

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, ACQUISITION, OR RELOCATION 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) "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 ~~—(jj) "PET equivalent" means the number calculated in accordance with Section 16 for a single~~
125 ~~patient visit.~~
126 ~~(kkP) "PET procedure" means the acquisition of a single image or image sequence involving a single~~
127 ~~injection of tracer.~~
128 ~~(llQ) "PET scan" means one (1) or more PET procedures performed during a single patient visit.~~
129 ~~(mmR) "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 ~~(nnS) "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 ~~(ooT) "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 ~~(wwU) "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 on the certificate issued by the Department of~~
188 Environmental Quality,
189 (b) single photon emission computed tomography (SPECT) services,
190 (c) computed tomography (CT) scanning services,
191 (d) magnetic resonance imaging (MRI) services,
192 (e) cardiac catheterization services
193 (f) open heart surgery,
194 (g) thoracic surgery,
195 (h) cardiology,
196 (i) oncology,
197 (j) radiation oncology,
198 (k) neurology,
199 (l) neurosurgery, and
200 (m) psychiatry.

201
202 ~~(2)~~ If the ~~applicant~~ PROPOSED SITE does not provide any of the services listed in ~~this~~ subsection
203 ~~(1) at the same site at which the proposed PET scanner service will be located~~ ON-SITE, the applicant
204 shall ~~include in the application~~ PROVIDE written contracts or agreements with a hospital(s) located within
205 the same planning area OR 20 MILES OF THE PROPOSED SITE for the services not provided at the
206 proposed ~~PET scanner service~~ site.
207

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

209 SOURCE OF RADIOPHARMACEUTICALS.

210
211 ~~(24)~~ If ~~a~~ THE proposed ~~PET scanner service~~ SITE does not ~~involve~~ PROVIDE an on-site source of
212 radiopharmaceuticals, ~~an~~ THE applicant ~~must~~ SHALL provide ~~in the application~~ a written contract or
213 agreement that demonstrates ~~that~~ a reliable supply of radiopharmaceuticals ~~will be available to the~~
214 ~~proposed PET scanner service.~~
215

216 (5) AN APPLICANT PROPOSING TO INITIATE A FIXED PET SCANNER SERVICE WITH ITS

217 FIRST PET SCANNER SHALL PROJECT 2,600 PET DATA UNITS OR SHALL DEMONSTRATE ALL
218 OF THE FOLLOWING:
219 (A) THE APPLICANT IS CURRENTLY A HOST SITE BEING SERVED BY ONE OR MORE
220 MOBILE PET SCANNER SERVICES.
221 (B) THE APPLICANT HAS RECEIVED:
222 (I) 1,700 PET SCANS IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE
223 DEPARTMENT FOR A HOST SITE IN A METROPOLITAN STATISTICAL AREA COUNTY, OR
224 (II) 1,500 PET SCANS IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE
225 DEPARTMENT FOR A HOST SITE IN A RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY.
226 (C) THE APPLICANT AGREES TO CEASE OPERATION AS A HOST SITE AND NOT BECOME A
227 HOST SITE FOR AT LEAST 12 MONTHS FROM THE DATE THE FIXED PET SCANNER BECOMES
228 OPERATIONAL.
229
230 (6) AN APPLICANT PROPOSING TO INITIATE A MOBILE PET SCANNER SERVICE WITH ITS
231 FIRST MOBILE PET SCANNER SHALL PROJECT 2,100 PET DATA UNITS.
232 (A) OF THE 2,100 PET DATA UNITS, THE APPLICANT SHALL PROJECT A MINIMUM OF 360
233 PET DATA UNITS WITHIN A 20-MILE RADIUS OF EACH PROPOSED HOST SITE FOR PLANNING
234 AREA 1, OR 240 PET DATA UNITS PER HOST SITE FOR ANY OTHER PLANNING AREA, FOR THE
235 PROPOSED SERVICE.
236 (B) THE APPLICATION FOR THE MOBILE PET SCANNER SERVICE IS ACCOMPANIED BY AT
237 LEAST TWO HOST SITE APPLICATIONS.
238 (C) THE APPLICANT PROVIDES A ROUTE SCHEDULE FOR THE PROPOSED MOBILE PET
239 SCANNER SERVICE.
240
241 (7) AN APPLICANT PROPOSING TO INITIATE A HOST SITE ON A PROPOSED OR EXISTING
242 MOBILE PET SCANNER SERVICE SHALL DEMONSTRATE THE FOLLOWING:
243 (A) THE APPLICANT PROVIDES A PROPOSED ROUTE SCHEDULE.
244 (B) THE APPLICANT PROVIDES A DRAFT CONTRACT FOR SERVICES BETWEEN THE
245 PROPOSED HOST SITE AND CENTRAL SERVICE COORDINATOR.
246 (C) THE APPLICANT HAS NOT INITIATED FIXED PET SCANNER SERVICES UNDER
247 SUBSECTION 3(5) WITHIN THE MOST RECENT 12-MONTH PERIOD AS OF THE DATE THE
248 APPLICATION IS SUBMITTED TO THE DEPARTMENT.
249 (D) AN APPLICANT INITIATING A HOST SITE IN HSA 8 ON A MOBILE PET SCANNER
250 SERVICE THAT OPERATES PREDOMINANTLY OUTSIDE OF MICHIGAN SHALL DEMONSTRATE
251 240 PET DATA UNITS FROM PLANNING AREA 6.
252
253 (8) AN APPLICANT PROPOSING TO INITIATE PET SCANNER SERVICES AS AN EXISTING
254 HOST SITE ON A DIFFERENT MOBILE PET SCANNER SERVICE SHALL DEMONSTRATE THE
255 FOLLOWING:
256 (A) THE APPLICANT PROVIDES A PROPOSED ROUTE SCHEDULE.
257 (B) THE APPLICANT PROVIDES A DRAFT CONTRACT FOR SERVICES BETWEEN THE
258 PROPOSED HOST SITE AND CENTRAL SERVICE COORDINATOR.
259 (C) THE APPLICANT HAS RECEIVED 50 PET SCANS IN THE MOST RECENT 12-MONTH
260 PERIOD VERIFIABLE BY THE DEPARTMENT FROM AN EXISTING MOBILE PET SCANNER
261 SERVICE FOR AN EXISTING HOST SITE PROPOSING TO INITIATE SERVICES ON A DIFFERENT
262 MOBILE PET SCANNER SERVICE.
263

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

267 Sec. 4. REPLACING A PET SCANNER(S) MEANS A CHANGE IN THE SCANNER EQUIPMENT
268 OR RELOCATION OF THE SERVICE TO A NEW SITE. AN UPGRADE TO SOFTWARE OR
269 COMPONENTS/PARTS OF AN EXISTING SCANNER DOES NOT CONSTITUTE REPLACEMENT OF
270 A PET SCANNER. (1) An applicant proposing to ~~initiate~~ REPLACE a ~~fixed~~ PET scanner(S) service shall

271 project ~~DEMONSTRATE~~ an operating level of at least 2,600 PET data units for each proposed PET
272 scanner based on the methodology used in Section 17 EACH OF THE FOLLOWING, AS APPLICABLE
273 TO THE PROPOSED PROJECT.

274
275 (21) An applicant proposing to ~~initiate~~ REPLACE a mobile PET scanner service shall project
276 DEMONSTRATE 2,100 PET data units for each proposed mobile PET scanner based on the methodology
277 used in Section 17. THE FOLLOWING:

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

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

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

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

296 (3C) ~~Initiation of a mobile PET host site does not include the provision of mobile PET services at a~~
297 ~~host site if the applicant, whether the host site or the central service coordinator, demonstrates or~~
298 ~~provides, as applicable, each of the following: THE APPLICANT AGREES THAT THE PET SCANNER(S)~~
299 TO BE REPLACED WILL BE REMOVED FROM SERVICE ON OR BEFORE BEGINNING OPERATION
300 OF THE REPLACEMENT SCANNER(S).

301
302 (a2) ~~The host site has received mobile PET services from an existing approved mobile PET unit~~
303 ~~within the most recent 12-month period as of the date the application is submitted to the Department. AN~~
304 APPLICANT PROPOSING TO REPLACE A FIXED PET SCANNER SERVICE TO A NEW SITE SHALL
305 DEMONSTRATE THE FOLLOWING:

306 (bA) ~~The addition of a host site to a mobile PET scanner service will not increase the number of PET~~
307 ~~units operated by the central service coordinator or by any other person PROPOSED SITE IS WITHIN A~~
308 10-MILE RADIUS OF THE EXISTING SITE FOR A METROPOLITAN STATISTICAL AREA COUNTY OR
309 A 25-MILE RADIUS FOR A RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY.

310 (eB) ~~The application is submitted to the Department prior to the provision of PET services on that~~
311 ~~network EXISTING FIXED PET SCANNER(S) PERFORMED 600 PET SCANS PER FIXED SCANNER~~
312 IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE DEPARTMENT.

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

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

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

- 325 ~~_____ (4) An applicant that meets all of the following requirements shall not be required to be in~~
326 ~~compliance with subsection (1):~~
327 ~~_____ (a) The applicant is proposing to initiate a fixed PET scanner service.~~
328 ~~_____ (b) The applicant is currently a host site being served by one or more mobile PET scanners.~~
329 ~~_____ (c) The applicant has received, in aggregate, the following:~~
330 ~~_____ (i) At least 4,500 PET equivalents, for an applicant in a metropolitan statistical area county, during~~
331 ~~the most recent 12-month period for which the Department has verifiable data.~~
332 ~~_____ (ii) At least 4,000 PET equivalents, for an applicant in a rural or micropolitan statistical area~~
333 ~~county, during the most recent 12-month period for which the Department has verifiable data.~~
334 ~~_____ (d) The applicant shall install the fixed PET unit at the same site as the existing approved host site.~~
335 ~~_____ (e) The applicant shall cease operation as a host site and not become a host site for at least 12~~
336 ~~months from the date the fixed PET scanner, including any temporary scanner used during the transition~~
337 ~~from mobile to fixed, becomes operational.~~

338
339 **Section 5. Requirements ~~for approval for applicants proposing to expand a PET scanner service~~**

340
341 ~~Sec. 5. (1) An applicant proposing to increase EXPAND A the number of fixed PET scanner~~
342 ~~sERVICE (second, third, etc.) shall demonstrate EACH OF the following, AS APPLICABLE TO THE~~
343 ~~PROPOSED PROJECT:~~
344

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

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

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

359
360 ~~_____ (c) In the case of a fixed PET scanner service, the additional PET scanner shall be located at the~~
361 ~~same geographic location as the existing fixed PET scanner service unless the applicant meets the~~
362 ~~applicable requirements for relocation in accordance with Section 9. THE ADDITIONAL PET~~
363 ~~SCANNER(S) SHALL BE LOCATED AT THE SAME SITE.~~

364
365 ~~(2) An applicant proposing to increase ADD the number of A mobile PET scanner(s) TO AN~~
366 ~~EXISTING MOBILE PET SCANNER SERVICE (second, third, etc.) shall demonstrate the following:~~

367 ~~(a) 2,000 PET SCANS WERE PERFORMED PER EXISTING AND APPROVED MOBILE~~
368 ~~SCANNER(S)~~

369 ~~For an applicant serving at least one existing host site in a metropolitan statistical area county, all of the~~
370 ~~applicant's approved mobile PET scanners on a mobile route have performed an average of at least~~
371 ~~5,000 PET equivalents per PET scanner during IN the most recent 12-month period VERIFIABLE BY for~~
372 ~~which the Department has verifiable data FOR AN APPLICANT SERVING AT LEAST ONE EXISTING~~
373 ~~HOST SITE IN A METROPOLITAN STATISTICAL AREA COUNTY, OR~~

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

379 | MICROPOLITAN STATISTICAL AREA COUNTIES.

380
381 | (3) An applicant PROPOSING TO ADD A FIXED PET SCANNER TO AN EXISTING FIXED PET
382 SCANNER SERVICE that ~~meets~~ ALSO RECEIVES MOBILE PET SCANNER SERVICES SHALL
383 DEMONSTRATE all of the following ~~requirements shall not be required to be in compliance with~~
384 subsection (1):

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

387 | (b) The applicant ~~is currently a fixed PET scanner service~~ HAS RECEIVED;

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

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

397 micropolitan statistical area county, all of the applicant's approved fixed PET scanners have performed an
398 average of at least 5,000 PET equivalents per PET scanner during the most recent 12-month period for
399 which the Department has verifiable data. (d) ~~At least two (2) separate CON applications have~~

400 been submitted simultaneously as host sites for the proposed mobile PET service, subject to Section
401 4(3).

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

405 | ~~The requirements of Section 3 have been met.~~

406 | ~~The applicant agrees to comply with sections (13) and (14).~~

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

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

411
412 | (4) THIS SECTION DOES NOT APPLY TO DEDICATED RESEARCH, DEDICATED PEDIATRIC
413 OR POSITRON EMISSION MAMMOGRAPHY (PEM) SCANNERS.

414
415 | **Section 6. Requirements for approval for applicants proposing to ~~replace~~ ACQUIRE a PET**
416 **scanner SERVICE OR SCANNER(S)**

417
418 | Sec. 6. (1) ~~An applicant proposing to replace an existing fixed~~ ACQUIRING A PET SCANNER
419 SERVICE AND ITS scanner(s) MEANS OBTAINING POSSESSION AND CONTROL BY CONTRACT,
420 OWNERSHIP, LEASE, OR OTHER COMPARABLE ARRANGEMENT AND RENEWAL OF LEASE FOR
421 AN EXISTING shall demonstrate that all of the applicant's approved and operating fixed OR MOBILE
422 PET scanners. AN APPLICANT PROPOSING TO ACQUIRE A ~~have performed an average of at least~~
423 4,500 PET SCANNER SERVICE equivalents SHALL DEMONSTRATE EACH OF THE FOLLOWING, AS
424 APPLICABLE TO THE PROPOSED PROJECT ~~per PET scanner during the most recent 12-month period~~
425 for which the Department has verifiable data.

426
427 | (2) FOR THE FIRST ~~An applicant~~ APPLICATION proposing to ~~replace~~ ACQUIRE an existing
428 FIXED, mobile, OR HOST SITE PET scanner(s) SERVICE shall demonstrate that all of the applicant's
429 approved and operating mobile PET scanners on OR AFTER <INSERT EFFECTIVE DATE OF
430 STANDARDS>, THE EXISTING ~~a mobile route~~ have performed an average of at least 3,000 PET
431 equivalents per PET scanner SERVICE AND ITS SCANNER(S) SHALL NOT BE REQUIRED TO BE IN
432 COMPLIANCE WITH THE APPLICABLE VOLUME REQUIREMENTS SET FORTH IN THIS SECTION

433 | during the most recent 12-month period for which the Department has verifiable data.

434 |
435 | ~~(32) An exemption APPLICANT to subsections (1) and (2) may be made by the Department, if an~~
436 | ~~applicant demonstrates to the satisfaction of the Department, the following: PROPOSING TO ACQUIRE~~
437 | ~~AN EXISTING FIXED OR MOBILE PET SCANNER SERVICE SHALL DEMONSTRATE THAT THE~~
438 | ~~EXISTING FIXED OR MOBILE SCANNER(S) PERFORMED AN AVERAGE OF 500 PET SCANS PER~~
439 | ~~SCANNER IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE DEPARTMENT.~~

440 |
441 | ~~(a3) The existing PET scanner is technologically incapable of performing the applicable minimum~~
442 | ~~number of PET equivalents. An applicant proposing a TO replacement ACQUIRE AN EXISTING HOST~~
443 | ~~SITE under this subsection shall provide documentation DEMONSTRATE, satisfactory to THAT the~~
444 | ~~Department, from a person or an organization with recognized professional expertise regarding that type~~
445 | ~~of equipment, other than the applicant or a representative of a manufacturer or vendor of that type of~~
446 | ~~equipment, indicating the number of PET equivalents the existing HOST SITE HAS equipment is~~
447 | ~~technologically capable of performing performed. 50 SCANS. The applicant also shall provide~~
448 | ~~documentation, satisfactory to the Department, that the number of PET equivalents performed during IN~~
449 | ~~the most recent 12-month period, for which VERIFIABLE BY the Department has verifiable data, was the~~
450 | ~~number the equipment is technologically capable of performing. (4) An applicant proposing to~~
451 | ~~replace a PET scanner(s), whether fixed or mobile, shall demonstrate:~~

452 | ~~— (a) the equipment to be replaced is fully depreciated according to generally accepted accounting~~
453 | ~~principles or~~

454 | ~~— (b) either of the following:~~

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

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

460 |
461 | ~~— (5) An applicant that meets all of the following requirements shall not be required to be in~~
462 | ~~compliance with subsections (1), (2), (3) and (4):~~

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

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

466 |
467 | ~~— (6) In the case of a fixed PET scanner, the proposed PET scanner will be located at the same site~~
468 | ~~as the applicant's existing fixed PET scanner to be replaced. If the proposed scanner will not be located~~
469 | ~~at the same site, the applicant must meet the requirements to relocate a PET scanner at the proposed~~
470 | ~~site, in accordance with Section 9.~~

471 |
472 | **Section 7. Requirements for approval for applicants proposing to acquire an existing A**
473 | **DEDICATED RESEARCH FIXED PET scanner**

474 |
475 | ~~Sec. 7. An applicant proposing to acquire ADD an existing FIXED PET scanner, whether fixed or~~
476 | ~~mobile, scanner TO EXPAND AN EXISTING PET SCANNER SERVICE FOR EXCLUSIVE RESEARCH~~
477 | ~~USE shall NOT NEED TO demonstrate that it meets all of the following REQUIREMENTS OF SECTIONS~~
478 | ~~3 AND 5 IF THE APPLICANT DEMONSTRATES EACH OF THE FOLLOWING:~~

479 |
480 | ~~(a1) The project is limited solely to the acquisition of an existing DEDICATED RESEARCH PET~~
481 | ~~scanner SHALL OPERATE UNDER A PROTOCOL APPROVED BY THE APPLICANT'S~~
482 | ~~INSTITUTIONAL REVIEW BOARD, AS DEFINED BY PUBLIC LAW 93-348 AND REGULATED BY~~
483 | ~~TITLE 45 CFR 46.~~

484 |
485 | ~~(b2) The project APPLICANT HAS ACCESS TO A CYCLOTRON FOR ACCELERATING~~
486 | ~~CHARGED PARTICLES TO HIGH ENERGIES BY MEANS will not change the number of PET scanners~~

487 | ~~listed on the Department Inventory of PET Scanners~~ELECTROMAGNETIC FIELDS.

488 |
489 | ~~(e3) The project APPLICANT HAS NO MORE THAN THREE DEDICATED RESEARCH FIXED~~will
490 | ~~not result in the replacement of the PET scanners~~scanners APPROVED UNDER THIS to be acquired
491 | ~~unless the applicant demonstrates that the requirements of Section 6 also have been met.~~

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

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

496 |
497 | **Section 8. Requirements for ~~approval for applicants proposing to acquire an existing A~~**
498 | **DEDICATED PEDIATRIC PET scanner service**

499 |
500 |
501 | ~~Sec. 8. An applicant proposing to acquire~~INITIATE an existing A PET scanner service, whether OR
502 | ADD A fixed PET SCANNER TO EXPAND AN EXISTING PET SCANNER SERVICE, FOR DEDICATED
503 | PEDIATRIC PET USE, or mobile, shall NOT NEED TO MEET demonstrate that it meets all of the
504 | REQUIREMENTS OF SECTION 5 IF THE APPLICANT DEMONSTRATES EACH OF THE following:

505 |
506 | ~~(a1) The project APPLICANT AGREES THAT THE DEDICATED PEDIATRIC is limited solely to the~~
507 | ~~acquisition of an existing PET scanner service~~scanner WILL BE USED PRIMARILY (70% OF THE
508 | SCANS) FOR PATIENTS UNDER 18 YEARS OF AGE.

509 |
510 | ~~(b2) The project APPLICANT SHALL DEMONSTRATE will not change the number~~EXISTING SITE
511 | of THE Pet-PET scanners SERVICE PROVIDED listed on the FOLLOWING FOR THE MOST RECENT
512 | CALENDAR YEAR OR A CONTINUOUS 12-MONTH PERIOD AT THE TIME THE APPLICATION IS
513 | SUBMITTED TO THE Department Inventory of PET Scanners.:

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

517 |
518 | ~~_____ (eB) AT LEAST 5,000 PEDIATRIC (< 18 YEARS OLD) SURGERIES, All PET scanners to be~~
519 | ~~acquired are listed on the Department Inventory of PET Scanners on the date the application is submitted~~
520 | ~~to the Department.~~AND

521 |
522 | ~~(eC) AT LEAST 50 NEW PEDIATRIC CANCER CASES ON ITS CANCER REGISTRY~~The applicant
523 | ~~agrees to operate the PET scanner service in accordance with all applicable project delivery~~
524 | ~~requirements set forth in Section 14.~~

525 |
526 | ~~_____ (3) THE APPLICANT SHALL HAVE AN ACTIVE MEDICAL STAFF AT THE TIME THE~~
527 | ~~APPLICATION IS SUBMITTED TO THE DEPARTMENT THAT INCLUDES PHYSICIANS WHO ARE~~
528 | ~~FELLOWSHIP-TRAINED IN THE FOLLOWING PEDIATRIC SPECIALTIES:~~

529 | ~~_____ (A) RADIOLOGY (AT LEAST TWO STAFF MEMBERS)~~

530 | ~~_____ (B) ANESTHESIOLOGY~~

531 | ~~_____ (C) CARDIOLOGY~~

532 | ~~_____ (D) CRITICAL CARE~~

533 | ~~_____ (E) GASTROENTEROLOGY~~

534 | ~~_____ (F) HEMATOLOGY/ONCOLOGY~~

535 | ~~_____ (G) NEUROLOGY~~

536 | ~~_____ (H) NEUROSURGERY~~

537 | ~~_____ (I) ORTHOPEDIC SURGERY~~

538 | ~~_____ (J) PATHOLOGY~~

539 | ~~_____ (K) PULMONOLOGY~~

540 | ~~_____ (L) SURGERY~~

541 (M) NEONATOLOGY

542
543 (4) THE APPLICANT SHALL HAVE IN OPERATION THE FOLLOWING PEDIATRIC SPECIALTY
544 PROGRAMS AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT:

545
546 (A) BONE MARROW TRANSPLANT PROGRAM

547 (B) SEDATION PROGRAM

548 (C) OPEN HEART PROGRAM

549
550 (5) THE APPLICANT MEETS THE REQUIREMENTS OF SECTION 3(1) THROUGH 3(4) IF THE
551 APPLICANT IS INITIATING A PET SCANNER SERVICE WITH A DEDICATED PEDIATRIC FIXED PET
552 SCANNER.

553
554 (6) THE APPLICANT HAS NO MORE THAN THREE DEDICATED PEDIATRIC FIXED PET
555 SCANNERS APPROVED UNDER THIS SECTION.

556
557 **Section 9. Requirements for approval for applicants proposing to relocate an existing PET A**
558 **POSITRON EMISSION MAMMOGRAPHY (PEM) scanner service or its unit(s)**

559
560 Sec. 9. ~~(1)~~ An applicant proposing to ~~relocate~~ ADD A PEM SCANNER TO EXPAND an existing
561 ~~fixed PET SCANNER~~ service FOR EXCLUSIVE USE IN A COMPREHENSIVE DIAGNOSTIC BREAST
562 PROGRAM and all its existing unit(s) shall NOT NEED TO MEET ~~demonstrate that it meets all of the~~
563 REQUIREMENTS OF SECTION 6 IF THE APPLICANT DEMONSTRATES EACH OF THE following:

564
565 (a1) The service-APPLICANT CURRENTLY OPERATES, AT THE TIME THE APPLICATION IS
566 SUBMITTED TO THE DEPARTMENT, A COMPREHENSIVE DIAGNOSTIC BREAST PROGRAM THAT
567 INCLUDES THE FOLLOWING SPECIALTIES, SERVICES, AND MEDICAL STAFF (DEPARTMENT
568 STILL DEVELOPING REQUIREMENTS); and all its existing units to be relocated are fixed PET scanners.

569
570 (b2) The existing The APPLICANT fixed PET service to be relocated has NO MORE THAN THREE
571 PEM SCANNERS APPROVED UNDER THIS SECTION ~~been in operation for at least 36 months as of the~~
572 ~~date of the application submitted to the Department.~~

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

574 ~~(d) The proposed project will not result in an increase in the number of PET scanner(s) operated~~
575 ~~by the applicant at the proposed site unless the applicant demonstrates that the requirements of Section~~
576 ~~5, as applicable, have also been met.~~

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

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

582
583 ~~(2) An applicant proposing to relocate a PET scanner of an existing PET service shall demonstrate~~
584 ~~that it meets all of the following:~~

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

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

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

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

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

593
594 **Section 10. Requirements for approval for applicants proposing a dedicated research fixed PET**

595 | **scannerMEDICAID PARTICIPATION**

596
597 | Sec. 10. ~~(1) An applicant proposing to operate a fixed PET scanner (whether new or replacement)~~
598 ~~to be used exclusively for research shall demonstrate each of the following~~ PROVIDE VERIFICATION OF
599 MEDICAID PARTICIPATION. AN APPLICANT THAT IS A NEW PROVIDER NOT CURRENTLY
600 ENROLLED IN MEDICAID SHALL CERTIFY THAT PROOF OF MEDICAID PARTICIPATION WILL BE
601 PROVIDED TO THE DEPARTMENT WITHIN (6) MONTHS FROM THE OFFERING OF SERVICES IF A
602 CON IS APPROVED.:

603 | ~~(a) The PET scanner shall operate under a protocol approved by the applicant's Institutional~~
604 ~~Review Board.~~

605 | ~~(b) The applicant agrees to operate the PET scanner in accordance with the terms of approval in~~
606 ~~Section 14(1)(a), (b), (c)(vi), (d)(iii), (iv) and (v); 14(2); 14(3); and 14(4).~~

607 | ~~(c) The applicant has access to a cyclotron.~~

608
609 | ~~(2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the~~
610 ~~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~~
611 ~~these standards.~~

612
613 | **Section 11. PROJECT DELIVERY Requirements for approval for applicants proposing to establish**
614 **a dedicated pediatric PET scanner AND TERMS OF APPROVAL FOR ALL APPLICANTS**

615
616 | Sec. 11. ~~(1) An applicant proposing to establish a dedicated pediatric PET scanner(s) shall~~ AGREE
617 THAT, IF APPROVED, demonstrate all of the following PET SCANNER SERVICES SHALL BE
618 DELIVERED IN COMPLIANCE WITH THE FOLLOWING TERMS OF APPROVAL.:

619
620 | ~~(a1) The applicant shall experience at least 7,000 pediatric (< 18 years old) discharges, excluding~~
621 ~~normal newborns, in the most recent year of operation~~ COMPLIANCE WITH THESE STANDARDS.

622
623 | ~~(b2) The applicant shall experience at least 5,000 pediatric (< 18 years old) surgeries in the most~~
624 ~~recent year of operation~~ COMPLIANCE WITH THE FOLLOWING QUALITY ASSURANCE
625 REQUIREMENTS.:

626 | ~~(c) The applicant shall experience at least 50 new pediatric cancer cases on its cancer registry in~~
627 ~~the most recent year of operation~~ A PET SCANNER SERVICE SHALL BE STAFFED SO THAT
628 SCREENING OF REQUESTS FOR AND INTERPRETATION OF PET PROCEDURES WILL BE
629 CARRIED OUT BY A PHYSICIAN(S) WITH APPROPRIATE TRAINING AND FAMILIARITY WITH THE
630 APPROPRIATE DIAGNOSTIC USE AND INTERPRETATION OF CROSS-SECTIONAL IMAGES OF
631 THE ANATOMICAL REGION(S) TO BE EXAMINED. FOR PURPOSES OF EVALUATING THIS
632 SUBSECTION, THE DEPARTMENT SHALL CONSIDER IT PRIMA FACIE EVIDENCE AS TO THE
633 TRAINING OF THE PHYSICIAN(S) IF THE PHYSICIAN IS BOARD CERTIFIED OR BOARD QUALIFIED
634 IN NUCLEAR MEDICINE OR NUCLEAR RADIOLOGY. HOWEVER, AN APPLICANT MAY SUBMIT,
635 AND THE DEPARTMENT MAY ACCEPT, OTHER EVIDENCE THAT THE PHYSICIAN(S) IS QUALIFIED
636 TO OPERATE THE PET SERVICE/SCANNER. THE PHYSICIAN(S) MUST BE ON-SITE OR
637 AVAILABLE THROUGH TELECOMMUNICATION CAPABILITIES TO PARTICIPATE IN THE
638 SCREENING OF PATIENTS FOR PET PROCEDURES AND TO PROVIDE OTHER CONSULTATION
639 SERVICES.

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

646 | ~~(i) pediatric radiology (at least two staff members)~~

647 | ~~(ii) pediatric anesthesiology~~

648 | ~~(iii) pediatric cardiology~~

- 649 ~~— (iv) pediatric critical care~~
- 650 ~~— (v) pediatric gastroenterology~~
- 651 ~~— (vi) pediatric hematology/oncology~~
- 652 ~~— (vii) pediatric neurology~~
- 653 ~~— (viii) pediatric neurosurgery~~
- 654 ~~— (ix) pediatric orthopedic surgery~~
- 655 ~~— (x) pediatric pathology~~
- 656 ~~— (xi) pediatric pulmonology~~
- 657 ~~— (xii) pediatric surgery~~
- 658 ~~— (xiii) neonatology~~

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

- 663 ~~(i) pediatric bone marrow transplant program~~
- 664 ~~(ii) established pediatric sedation program~~
- 665 ~~(iii) pediatric open heart program~~

666 (D) THE APPLICANT MAINTAINS THE SERVICES AND SPECIALTIES AS SET FOR THE IN
667 SECTION 3(1) THROUGH 3(4).

668
669 ~~(23) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the~~
670 ~~requirements of Section 4 or Section 5 of these standards but must meet Section 6.~~ COMPLIANCE WITH
671 THE FOLLOWING ACCESS TO CARE REQUIREMENTS:

672
673 ~~(3A) The dedicated pediatric PET scanner SERVICE shall be excluded~~ ACCEPT REFERRALS FOR
674 PET SCANNER SERVICES from the adult count for ALL APPROPRIATELY LICENSED
675 PRACTITIONERS ~~the facility.~~

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

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

681 (D) THE OPERATION OF AND REFERRAL OF PATIENTS TO THE PET SCANNER SERVICE
682 SHALL BE IN CONFORMANCE WITH 1978 PA 368, SEC. 16221, AS AMENDED BY 1986 PA 319; MCL
683 333.16221; MSA 14.15 (16221).

684
685 (4) COMPLIANCE WITH THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:

686 (A) THE PET SCANNERS SHALL BE OPERATING AT AN AVERAGE OF 500 PET SCANS PER
687 SCANNER DURING THE SECOND 12 MONTHS OF OPERATIONS, AND ANNUALLY THEREAFTER.
688 THIS REQUIREMENT SHALL BE WAIVED DURING REVIEW OF APPLICATIONS UNDER SECTION
689 4(1), IF APPLICABLE.

690 (B) THE PET SCANNER SERVICE SHALL PARTICIPATE IN A DATA COLLECTION SYSTEM
691 ESTABLISHED AND ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE. THE DATA MAY
692 INCLUDE, BUT ARE NOT LIMITED TO, CLINICAL SCAN DATA, ANNUAL BUDGET AND COST
693 INFORMATION, OPERATING SCHEDULES, THROUGH-PUT SCHEDULES, DEMOGRAPHIC AND
694 DIAGNOSTIC INFORMATION, AND THE VOLUME OF CARE PROVIDED TO PATIENTS FROM ALL
695 PAYOR SOURCES. THE APPLICANT SHALL PROVIDE THE REQUIRED DATA ON A SEPARATE
696 BASIS FOR EACH SEPARATE AND DISTINCT SITE, PET SCANNER, OR PET SCANNER SERVICE
697 AS REQUIRED BY THE DEPARTMENT, IN A FORMAT ESTABLISHED BY THE DEPARTMENT. THE
698 DEPARTMENT MAY ELECT TO VERIFY THE DATA THROUGH ON-SITE REVIEW OF APPROPRIATE
699 RECORDS.

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

703
704
705 (5) COMPLIANCE WITH THE FOLLOWING DEDICATED RESEARCH PET SCANNER
706 REQUIREMENTS, IF APPLICABLE:

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

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

712
713 (6) COMPLIANCE WITH THE FOLLOWING DEDICATED PEDIATRIC PET SCANNER
714 REQUIREMENTS, IF APPLICABLE:

715 (A) THE DEDICATED PEDIATRIC PET SCANNER WILL BE USED PRIMARILY (70% OF THE
716 SCANS) FOR PATIENTS UNDER 18 YEARS OF AGE.

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

719
720 (7) COMPLIANCE WITH THE FOLLOWING PEM SCANNER REQUIREMENTS, IF APPLICABLE:

721 (A) (DEPARTMENT TO DEVELOP)

722
723 (8) COMPLIANCE WITH THE FOLLOWING MOBILE PET SCANNER REQUIREMENTS, IF
724 APPLICABLE:

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

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

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

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

738
739 (9) THE AGREEMENTS AND ASSURANCES REQUIRED BY THIS SECTION SHALL BE IN THE
740 FORM OF A CERTIFICATION AGREED TO BY THE APPLICANT OR ITS AUTHORIZED AGENT.

741
742 **Section 12. ~~Additional requirements~~METHODOLOGY for mobile ~~COMPUTING THE PROJECTED~~**
743 **PET serviceDATA UNITS**

744
745 ~~Sec. 12. (1)-An applicant proposing to begin operation of a mobile PET service shall demonstrate all~~
746 ~~of the following~~BEING REVIEWED UNDER SECTION 4 SHALL APPLY THE METHODOLOGY SET
747 FORTH IN THIS SECTION IN COMPUTING THE PROJECTED NUMBER OF PET DATA UNITS:.

748
749 ~~(a1) A separate CON application has been submitted by the central service coordinator and each~~
750 ~~proposed host site~~IDENTIFY THE NUMBER OF DIAGNOSIS-SPECIFIC NEW CANCER CASES
751 DOCUMENTED IN ACCORDANCE WITH THE REQUIREMENTS OF SECTION 13.

752 ~~(bA) A proposed regular route schedule, the procedures for handling emergency situations, and~~
753 ~~copies of all proposed contracts related to the mobile PET service have been included in the CON~~
754 ~~application~~COMBINE THE NUMBER OF CANCER CASES FOR LUNG (SITE CODES C340-C349),
755 ESOPHAGUS (SITE CODES C150-C159), COLORECTAL (SITE CODES C180-C209), LYMPHOMA
756 (MORPHOLOGY CODES (9590-9729), MELANOMA (MORPHOLOGY CODES 8720-8790), AND HEAD

757 & NECK [SITE CODES C000-C148, C300-C329, C410, C411, C470 OR C490 EXCLUDING C440-C444
758 (SKIN OF HEAD AND NECK), AND ADDITIONAL CODES APPROVED BY NATIONAL COVERAGE
759 DETERMINATION]. USE THE NAME "COMBINED" FOR THIS GROUPING.

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

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

767
768 (2) An applicant proposing to become a host site on an existing mobile PET scanner service shall
769 demonstrate that it meets all of the following: IDENTIFY THE NUMBER OF DIAGNOSIS-SPECIFIC NEW
770 CANCER CASES DOCUMENTED IN ACCORD WITH THE REQUIREMENTS OF SECTION 13.

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

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

781
782 (3) MULTIPLY THE NUMBER OF DIAGNOSTIC CARDIAC CATHETERIZATION CASES
783 IDENTIFIED IN ACCORD WITH THE REQUIREMENTS OF SECTION 15 BY 0.1, WHICH IS THE
784 ESTIMATED PROBABILITY THAT A PATIENT HAVING A DIAGNOSTIC CARDIAC
785 CATHETERIZATION WILL REQUIRE A PET SCAN.

786
787 (4) MULTIPLY THE NUMBER OF INTRACTABLE EPILEPSY CASES (ICD-9-CM CODES 345.01,
788 345.11, 345.41, 345.51, 345.61, 345.71, 345.81, OR 345.91) IDENTIFIED IN ACCORD WITH THE
789 REQUIREMENTS OF SECTION 16 BY 1.0, WHICH IS THE ESTIMATED PROBABILITY THAT A
790 PATIENT HAVING AN INTRACTABLE EPILEPSY PROCEDURE WILL REQUIRE A PET SCAN.
791 MULTIPLY THE NUMBER RESULTING FROM THE CALCULATION IN SUBSECTION (3) BY 1.0,
792 WHICH IS THE ESTIMATED NUMBER OF PET SCANS NEEDED FOR EACH PATIENT REQUIRING A
793 PET SCAN.

794
795 (5) SUM THE NUMBERS RESULTING FROM THE CALCULATIONS IN SUBSECTIONS (1)
796 THROUGH (4) TO DETERMINE THE TOTAL NUMBER OF PROJECTED PET DATA UNITS.

797
798 (6) MULTIPLY THE RESULT CALCULATED IN SUBSECTION (5) ABOVE BY A FACTOR OF 3.0
799 IF THE APPLICANT IS PROPOSING TO SERVE ONLY PLANNING AREA 6 TO DETERMINE THE
800 TOTAL NUMBER OF PROJECTED PET DATA UNITS.

801
802 (7) MULTIPLY THE RESULT CALCULATED IN SUBSECTION (5) ABOVE BY A FACTOR OF 2.0
803 IF THE APPLICANT IS PROPOSING TO SERVE ONLY PLANNING AREA 5 TO DETERMINE THE
804 TOTAL NUMBER OF PROJECTED PET DATA UNITS.

805
806
807 **Section 13. Requirements for approval for all applicants****COMMITMENT OF DIAGNOSIS-SPECIFIC**
808 **NEW CANCER CASES**

809
810 Sec. 13. An applicant shall provide verification of Medicaid participation at the time the application is

811 submitted to the Department. If the required documentation is not submitted with the application on the
812 designated application date, the application will be deemed filed on the first applicable designated
813 application date after all required documentation is received by the Department. AN APPLICANT
814 PROPOSING TO USE DIAGNOSIS-SPECIFIC NEW CANCER CASES SHALL DEMONSTRATE ALL OF
815 THE FOLLOWING:

816
817 (1) ONLY THOSE CANCER DIAGNOSES IDENTIFIED IN SECTION 12(1) AND 12(2) SHALL BE
818 INCLUDED.

819
820 (2) EACH ENTITY CONTRIBUTING DIAGNOSIS SPECIFIC NEW CANCER CASE DATA
821 PROVIDES, AS PART OF THE APPLICATION AT THE TIME IT IS SUBMITTED TO THE
822 DEPARTMENT, A SIGNED GOVERNING BODY RESOLUTION THAT IDENTIFIES THE NUMBER OF
823 DIAGNOSIS-SPECIFIC CANCER CASES BEING COMMITTED TO THE APPLICATION AND THAT
824 STATES NO CURRENT OR FUTURE DIAGNOSIS-SPECIFIC NEW CANCER CASE DATA WILL BE
825 USED IN SUPPORT OF ANY OTHER APPLICATION FOR A PET UNIT FOR A PERIOD OF FIVE (5)
826 YEARS FROM THE DATE OF START OF OPERATIONS OF THE APPROVED PET SCANNER
827 SERVICE FOR WHICH DATA ARE BEING COMMITTED. IF THE REQUIRED DOCUMENTATION FOR
828 THIS SUBSECTION IS NOT SUBMITTED WITH THE APPLICATION ON THE DESIGNATED
829 APPLICATION DATE, THE APPLICATION WILL BE DEEMED FILED ON THE FIRST APPLICABLE
830 DESIGNATED APPLICATION DATE AFTER ALL REQUIRED DOCUMENTATION IS RECEIVED BY
831 THE DEPARTMENT.

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

835 (B) FOR MOBILE PET SCANNER SERVICES, THE GEOGRAPHIC LOCATION OF EACH
836 ENTITY CONTRIBUTING DIAGNOSIS-SPECIFIC NEW CANCER CASE DATA IN THE PLANNING
837 AREA(S) FOR WHICH THE PROPOSED PET SERVICE CONTAINS A PROPOSED HOST SITE OR
838 WITHIN A 75-MILE RADIUS OF THE PROPOSED HOST SITE FOR RURAL AND MICROPOLITAN
839 STATISTICAL AREA COUNTIES OR 25-MILE RADIUS FOR METROPOLITAN STATISTICAL AREA
840 COUNTIES.

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

844
845 (2) NO ENTITY CURRENTLY OPERATING OR APPROVED TO OPERATE A PET SCANNER
846 SERVICE SHALL CONTRIBUTE DIAGNOSIS-SPECIFIC NEW CANCER CASES.

847
848 (3) THE DEPARTMENT MAY NOT CONSIDER A WITHDRAWAL OF DIAGNOSIS-SPECIFIC
849 NEW CANCER CASE DATA DURING THE 120-DAY APPLICATION REVIEW CYCLE FOLLOWING
850 THE DATE ON WHICH THE DEPARTMENT REVIEW OF THE APPLICATION COMMENCES OR
851 AFTER A PROPOSED DECISION TO APPROVE THE APPLICATION HAS BEEN ISSUED UNLESS
852 THE APPLICATION IS DENIED, WITHDRAWN, OR EXPIRED. THE WITHDRAWAL MUST BE
853 SUBMITTED TO THE DEPARTMENT IN THE FORM OF A GOVERNING BODY RESOLUTION THAT
854 CONTAINS THE SPECIFIC CON APPLICATION NUMBER TO WHICH THE DATA WERE ORIGINALLY
855 COMMITTED, THE LEGAL APPLICANT ENTITY, THE COMMITTING ENTITY, THE TYPE OF DATA,
856 THE DATE OF THE MEETING IN WHICH THE GOVERNING BODY AUTHORIZED THE WITHDRAWAL
857 OF THE DATA, THE GOVERNING BODY PRESIDENT'S SIGNATURE, AND THE DATE OF THE
858 SIGNATURE.

859
860 **Section 14. Project delivery requirements and terms of approval for all applicants**
861 **DOCUMENTATION OF DIAGNOSIS-SPECIFIC NEW CANCER CASE DATA**

862
863 Sec. 14. AN APPLICANT REQUIRED TO DOCUMENT VOLUMES OF DIAGNOSIS-SPECIFIC
864 NEW CANCER CASES SHALL SUBMIT, AS PART OF ITS APPLICATION AT THE TIME IT IS

865 SUBMITTED TO THE DEPARTMENT, DOCUMENTATION FROM THE DIVISION FOR VITAL
866 RECORDS AND HEALTH STATISTICS VERIFYING THE NUMBER OF DIAGNOSIS-SPECIFIC NEW
867 CANCER CASES PROVIDED IN SUPPORT OF THE APPLICATION FOR THE MOST RECENT
868 CALENDAR YEAR FOR WHICH VERIFIABLE DATA ARE AVAILABLE FROM THE STATE
869 REGISTRAR. IF THE REQUIRED DOCUMENTATION FOR THIS SUBSECTION IS NOT SUBMITTED
870 WITH THE APPLICATION ON THE DESIGNATED APPLICATION DATE, THE APPLICATION WILL BE
871 DEEMED FILED ON THE FIRST APPLICABLE DESIGNATED APPLICATION DATE AFTER ALL
872 REQUIRED DOCUMENTATION IS RECEIVED BY THE DEPARTMENT. DIAGNOSIS-SPECIFIC NEW
873 CANCER CASE DATA SUPPORTING AN APPLICATION UNDER THESE STANDARDS SHALL BE
874 SUBMITTED TO THE DIVISION FOR VITAL RECORDS AND HEALTH STATISTICS USING A FORMAT
875 AND MEDIA SPECIFIED IN INSTRUCTIONS FROM THE DEPARTMENT OF COMMUNITY HEALTH.

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

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

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

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

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

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

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

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

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

913 ~~— (vi) The applicant shall have, within the PET service, equipment and supplies to handle clinical~~
914 ~~emergencies that might occur within the PET service, with PET staff trained in CPR and other appropriate~~
915 ~~emergency interventions, and a physician on-site or immediately available to the PET service at all times~~
916 ~~when patients are undergoing PET procedures.~~

917 ~~— (vii) An applicant shall participate in Medicaid at least 12 consecutive months within the first two~~
918 ~~years of operation and continue to participate annually thereafter.~~

919 ~~— (viii) Fixed and mobile PET scanner units shall be operating at a minimum average annual level of~~
920 ~~utilization during the second twelve months of operation, and annually thereafter, of 1,500 PET~~
921 ~~equivalents per unit.~~
922 ~~— (d) Compliance with the following requirements:~~
923 ~~— (i) The applicant shall accept referrals for PET scanner services from all appropriately licensed~~
924 ~~practitioners.~~
925 ~~— (ii) The applicant, to assure that the PET scanner services will be utilized by all segments of the~~
926 ~~Michigan population, shall (A) not deny PET scanner services to any individual based on ability to pay or~~
927 ~~source of payment, (B) provide PET scanning services to any individual based on the clinical indications~~
928 ~~of need for the service, and (C) maintain information by payor and non-paying sources to indicate the~~
929 ~~volume of care from each source provided annually.~~
930 ~~— Compliance with selective contracting requirements shall not be construed as a violation of this~~
931 ~~term.~~
932 ~~— (iii) The applicant shall participate in a data collection network established and administered by the~~
933 ~~Department or its designee. The data may include, but are not limited to annual budget and cost~~
934 ~~information, operating schedules, through-put schedules, demographic and diagnostic information, the~~
935 ~~volume of care provided to patients from all payor sources, and other data requested by the Department~~
936 ~~or its designee. The applicant shall provide the required data on a separate basis for each separate and~~
937 ~~distinct site, PET scanner, or PET service as required by the Department, in a format established by the~~
938 ~~Department, and in a mutually agreed upon media. The Department may elect to verify the data through~~
939 ~~on-site review of appropriate records. If the applicant intends to include research PET equivalents~~
940 ~~conducted by a PET scanner other than a dedicated research PET scanner in its utilization statistics, the~~
941 ~~applicant shall submit to the Department a copy of the research protocol with evidence of approval by the~~
942 ~~Institutional Review Board. The applicant shall submit this at the time the applicant intends to include~~
943 ~~research procedures in its utilization statistics. The applicant shall separately report to the Department~~
944 ~~any PET equivalents conducted by a dedicated research PET scanner.~~
945 ~~— (iv) PET equipment to be replaced shall be removed from service on or before beginning operation~~
946 ~~of the replacement equipment, including the use of temporary scanners as part of the replacement~~
947 ~~project.~~
948 ~~— (v) The applicant shall provide the Department with a notice stating the first date on which the PET~~
949 ~~scanner became operational, and such notice shall be submitted to the Department consistent with~~
950 ~~applicable statute and promulgated rules.~~
951
952 ~~— (2) An applicant for a dedicated research PET scanner under Section 10 shall agree that the~~
953 ~~services provided by the PET scanner approved pursuant to Section 10 shall be delivered in compliance~~
954 ~~with the following terms of CON approval:~~
955 ~~— (a) The capital and operating costs relating to the dedicated research PET scanner approved~~
956 ~~pursuant to Section 8 shall be charged only to a specific research account(s) and not to any patient or~~
957 ~~third-party payor.~~
958 ~~— (b) The dedicated research PET scanner approved pursuant to Section 10 shall not be used for~~
959 ~~any purposes other than as approved by the Institutional Review Board unless the applicant has obtained~~
960 ~~CON approval for the PET scanner pursuant to Part 222 and these standards, other than Section 10.~~
961
962 ~~— (3) The operation of and referral of patients to the PET service shall be in conformance with 1978~~
963 ~~PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).~~
964
965 ~~— (4) The agreements and assurances required by this section shall be in the form of a certification~~
966 ~~authorized by the governing body of the applicant or its authorized agent.~~
967

968 **Section 15. Project delivery requirements and additional terms of approval for applicants**
969 **involving mobile PET services**COMMITMENT AND DOCUMENTATION OF DIAGNOSTIC CARDIAC
970 CATHETERIZATION DATA
971

972 Sec. 15. AN APPLICANT PROPOSING TO USE DIAGNOSTIC CARDIAC CATHETERIZATION

973 DATA SHALL DEMONSTRATE ALL OF THE FOLLOWING:

974
975 (1) EACH ENTITY CONTRIBUTING DIAGNOSTIC CARDIAC CATHETERIZATION DATA
976 PROVIDES, AS PART OF THE APPLICATION AT THE TIME IT IS SUBMITTED TO THE
977 DEPARTMENT, A SIGNED GOVERNING BODY RESOLUTION THAT IDENTIFIES THE NUMBER OF
978 DIAGNOSTIC CARDIAC CATHETERIZATION CASES (SESSIONS) COMMITTED TO THE
979 APPLICATION AND THAT STATES NO CURRENT OR FUTURE DIAGNOSTIC CARDIAC
980 CATHETERIZATION DATA WILL BE USED IN SUPPORT OF ANY OTHER APPLICATION FOR A PET
981 UNIT FOR THE DURATION OF THE PET SERVICE FOR WHICH DATA ARE BEING COMMITTED
982 FOR A PERIOD OF FIVE (5) YEARS FROM THE DATE OF START OF OPERATIONS OF THE
983 APPROVED PET SERVICE FOR WHICH DATA ARE BEING COMMITTED. IF THE REQUIRED
984 DOCUMENTATION FOR THIS SUBSECTION IS NOT SUBMITTED WITH THE APPLICATION ON THE
985 DESIGNATED APPLICATION DATE, THE APPLICATION WILL BE DEEMED FILED ON THE FIRST
986 APPLICABLE DESIGNATED APPLICATION DATE AFTER ALL REQUIRED DOCUMENTATION IS
987 RECEIVED BY THE DEPARTMENT.

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

991 (B) FOR MOBILE PET SCANNER SERVICES, THE GEOGRAPHIC LOCATION OF EACH
992 ENTITY CONTRIBUTING DIAGNOSIS SPECIFIC NEW CANCER CASE DATA IN THE PLANNING
993 AREA(S) FOR WHICH THE PROPOSED PET SERVICE CONTAINS A PROPOSED HOST SITE OR
994 WITHIN A 75-MILE RADIUS OF THE PROPOSED HOST SITE FOR RURAL AND MICROPOLITAN
995 STATISTICAL AREA COUNTIES OR 25-MILE RADIUS FOR METROPOLITAN STATISTICAL AREA
996 COUNTIES.

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

1000 (D) THE DIAGNOSTIC CARDIAC CATHETERIZATION CASE DATA IS FROM THE MOST
1001 RECENTLY COMPLETED REPORT(S) OF THE ANNUAL SURVEY PRODUCED BY THE
1002 DEPARTMENT, AND THE CONTRIBUTING ENTITY HAS CON APPROVAL TO PROVIDE
1003 DIAGNOSTIC CARDIAC CATHETERIZATION SERVICES.

1004
1005 (2) NO ENTITY CURRENTLY OPERATING OR APPROVED TO OPERATE A PET SCANNER
1006 SERVICE SHALL CONTRIBUTE DIAGNOSTIC CARDIAC CATHETERIZATION CASE DATA.

1007
1008 (3) THE DEPARTMENT MAY NOT CONSIDER A WITHDRAWAL OF DIAGNOSTIC CARDIAC
1009 CATHETERIZATION CASE DATA DURING THE 120-DAY APPLICATION REVIEW CYCLE
1010 FOLLOWING THE DATE ON WHICH THE DEPARTMENT REVIEW OF THE APPLICATION
1011 COMMENCES OR AFTER A PROPOSED DECISION TO APPROVE THE APPLICATION HAS BEEN
1012 DENIED UNLESS THE APPLICATION IS DENIED, WITHDRAWN, OR EXPIRED. THE WITHDRAWAL
1013 MUST BE SUBMITTED TO THE DEPARTMENT IN THE FORM OF A GOVERNING BODY
1014 RESOLUTION THAT CONTAINS THE SPECIFIC CON APPLICATION NUMBER TO WHICH THE DATA
1015 WERE ORIGINALLY COMMITTED, THE LEGAL APPLICANT ENTITY, THE COMMITTING ENTITY,
1016 THE TYPE OF DATA, THE DATE OF THE MEETING IN WHICH THE GOVERNING BODY
1017 AUTHORIZED THE WITHDRAWAL OF THE DATA, THE GOVERNING BODY PRESIDENT'S
1018 SIGNATURE, AND THE DATE OF THE SIGNATURE.

1019
1020 ~~(1) In addition to the provisions of Section 14, an applicant for a mobile PET services shall agree that the~~
1021 ~~services provided by the mobile PET scanner(s) shall be delivered in compliance with the following terms~~
1022 ~~of CON approval:~~

1023 ~~— (a) The central service coordinator for a mobile PET service, with an approved CON, shall notify~~
1024 ~~the administrative unit of the Department of Community Health responsible for administering the CON~~
1025 ~~program 30 days prior to dropping an existing host site.~~

1026 ~~— (b) Each host site must have at least one physician who is board certified or board eligible in~~

nuclear medicine or nuclear radiology on its medical staff. The physician(s) shall be responsible for (i) establishing patient examination and infusion protocol and (ii) providing for the interpretation of scans performed by the mobile PET service/scanner.

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

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

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

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

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

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

Section 16. Determination of PET equivalents COMMITMENT AND DOCUMENTATION OF INTACTABLE EPILEPSY DATA

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

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

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

(B) FOR MOBILE PET SCANNER SERVICES, THE GEOGRAPHIC LOCATION OF EACH ENTITY CONTRIBUTING DIAGNOSIS SPECIFIC NEW CANCER CASE DATA IN THE PLANNING AREA(S) FOR WHICH THE PROPOSED PET SCANNER SERVICE CONTAINS A PROPOSED HOST

1081 SITE OR WITHIN A 75-MILE RADIUS OF THE PROPOSED HOST SITE FOR RURAL AND
1082 MICROPOLITAN STATISTICAL AREA COUNTIES OR 25-MILE RADIUS FOR METROPOLITAN
1083 STATISTICAL AREA COUNTIES.

1084 (C) NO ENTITY CONTRIBUTING INTRACTABLE EPILEPSY CASE DATA HAS PREVIOUSLY
1085 COMMITTED OR IS COMMITTING DATA TO ANOTHER SERVICE THAT IS LESS THAN FIVE (5)
1086 YEARS FROM THE START OF OPERATIONS OF THAT SERVICE.

1087 (D) THE INTRACTABLE EPILEPSY CASE DATA IS FROM THE MOST RECENT MICHIGAN
1088 INPATIENT DATA BASE (MIDB) AVAILABLE TO THE DEPARTMENT.

1089
1090 (2) NO ENTITY CURRENTLY OPERATING OR APPROVED TO OPERATE A SCANNER SHALL
1091 CONTRIBUTE INTRACTABLE EPILEPSY CASE DATA.

1092
1093 (3) THE DEPARTMENT MAY NOT CONSIDER A WITHDRAWAL OF INTRACTABLE EPILEPSY
1094 CASE DATA DURING THE 120-DAY APPLICATION REVIEW CYCLE FOLLOWING THE DATE ON
1095 WHICH THE DEPARTMENT REVIEW OF THE APPLICATION COMMENCES OR AFTER A
1096 PROPOSED DECISION TO APPROVE THE APPLICATION UNLESS THE APPLICATION IS DENIED,
1097 WITHDRAWN, OR EXPIRED. THE WITHDRAWAL MUST BE SUBMITTED TO THE DEPARTMENT IN
1098 THE FORM OF A GOVERNING BODY RESOLUTION THAT CONTAINS THE SPECIFIC CON
1099 APPLICATION NUMBER TO WHICH THE DATA WERE ORIGINALLY COMMITTED, THE LEGAL
1100 APPLICANT ENTITY, THE COMMITTING ENTITY, THE TYPE OF DATA, THE DATE OF THE
1101 MEETING IN WHICH THE GOVERNING BODY AUTHORIZED THE WITHDRAWAL OF THE DATA,
1102 THE GOVERNING BODY PRESIDENT'S SIGNATURE, AND THE DATE OF THE SIGNATURE.

1103 For purposes of these standards, PET equivalents shall be calculated as follows:

1104 ~~_____ (a) Each actual patient visit performed during the time period specified in the applicable section(s)~~
1105 ~~of these standards shall be assigned a number of PET equivalents based on the sum of the applicable~~
1106 ~~values set forth in subsections (i) through (vii).~~

1107 ~~_____ (i) A single patient visit _____ 1.0~~

1108 ~~_____ (ii) Number of chemically different tracers~~
1109 ~~used during a single patient visit.~~

1110 ~~_____ 1 tracers = 0~~

1111 ~~_____ ≥2 tracers = 0.8~~

1112 ~~_____ (iii) Number of tracer injections performed~~
1113 ~~during a single patient visit.~~

1114 ~~_____ 1 tracer injection = 0~~

1115 ~~_____ 2 tracer injections = 0.3~~

1116 ~~_____ ≥3 tracer injections = 0.6~~

1117 ~~_____ (iv) Dynamic scan(s) performed during a single _____ 0.5~~
1118 ~~patient visit.~~

1119 ~~_____ (v) Number of bed positions used during a single~~
1120 ~~patient visit.~~

1121 ~~_____ 1 bed position = 0~~

1122 ~~_____ ≥2 bed positions = 0.2 for each additional position~~

1123 ~~_____ (vi) Arterial sampling performed during a single _____ 0.5~~
1124 ~~patient visit.~~

1125 ~~_____ (vii) Transmission scan _____ .1 per bed position~~

1126 ~~_____ **Total PET Equivalents for a Single Patient Visit**~~

1127 ~~_____ (b) For each pediatric patient visit, the PET equivalent(s) determined pursuant to subdivision (a)~~
1128 ~~shall be multiplied as follows:~~

1129 ~~_____ patient ≤ 5 years of age multiply by 4.0~~

1130 ~~_____ patient >5 ≤ 10 years of age multiply by 3.0~~

1131 ~~_____ patient >10 ≤ 17 years of age multiply by 2.0~~

1132 ~~_____ (c) For each radiation therapy patient visit, the PET equivalent(s) determined pursuant to~~
1133 ~~subdivision (a) shall be multiplied by 1.5.~~

1134 ~~_____ (d) The PET equivalents for each patient visit determined pursuant to subdivisions (a), (b) and (c)~~

1135 shall be summed to determine the total PET equivalents for the time period specified in the applicable
1136 section(s) of these standards.
1137

1138 **Section 17. Methodology for computing the projected number of PET data units**
1139 **DEPARTMENT INVENTORY OF PET SCANNERS**
1140

1141 Sec. 17. THE DEPARTMENT SHALL MAINTAIN AND PUBLICLY POST ON ITS WEB SITE A LIST
1142 OF PET SCANNER SERVICES ANNUALLY.

1143 ~~—The applicant being reviewed under Section 4 shall apply the methodology set forth in this section in~~
1144 ~~computing the projected number of PET data units.~~

1145 ~~—(1)(a) Identify the number of diagnosis specific new cancer cases documented in accord with the~~
1146 ~~requirements of Section 18.~~

1147 ~~—(b) Combine the number of cancer cases for lung (site codes C340-C349), esophagus (site codes~~
1148 ~~C150-C159), colorectal (site codes C180-C209), lymphoma (morphology codes 9590-9729), melanoma~~
1149 ~~(morphology codes 8720-8790), and head & neck [site codes C000-C148, C300-C329, C410, C411,~~
1150 ~~C470 OR C490 excluding C440-C444 (skin of head and neck), and additional codes approved by~~
1151 ~~National Coverage Determination]. Use the name “combined” for this grouping.~~

1152 ~~—(c) Multiply the number resulting from the calculation in “combined” cancer cases identified in~~
1153 ~~subsection (1)(b) by 0.8, which is the estimated probability that a “combined” cancer case will require a~~
1154 ~~PET scan.~~

1155 ~~—(d) Multiply the number resulting from the calculation in subsection (1)(c) by 2.5, which is the~~
1156 ~~estimated number of PET scans needed for each patient requiring a PET scan.~~

1157 ~~—(2)(a) Identify the number of diagnosis specific new cancer cases documented in accord with the~~
1158 ~~requirements of Section 18.~~

1159 ~~—(b) Multiply the number of breast cancer cases (site codes C500-C509) by 0.25, which is the~~
1160 ~~estimated probability that a breast cancer case will require a PET scan.~~

1161 ~~—(c) Multiply the number resulting from the calculation in subsection (2)(b) by 1.0, which is the~~
1162 ~~estimated number of PET scans needed for each patient requiring a PET scan.~~

1163 ~~—(3)(a) Multiply the number of diagnostic cardiac catheterization cases identified in accord with the~~
1164 ~~requirements of Section 20 by 0.1, which is the estimated probability that a patient having a diagnostic~~
1165 ~~cardiac catheterization will require a PET scan.~~

1166 ~~—(b) Multiply the number resulting from the calculation in subsection (3)(a) by 1.0, which is the~~
1167 ~~estimated number of PET scans needed for each patient requiring a PET scan.~~

1168 ~~(4)(a)(b) Multiply the number resulting from the calculation in subsection (4)(a) by 1.0, which is the~~
1169 ~~estimated number of PET scans needed for each patient requiring a PET scan.~~

1170 ~~—(5) Sum the numbers resulting from the calculations in subsections (1) through (4) to determine the~~
1171 ~~total number of projected PET data units.~~

1172 ~~—(6) Multiply the result calculated in subsection (5) above by a factor of 3.0 if the applicant is~~
1173 ~~proposing to serve only Planning Area 6 to determine the total number of projected PET data units.~~

1174 ~~—(7) Multiply the result calculated in subsection (5) above by a factor of 2.0 if the applicant is~~
1175 ~~proposing to serve only Planning Area 5 to determine the total number of projected PET data units.~~

1176 **Section 18. Commitment of diagnosis specific new cancer cases COMPARATIVE REVIEWS;**
1177 **EFFECT ON PRIOR PLANNING POLICIES**
1178

1179 Sec. 18. PROPOSED PROJECTS REVIEWED UNDER THESE STANDARDS SHALL NOT BE
1180

1189 SUBJECT TO COMPARATIVE REVIEW. THESE CON REVIEW STANDARDS SUPERSEDE AND
1190 REPLACE THE CON STANDARDS FOR PET SCANNER SERVICES APPROVED BY THE CON
1191 COMMISSION ON DECEMBER 12, 2006 AND EFFECTIVE MARCH 8, 2007.
1192

1193 ~~(1) An applicant proposing to use diagnosis specific new cancer cases shall demonstrate all of the~~
1194 ~~following:~~

1195 ~~— (a) Only those cancer diagnoses identified in Section 17(1) and 17(2) shall be included.~~

1196 ~~— (b) Each entity contributing diagnosis specific new cancer case data provides, as part of the~~
1197 ~~application at the time it is submitted to the Department, a signed governing body resolution that identifies~~
1198 ~~the number of diagnosis specific cancer cases being committed to the application and that states no~~
1199 ~~current or future diagnosis specific new cancer case data will be used in support of any other application~~
1200 ~~for a PET unit for a period of five (5) years from the date of start of operations of the approved PET~~
1201 ~~service for which data are being committed. If the required documentation for this subsection is not~~
1202 ~~submitted with the application on the designated application date, the application will be deemed filed on~~
1203 ~~the first applicable designated application date after all required documentation is received by the~~
1204 ~~Department.~~

1205 ~~— (c) For fixed PET scanner services, the geographic location of each entity contributing diagnosis~~
1206 ~~specific new cancer case data is in the same planning area as the proposed PET service.~~

1207 ~~— (d) For mobile PET scanner services, the geographic location of each entity contributing diagnosis~~
1208 ~~specific new cancer case data in the planning area(s) for which the proposed PET service contains a~~
1209 ~~proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical~~
1210 ~~area counties or 25-mile radius for metropolitan statistical area counties.~~

1211 ~~— (e) No entity contributing diagnosis specific new cancer case data has previously committed or is~~
1212 ~~committing data to another service that is less than five (5) years from the start of operations of that~~
1213 ~~service and is listed on the "Department Inventory of Pet Scanners."~~

1214
1215 ~~— (2) No entity currently operating or approved to operate a scanner, whether fixed or mobile, listed~~
1216 ~~on the "Department Inventory of PET Scanners" shall contribute diagnosis specific new cancer cases.~~

1217
1218 ~~— (3)(a) The Department may not consider a withdrawal of diagnosis specific new cancer case data~~
1219 ~~during the 120-day application review cycle following the date on which the Department review of the~~
1220 ~~application commences or after a proposed decision to approve the application has been issued unless~~
1221 ~~the application is denied, withdrawn, or expired.~~

1222 ~~— (b) The withdrawal must be submitted to the Department in the form of a governing body resolution~~
1223 ~~that contains the specific CON application number to which the data were originally committed, the legal~~
1224 ~~applicant entity, the committing entity, the type of data, the date of the meeting in which the governing~~
1225 ~~body authorized the withdrawal of the data, the governing body president's signature, and the date of the~~
1226 ~~signature.~~

1227
1228 **Section 19. Documentation of diagnosis specific new cancer case data**

1229
1230 ~~Sec. 19. (1) An applicant required to document volumes of diagnosis specific new cancer cases~~
1231 ~~shall submit, as part of its application at the time it is submitted to the Department, documentation from~~
1232 ~~the Division for Vital Records and Health Statistics verifying the number of diagnosis specific new cancer~~
1233 ~~cases provided in support of the application for the most recent calendar year for which verifiable data are~~
1234 ~~available from the State Registrar. If the required documentation for this subsection is not submitted with~~
1235 ~~the application on the designated application date, the application will be deemed filed on the first~~
1236 ~~applicable designated application date after all required documentation is received by the Department.~~

1237
1238 ~~— (2) Diagnosis specific new cancer case data supporting an application under these standards shall~~
1239 ~~be submitted to the Division for Vital Records and Health Statistics using a format and media specified in~~
1240 ~~instructions from the Department of Community Health.~~

1242 **Section 20. Commitment and documentation of diagnostic cardiac catheterization data**
1243

1244 ~~Sec. 20. (1) An applicant proposing to use diagnostic cardiac catheterization data shall demonstrate~~
1245 ~~all of the following:~~

1246 ~~(a) Each entity contributing diagnostic cardiac catheterization data [pursuant to Section 17(3)(a)]~~
1247 ~~provides, as part of the application at the time it is submitted to the Department, a signed governing body~~
1248 ~~resolution that identifies the number of diagnostic cardiac catheterization cases (sessions) committed to~~
1249 ~~the application and that states no current or future diagnostic cardiac catheterization data will be used in~~
1250 ~~support of any other application for a PET unit for the duration of the PET service for which data are~~
1251 ~~being committed for a period of five (5) years from the date of start of operations of the approved PET~~
1252 ~~service for which data are being committed. If the required documentation for this subsection is not~~
1253 ~~submitted with the application on the designated application date, the application will be deemed filed on~~
1254 ~~the first applicable designated application date after all required documentation is received by the~~
1255 ~~Department.~~

1256 ~~—(b) For fixed PET scanner services, the geographic location of each entity contributing diagnostic~~
1257 ~~cardiac catheterization data is in the same planning area as the proposed PET unit/service.~~

1258 ~~—(c) For mobile PET scanner services, the geographic location of each entity contributing diagnosis~~
1259 ~~specific new cancer case data in the planning area(s) for which the proposed PET service contains a~~
1260 ~~proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical~~
1261 ~~area counties or 25-mile radius for metropolitan statistical area counties.~~

1262 ~~—(d) No entity contributing diagnostic cardiac catheterization data has previously committed or is~~
1263 ~~committing data to another service that is less than five (5) years from the start of operations of that~~
1264 ~~service and is listed on the "Department Inventory of Pet Scanners."~~

1265 ~~—(e) The diagnostic cardiac catheterization case data is from the most recently completed report(s)~~
1266 ~~of the "Annual Hospital Statistical Questionnaire" produced by the Department, and the contributing entity~~
1267 ~~has CON Approval to provide diagnostic cardiac catheterization services.~~

1268
1269 ~~—(2) No entity currently operating or approved to operate a PET scanner, whether fixed or mobile,~~
1270 ~~listed on the "Department Inventory of PET Scanners" shall contribute diagnostic cardiac catheterization~~
1271 ~~case data.~~

1272
1273 ~~—(3)(a) The Department may not consider a withdrawal of diagnostic cardiac catheterization case data~~
1274 ~~during the 120-day application review cycle following the date on which the Department review of the~~
1275 ~~application commences or after a proposed decision to approve the application has been denied unless~~
1276 ~~the application is denied, withdrawn, or expired.~~

1277 ~~—(b) The withdrawal must be submitted to the Department in the form of a governing body resolution~~
1278 ~~that contains the specific CON application number to which the data were originally committed, the legal~~
1279 ~~applicant entity, the committing entity, the type of data, the date of the meeting in which the governing~~
1280 ~~body authorized the withdrawal of the data, the governing body president's signature, and the date of the~~
1281 ~~signature.~~

1282
1283 **Section 21. Commitment and documentation of intractable epilepsy data**
1284

1285 ~~—Sec. 21. (1) An applicant proposing to use intractable epilepsy cases shall demonstrate all of the~~
1286 ~~following:~~

1287 ~~—(a) Each entity contributing intractable epilepsy data [pursuant to Section 17(4)(a)] provides, as~~
1288 ~~part of the application at the time it is submitted to the Department, a signed governing body resolution~~
1289 ~~that identifies the number of intractable epilepsy cases committed to the application and that states no~~
1290 ~~current or future intractable epilepsy case data will be used in support of any other application for a PET~~
1291 ~~unit for the duration of the PET service for which the data are being committed for a period of five (5)~~
1292 ~~years from the date of start of operations of the approved PET service for which data are being~~
1293 ~~committed. If the required documentation for this subsection is not submitted with the application on the~~
1294 ~~designated application date, the application will be deemed filed on the first applicable designated~~
1295 ~~application date after all required documentation is received by the Department.~~

1296 ~~—— (b) For fixed PET scanner services, the geographic location of each entity contributing intractable~~
1297 ~~epilepsy case data is in the same planning area as the proposed PET unit/service.~~
1298 ~~—— (c) For mobile PET scanner services, the geographic location of each entity contributing diagnosis~~
1299 ~~specific new cancer case data in the planning area(s) for which the proposed PET service contains a~~
1300 ~~proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical~~
1301 ~~area counties or 25-mile radius for metropolitan statistical area counties.~~
1302 ~~—— (d) No entity contributing intractable epilepsy case data has previously committed or is committing~~
1303 ~~data to another service that is less than five (5) years from the start of operations of that service and is~~
1304 ~~listed on the "Department Inventory of Pet Scanners."~~
1305 ~~—— (e) The intractable epilepsy case data is from the most recent Michigan Inpatient Data Base~~
1306 ~~(MIDB) available to the Department.~~
1307
1308 ~~—— (2) No entity currently operating or approved to operate a scanner, whether fixed or mobile, listed~~
1309 ~~on the "Department Inventory of Pet Scanners" shall contribute intractable epilepsy case data.~~
1310
1311 ~~—— (3)(a) The Department may not consider a withdrawal of intractable epilepsy case data during the~~
1312 ~~120-day application review cycle following the date on which the Department review of the application~~
1313 ~~commences or after a proposed decision to approve the application unless the application is denied,~~
1314 ~~withdrawn, or expired.~~
1315 ~~—— (b) The withdrawal must be submitted to the Department in the form of a governing body resolution~~
1316 ~~that contains the specific CON application number to which the data were originally committed, the legal~~
1317 ~~applicant entity, the committing entity, the type of data, the date of the meeting in which the governing~~
1318 ~~body authorized the withdrawal of the data, the governing body president's signature, and the date of the~~
1319 ~~signature.~~
1320

1322

1323 | ~~Sec. 22.~~ Counties assigned to each health service area are as follows:

1324

1325 **HEALTH SERVICE AREA****COUNTIES**

1326

1327	1	Livingston	Monroe	St. Clair
1328		Macomb	Oakland	Washtenaw
1329		Wayne		

1330

1331	2	Clinton	Hillsdale	Jackson
1332		Eaton	Ingham	Lenawee

1333

1334	3	Barry	Calhoun	St. Joseph
1335		Berrien	Cass	Van Buren
1336		Branch	Kalamazoo	

1337

1338	4	Allegan	Mason	Newaygo
1339		Ionia	Mecosta	Oceana
1340		Kent	Montcalm	Osceola
1341		Lake	Muskegon	Ottawa

1342

1343	5	Genesee	Lapeer	Shiawassee
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1345	6	Arenac	Huron	Roscommon
1346		Bay	Iosco	Saginaw
1347		Clare	Isabella	Sanilac
1348		Gladwin	Midland	Tuscola
1349		Gratiot	Ogemaw	

1350

1351	7	Alcona	Crawford	Missaukee
1352		Alpena	Emmet	Montmorency
1353		Antrim	Gd Traverse	Oscoda
1354		Benzie	Kalkaska	Otsego
1355		Charlevoix	Leelanau	Presque Isle
1356		Cheboygan	Manistee	Wexford

1357

1358	8	Alger	Gogebic	Mackinac
1359		Baraga	Houghton	Marquette
1360		Chippewa	Iron	Menominee
1361		Delta	Keweenaw	Ontonagon
1362		Dickinson	Luce	Schoolcraft

1363

1365

1366 | **Sec. 23. COUNTIES BY** Health service areas assigned to each planning area are as follows:

1367

1368 **PLANNING AREA 1****COUNTIES**

1369

1370 HSA 1

Livingston

Monroe

St. Clair

1371

Macomb

Oakland

Washtenaw

1372

Wayne

1373

1374 **PLANNING AREA 2**

1375

1376 HSA 2

Clinton

Hillsdale

Jackson

1377

Eaton

Ingham

Lenawee

1378 HSA 3

Barry

Calhoun

St. Joseph

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Berrien

Cass

Van Buren

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Branch

Kalamazoo

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1382 **PLANNING AREA 3**

1383

1384 HSA 4

Allegan

Mason

Newaygo

1385

Ionia

Mecosta

Oceana

1386

Kent

Montcalm

Osceola

1387

Lake

Muskegon

Ottawa

1388

1389 **PLANNING AREA 4**

1390

1391 HSA 5

Genesee

Lapeer

Shiawassee

1392 HSA 6

Arenac

Huron

Roscommon

1393

Bay

Iosco

Saginaw

1394

Clare

Isabella

Sanilac

1395

Gladwin

Midland

Tuscola

1396

Gratiot

Ogemaw

1397

1398 **PLANNING AREA 5**

1399

1400 HSA 7

Alcona

Crawford

Missaukee

1401

Alpena

Emmet

Montmorency

1402

Antrim

Gd Traverse

Oscoda

1403

Benzie

Kalkaska

Otsego

1404

Charlevoix

Leelanau

Presque Isle

1405

Cheboygan

Manistee

Wexford

1406

1407 **PLANNING AREA 6**

1408

1409 HSA 8

Alger

Gogebic

Mackinac

1410

Baraga

Houghton

Marquette

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Chippewa

Iron

Menominee

1412

Delta

Keweenaw

Ontonagon

1413

Dickinson

Luce

Schoolcraft

1414

**CON REVIEW STANDARDS
FOR PET SCANNER SERVICES**

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Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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