THE WITHDRAWAL MUST BE SUBMITTED TO THE DEPARTMENT IN
1155 THE FORM OF A GOVERNING BODY RESOLUTION THAT CONTAINS THE SPECIFIC CON
1156 APPLICATION NUMBER TO WHICH THE DATA WERE ORIGINALLY COMMITTED, THE LEGAL
1157 APPLICANT ENTITY, THE COMMITTING ENTITY, THE TYPE OF DATA, THE DATE OF THE
1158 MEETING IN WHICH THE GOVERNING BODY AUTHORIZED THE WITHDRAWAL OF THE DATA,
1159 THE GOVERNING BODY PRESIDENT'S SIGNATURE, AND THE DATE OF THE SIGNATURE.

1160
1161
1162 ~~For purposes of these standards, PET equivalents shall be calculated as follows:~~

1163 ~~_____ (a) Each actual patient visit performed during the time period specified in the applicable section(s)~~
1164 ~~of these standards shall be assigned a number of PET equivalents based on the sum of the applicable~~
1165 ~~values set forth in subsections (i) through (vii).~~

1166 ~~_____ (i) A single patient visit _____ 1.0~~

1167 ~~_____ (ii) Number of chemically different tracers~~
1168 ~~used during a single patient visit.~~

1169 ~~_____ 1 tracers = 0~~

1170 ~~_____ ≥2 tracers = 0.8~~

1171 ~~_____ (iii) Number of tracer injections performed~~
1172 ~~during a single patient visit.~~

1173 ~~_____ 1 tracer injection = 0~~

1174 ~~_____ 2 tracer injections = 0.3~~

1175 ~~_____ ≥3 tracer injections = 0.6~~

1176 ~~_____ (iv) Dynamic scan(s) performed during a single _____ 0.5~~
1177 ~~patient visit.~~

1178 ~~_____ (v) Number of bed positions used during a single~~
1179 ~~patient visit.~~

1180 ~~_____ 1 bed position = 0~~

1181 ~~_____ ≥2 bed positions = 0.2 for each additional position~~

1182 ~~_____ (vi) Arterial sampling performed during a single _____ 0.5~~
1183 ~~patient visit.~~

1184 ~~_____ (vii) Transmission scan _____ .1 per bed position~~

1185 ~~_____ **Total PET Equivalents for a Single Patient Visit**~~

1186 ~~_____ (b) For each pediatric patient visit, the PET equivalent(s) determined pursuant to subdivision (a)~~

1187 shall be multiplied as follows:
 1188 ~~_____ patient ≤ 5 years of age multiply by 4.0~~
 1189 ~~_____ patient >5≤10 years of age multiply by 3.0~~
 1190 ~~_____ patient >10≤17 years of age multiply by 2.0~~
 1191 ~~_____ (c) For each radiation therapy patient visit, the PET equivalent(s) determined pursuant to~~
 1192 ~~subdivision (a) shall be multiplied by 1.5.~~
 1193 ~~_____ (d) The PET equivalents for each patient visit determined pursuant to subdivisions (a), (b) and (c)~~
 1194 ~~shall be summed to determine the total PET equivalents for the time period specified in the applicable~~
 1195 ~~section(s) of these standards.~~

1196 **SECTION 17. METHODOLOGY FOR COMPUTING PET EQUIVALENTS**

1197 _____
 1198 Sec. 17. For purposes of these standards, PET equivalents shall be calculated as follows:
 1199 _____

<u>TABLE1</u> <u>PET EQUIVALENTS</u>	
<u>Scan Category</u>	<u>Weight</u>
<u>Simple</u> ¹	<u>0.75</u>
<u>Standard</u>	<u>1.0</u>
<u>Complex</u> ²	<u>1.5</u>
¹ Brain and single cardiac scans.	
² Inpatient radiation treatment when patient position device is used, cardiac rest/stress perfusion and metabolism, standard study with additional limited scan, and all pediatric scans.	

1200 _____
 1201 **Section 4718. Methodology for computing the projected number of PET data units**
 1202 **DEPARTMENT INVENTORY OF PET SCANNERS**
 1203 _____

1204 Sec. 4718. THE DEPARTMENT SHALL MAINTAIN AND PUBLICLY POST ON ITS WEB SITE A
 1205 LIST OF PET SCANNER SERVICES ANNUALLY.

1206 ~~—The applicant being reviewed under Section 4 shall apply the methodology set forth in this section in~~
 1207 ~~computing the projected number of PET data units.~~

1208 _____
 1209 ~~—(1)(a) Identify the number of diagnosis-specific new cancer cases documented in accord with the~~
 1210 ~~requirements of Section 18.~~

1211 ~~_____ (b) Combine the number of cancer cases for lung (site codes C340-C349), esophagus (site codes~~
 1212 ~~C150-C159), colorectal (site codes C180-C209), lymphoma (morphology codes 9590-9729), melanoma~~
 1213 ~~(morphology codes 8720-8790), and head & neck [site codes C000-C148, C300-C329, C410, C411,~~
 1214 ~~C470-OR-C490 excluding C440-C444 (skin of head and neck), and additional codes approved by~~
 1215 ~~National Coverage Determination]. Use the name “combined” for this grouping.~~

1216 ~~_____ (c) Multiply the number resulting from the calculation in “combined” cancer cases identified in~~
 1217 ~~subsection (1)(b) by 0.8, which is the estimated probability that a “combined” cancer case will require a~~
 1218 ~~PET scan.~~

1219 ~~_____ (d) Multiply the number resulting from the calculation in subsection (1)(c) by 2.5, which is the~~
 1220 ~~estimated number of PET scans needed for each patient requiring a PET scan.~~

1221 _____
 1222 ~~—(2)(a) Identify the number of diagnosis-specific new cancer cases documented in accord with the~~
 1223 ~~requirements of Section 18.~~

1224 ~~_____ (b) Multiply the number of breast cancer cases (site codes C500-C509) by 0.25, which is the~~
 1225 ~~estimated probability that a breast cancer case will require a PET scan.~~

1226 ~~_____ (c) Multiply the number resulting from the calculation in subsection (2)(b) by 1.0, which is the~~
 1227 ~~estimated number of PET scans needed for each patient requiring a PET scan.~~
 1228 _____

- 1229 ~~—(3)(a) Multiply the number of diagnostic cardiac catheterization cases identified in accord with the~~
1230 ~~requirements of Section 20 by 0.1, which is the estimated probability that a patient having a diagnostic~~
1231 ~~cardiac catheterization will require a PET scan.~~
1232 ~~—(b) Multiply the number resulting from the calculation in subsection (3)(a) by 1.0, which is the~~
1233 ~~estimated number of PET scans needed for each patient requiring a PET scan.~~
1234
1235 ~~(4)(a)(b) Multiply the number resulting from the calculation in subsection (4)(a) by 1.0, which is the~~
1236 ~~estimated number of PET scans needed for each patient requiring a PET scan.~~
1237
1238 ~~—(5) Sum the numbers resulting from the calculations in subsections (1) through (4) to determine the~~
1239 ~~total number of projected PET data units.~~
1240
1241 ~~—(6) Multiply the result calculated in subsection (5) above by a factor of 3.0 if the applicant is~~
1242 ~~proposing to serve only Planning Area 6 to determine the total number of projected PET data units.~~
1243
1244 ~~—(7) Multiply the result calculated in subsection (5) above by a factor of 2.0 if the applicant is~~
1245 ~~proposing to serve only Planning Area 5 to determine the total number of projected PET data units.~~
1246
1247

1248 **Section 1819. Commitment of diagnosis specific new cancer cases COMPARATIVE REVIEWS;**
1249 **EFFECT ON PRIOR PLANNING POLICIES**

1250
1251 Sec. 1819. PROPOSED PROJECTS REVIEWED UNDER THESE STANDARDS SHALL NOT BE
1252 SUBJECT TO COMPARATIVE REVIEW. THESE CON REVIEW STANDARDS SUPERSEDE AND
1253 REPLACE THE CON STANDARDS FOR PET SCANNER SERVICES APPROVED BY THE CON
1254 COMMISSION ON DECEMBER 12, 2006 AND EFFECTIVE MARCH 8, 2007.
1255

1256 ~~(1) An applicant proposing to use diagnosis specific new cancer cases shall demonstrate all of the~~
1257 ~~following:~~

- 1258 ~~—(a) Only those cancer diagnoses identified in Section 17(1) and 17(2) shall be included.~~
1259 ~~—(b) Each entity contributing diagnosis specific new cancer case data provides, as part of the~~
1260 ~~application at the time it is submitted to the Department, a signed governing body resolution that identifies~~
1261 ~~the number of diagnosis specific cancer cases being committed to the application and that states no~~
1262 ~~current or future diagnosis specific new cancer case data will be used in support of any other application~~
1263 ~~for a PET unit for a period of five (5) years from the date of start of operations of the approved PET~~
1264 ~~service for which data are being committed. If the required documentation for this subsection is not~~
1265 ~~submitted with the application on the designated application date, the application will be deemed filed on~~
1266 ~~the first applicable designated application date after all required documentation is received by the~~
1267 ~~Department.~~
1268 ~~—(c) For fixed PET scanner services, the geographic location of each entity contributing diagnosis~~
1269 ~~specific new cancer case data is in the same planning area as the proposed PET service.~~
1270 ~~—(d) For mobile PET scanner services, the geographic location of each entity contributing diagnosis~~
1271 ~~specific new cancer case data in the planning area(s) for which the proposed PET service contains a~~
1272 ~~proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical~~
1273 ~~area counties or 25-mile radius for metropolitan statistical area counties.~~
1274 ~~—(e) No entity contributing diagnosis specific new cancer case data has previously committed or is~~
1275 ~~committing data to another service that is less than five (5) years from the start of operations of that~~
1276 ~~service and is listed on the "Department Inventory of Pet Scanners."~~

1277
1278 ~~—(2) No entity currently operating or approved to operate a scanner, whether fixed or mobile, listed~~
1279 ~~on the "Department Inventory of PET Scanners" shall contribute diagnosis specific new cancer cases.~~

1280
1281 ~~—(3)(a) The Department may not consider a withdrawal of diagnosis specific new cancer case data~~
1282 ~~during the 120-day application review cycle following the date on which the Department review of the~~

1283 application commences or after a proposed decision to approve the application has been issued unless
1284 the application is denied, withdrawn, or expired.

1285 ~~— (b) The withdrawal must be submitted to the Department in the form of a governing body resolution~~
1286 ~~that contains the specific CON application number to which the data were originally committed, the legal~~
1287 ~~applicant entity, the committing entity, the type of data, the date of the meeting in which the governing~~
1288 ~~body authorized the withdrawal of the data, the governing body president's signature, and the date of the~~
1289 ~~signature.~~

1290
1291 **Section 19. Documentation of diagnosis specific new cancer case data**

1292
1293 ~~— Sec. 19. (1) An applicant required to document volumes of diagnosis specific new cancer cases~~
1294 ~~shall submit, as part of its application at the time it is submitted to the Department, documentation from~~
1295 ~~the Division for Vital Records and Health Statistics verifying the number of diagnosis specific new cancer~~
1296 ~~cases provided in support of the application for the most recent calendar year for which verifiable data are~~
1297 ~~available from the State Registrar. If the required documentation for this subsection is not submitted with~~
1298 ~~the application on the designated application date, the application will be deemed filed on the first~~
1299 ~~applicable designated application date after all required documentation is received by the Department.~~

1300
1301 ~~— (2) Diagnosis specific new cancer case data supporting an application under these standards shall~~
1302 ~~be submitted to the Division for Vital Records and Health Statistics using a format and media specified in~~
1303 ~~instructions from the Department of Community Health.~~

1304
1305 **Section 20. Commitment and documentation of diagnostic cardiac catheterization data**

1306
1307 ~~— Sec. 20. (1) An applicant proposing to use diagnostic cardiac catheterization data shall demonstrate~~
1308 ~~all of the following:~~

1309 ~~— (a) Each entity contributing diagnostic cardiac catheterization data [pursuant to Section 17(3)(a)]~~
1310 ~~provides, as part of the application at the time it is submitted to the Department, a signed governing body~~
1311 ~~resolution that identifies the number of diagnostic cardiac catheterization cases (sessions) committed to~~
1312 ~~the application and that states no current or future diagnostic cardiac catheterization data will be used in~~
1313 ~~support of any other application for a PET unit for the duration of the PET service for which data are~~
1314 ~~being committed for a period of five (5) years from the date of start of operations of the approved PET~~
1315 ~~service for which data are being committed. If the required documentation for this subsection is not~~
1316 ~~submitted with the application on the designated application date, the application will be deemed filed on~~
1317 ~~the first applicable designated application date after all required documentation is received by the~~
1318 ~~Department.~~

1319 ~~— (b) For fixed PET scanner services, the geographic location of each entity contributing diagnostic~~
1320 ~~cardiac catheterization data is in the same planning area as the proposed PET unit/service.~~

1321 ~~— (c) For mobile PET scanner services, the geographic location of each entity contributing diagnosis~~
1322 ~~specific new cancer case data in the planning area(s) for which the proposed PET service contains a~~
1323 ~~proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical~~
1324 ~~area counties or 25-mile radius for metropolitan statistical area counties.~~

1325 ~~— (d) No entity contributing diagnostic cardiac catheterization data has previously committed or is~~
1326 ~~committing data to another service that is less than five (5) years from the start of operations of that~~
1327 ~~service and is listed on the "Department Inventory of Pet Scanners."~~

1328 ~~— (e) The diagnostic cardiac catheterization case data is from the most recently completed report(s)~~
1329 ~~of the "Annual Hospital Statistical Questionnaire" produced by the Department, and the contributing entity~~
1330 ~~has CON Approval to provide diagnostic cardiac catheterization services.~~

1331
1332 ~~— (2) No entity currently operating or approved to operate a PET scanner, whether fixed or mobile,~~
1333 ~~listed on the "Department Inventory of PET Scanners" shall contribute diagnostic cardiac catheterization~~
1334 ~~case data.~~

1335
1336 ~~— (3)(a) The Department may not consider a withdrawal of diagnostic cardiac catheterization case data~~

1337 during the 120-day application review cycle following the date on which the Department review of the
1338 application commences or after a proposed decision to approve the application has been denied unless
1339 the application is denied, withdrawn, or expired.

1340 (b) The withdrawal must be submitted to the Department in the form of a governing body resolution
1341 that contains the specific CON application number to which the data were originally committed, the legal
1342 applicant entity, the committing entity, the type of data, the date of the meeting in which the governing
1343 body authorized the withdrawal of the data, the governing body president's signature, and the date of the
1344 signature.

1345 **Section 21. Commitment and documentation of intractable epilepsy data**

1346 ~~Sec. 21. (1) An applicant proposing to use intractable epilepsy cases shall demonstrate all of the~~
1347 ~~following:~~

1348 ~~(a) Each entity contributing intractable epilepsy data [pursuant to Section 17(4)(a)] provides, as~~
1349 ~~part of the application at the time it is submitted to the Department, a signed governing body resolution~~
1350 ~~that identifies the number of intractable epilepsy cases committed to the application and that states no~~
1351 ~~current or future intractable epilepsy case data will be used in support of any other application for a PET~~
1352 ~~unit for the duration of the PET service for which the data are being committed for a period of five (5)~~
1353 ~~years from the date of start of operations of the approved PET service for which data are being~~
1354 ~~committed. If the required documentation for this subsection is not submitted with the application on the~~
1355 ~~designated application date, the application will be deemed filed on the first applicable designated~~
1356 ~~application date after all required documentation is received by the Department.~~

1357 ~~(b) For fixed PET scanner services, the geographic location of each entity contributing intractable~~
1358 ~~epilepsy case data is in the same planning area as the proposed PET unit/service.~~

1359 ~~(c) For mobile PET scanner services, the geographic location of each entity contributing diagnosis~~
1360 ~~specific new cancer case data in the planning area(s) for which the proposed PET service contains a~~
1361 ~~proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical~~
1362 ~~area counties or 25-mile radius for metropolitan statistical area counties.~~

1363 ~~(d) No entity contributing intractable epilepsy case data has previously committed or is committing~~
1364 ~~data to another service that is less than five (5) years from the start of operations of that service and is~~
1365 ~~listed on the "Department Inventory of Pet Scanners."~~

1366 ~~(e) The intractable epilepsy case data is from the most recent Michigan Inpatient Data Base~~
1367 ~~(MIDB) available to the Department.~~

1370 ~~(2) No entity currently operating or approved to operate a scanner, whether fixed or mobile, listed~~
1371 ~~on the "Department Inventory of Pet Scanners" shall contribute intractable epilepsy case data.~~

1372 ~~(3)(a) The Department may not consider a withdrawal of intractable epilepsy case data during the~~
1373 ~~120-day application review cycle following the date on which the Department review of the application~~
1374 ~~commences or after a proposed decision to approve the application unless the application is denied,~~
1375 ~~withdrawn, or expired.~~

1376 ~~(b) The withdrawal must be submitted to the Department in the form of a governing body resolution~~
1377 ~~that contains the specific CON application number to which the data were originally committed, the legal~~
1378 ~~applicant entity, the committing entity, the type of data, the date of the meeting in which the governing~~
1379 ~~body authorized the withdrawal of the data, the governing body president's signature, and the date of the~~
1380 ~~signature.~~

1384

1385 | ~~Sec. 22.~~ Counties assigned to each health service area are as follows:

1386

1387 **HEALTH SERVICE AREA****COUNTIES**

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1389	1	Livingston	Monroe	St. Clair
1390		Macomb	Oakland	Washtenaw
1391		Wayne		

1392

1393	2	Clinton	Hillsdale	Jackson
1394		Eaton	Ingham	Lenawee

1395

1396	3	Barry	Calhoun	St. Joseph
1397		Berrien	Cass	Van Buren
1398		Branch	Kalamazoo	

1399

1400	4	Allegan	Mason	Newaygo
1401		Ionia	Mecosta	Oceana
1402		Kent	Montcalm	Osceola
1403		Lake	Muskegon	Ottawa

1404

1405	5	Genesee	Lapeer	Shiawassee
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1406

1407	6	Arenac	Huron	Roscommon
1408		Bay	Iosco	Saginaw
1409		Clare	Isabella	Sanilac
1410		Gladwin	Midland	Tuscola
1411		Gratiot	Ogemaw	

1412

1413	7	Alcona	Crawford	Missaukee
1414		Alpena	Emmet	Montmorency
1415		Antrim	Gd Traverse	Oscoda
1416		Benzie	Kalkaska	Otsego
1417		Charlevoix	Leelanau	Presque Isle
1418		Cheboygan	Manistee	Wexford

1419

1420	8	Alger	Gogebic	Mackinac
1421		Baraga	Houghton	Marquette
1422		Chippewa	Iron	Menominee
1423		Delta	Keweenaw	Ontonagon
1424		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

Lapeer

Shiawassee

HSA 6

Arenac
Bay
Clare
Gladwin
Gratiot

Huron
Iosco
Isabella
Midland
Ogemaw

Roscommon
Saginaw
Sanilac
Tuscola

PLANNING AREA 5

HSA 7

Alcona
Alpena
Antrim
Benzie
Charlevoix
Cheboygan

Crawford
Emmet
Gd Traverse
Kalkaska
Leelanau
Manistee

Missaukee
Montmorency
Oscoda
Otsego
Presque Isle
Wexford

PLANNING AREA 6

HSA 8

Alger
Baraga
Chippewa
Delta
Dickinson

Gogebic
Houghton
Iron
Keweenaw
Luce

Mackinac
Marquette
Menominee
Ontonagon
Schoolcraft

CON REVIEW STANDARDS
FOR PET SCANNER SERVICES

Rural Michigan counties are as follows:

1486	Alcona	Hillsdale	Ogemaw
1487	Alger	Huron	Ontonagon
1488	Antrim	Iosco	Osceola
1489	Arenac	Iron	Oscoda
1490	Baraga	Lake	Otsego
1491	Charlevoix	Luce	Presque Isle
1492	Cheboygan	Mackinac	Roscommon
1493	Clare	Manistee	Sanilac
1494	Crawford	Mason	Schoolcraft
1495	Emmet	Montcalm	Tuscola
1496	Gladwin	Montmorency	
1497	Gogebic	Oceana	

Micropolitan statistical area Michigan counties are as follows:

1501	Allegan	Gratiot	Mecosta
1502	Alpena	Houghton	Menominee
1503	Benzie	Isabella	Midland
1504	Branch	Kalkaska	Missaukee
1505	Chippewa	Keweenaw	St. Joseph
1506	Delta	Leelanau	Shiawassee
1507	Dickinson	Lenawee	Wexford
1508	Grand Traverse	Marquette	

Metropolitan statistical area Michigan counties are as follows:

1512	Barry	Ionia	Newaygo
1513	Bay	Jackson	Oakland
1514	Berrien	Kalamazoo	Ottawa
1515	Calhoun	Kent	Saginaw
1516	Cass	Lapeer	St. Clair
1517	Clinton	Livingston	Van Buren
1518	Eaton	Macomb	Washtenaw
1519	Genesee	Monroe	Wayne
1520	Ingham	Muskegon	

Source:

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