

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~~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~~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 47142.
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.

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 4(43 (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)~~**

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 OR 25-MILE
309 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 ~~(a1) For an 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 SCANNER(S)~~
368 ~~For an applicant serving at least one existing host site in a metropolitan statistical area county, all of the~~
369 ~~applicant's approved mobile PET scanners on a mobile route have performed an average of at least~~
370 ~~5,000 PET equivalents per PET scanner during IN the most recent 12-month period VERIFIABLE BY for~~
371 ~~which the Department has verifiable data FOR AN APPLICANT SERVING AT LEAST ONE EXISTING~~
372 ~~HOST SITE IN A METROPOLITAN STATISTICAL AREA COUNTY, OR~~

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

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

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

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

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

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

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

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

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

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

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

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

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

(4) THIS SECTION DOES NOT APPLY TO DEDICATED RESEARCH, DEDICATED PEDIATRIC OR PEM SCANNERS.

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

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

~~(2) FOR THE FIRST~~ An applicant APPLICATION proposing to replace ACQUIRE an existing FIXED, mobile, OR HOST SITE PET scanner(s) SERVICE shall demonstrate that all of the applicant's approved and operating mobile PET scanners on OR AFTER <INSERT EFFECTIVE DATE OF STANDARDS>, THE EXISTING-a mobile route have performed an average of at least 3,000 PET equivalents per PET scanner SERVICE AND ITS SCANNER(S) SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE APPLICABLE VOLUME REQUIREMENTS SET FORTH IN THIS SECTION during the most recent 12-month period for which the Department has verifiable data.

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

438 (a3) The existing PET scanner is technologically incapable of performing the applicable minimum
439 number of PET equivalents. An applicant proposing a-TO replacement-ACQUIRE AN EXISTING HOST
440 SITEunder this subsection shall provide documentationDEMONSTRATE, satisfactory toTHAT the
441 Department, from a person or an organization with recognized professional expertise regarding that type
442 of equipment, other than the applicant or a representative of a manufacturer or vendor of that type of
443 equipment, indicating the number of PET equivalents the existing HOST SITE HAS equipment is
444 technologically capable of performingperformed. 50 SCANS The applicant also shall provide
445 documentation, satisfactory to the Department, that the number of PET equivalents performed duringIN
446 the most recent 12-month period, for which VERIFIABLE BY the Department has verifiable data, was the
447 number the equipment is technologically capable of performing.

448
449 (4) An applicant proposing to replace a PET scanner(s), whether fixed or mobile, shall
450 demonstrate:

451 (a) the equipment to be replaced is fully depreciated according to generally accepted accounting
452 principles or

453 (b) either of the following:

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

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

459
460 (5) An applicant that meets all of the following requirements shall not be required to be in
461 compliance with subsections (1), (2), (3) and (4):

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

464 (b) The proposed PET scanner is a PET/CT scanner hybrid.

465
466 (6) In the case of a fixed PET scanner, the proposed PET scanner will be located at the same site
467 as the applicant's existing fixed PET scanner to be replaced. If the proposed scanner will not be located
468 at the same site, the applicant must meet the requirements to relocate a PET scanner at the proposed
469 site, in accordance with Section 9.

470 471 **Section 7. Requirements for approval for applicants proposing to acquire an existingA** 472 **DEDICATED RESEARCH FIXED PET scanner**

473
474 Sec. 7. An applicant proposing to acquire-ADD an existing-FIXED PET scanner, whether fixed or
475 mobile-scanner TO EXPAND AN EXISTING PET SCANNER SERVICE FOR EXCLUSIVE RESEARCH
476 USE shall NOT NEED TO demonstrate that it meets all of the followingREQUIREMENTS OF SECTIONS
477 3 AND 5 IF THE APPLICANT DEMONSTRATES EACH OF THE FOLLOWING:;

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

482 (b2) The project-APPLICANT HAS ACCESS TO A CYCLOTRON FOR ACCELERATING
483 CHARGED PARTICLES TO HIGH ENERGIES BY MEANS will not change the number of PET scanners
484 listed on the Department Inventory of PET ScannersELECTROMAGNETIC FIELDS.

485 (c3) The project-APPLICAN THAS NO MORE THAN THREE DEDICATED RESEARCHFIXEDwill
486 not result in the replacement of the PET scannerscanners APPROVED UNDER THIS to be acquired

487 unless the applicant demonstrates that the requirements of Section 6 also have been met.
488 (d) The PET scanner to be acquired is listed on the Department Inventory of PET Scanners on the
489 date the application is submitted to the Department.
490 (e) The applicant agrees to operate the PET scanner in accordance with all applicable project
491 delivery requirements set forth in Section 14 of these standards.
492

493 **Section 8. Requirements for approval for applicants proposing to acquire an existing A**
494 **DEDICATED PEDIATRIC PET scanner service**
495

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

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

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

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

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

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

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

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

520 (B) ANESTHESIOLOGY

521 (C) CARDIOLOGY

522 (D) CRITICAL CARE

523 (E) GASTROENTEROLOGY

524 (F) HEMATOLOGY/ONCOLOGY

525 (G) NEUROLOGY

526 (H) NEUROSURGERY

527 (I) ORTHOPEDIC SURGERY

528 (J) PATHOLOGY

529 (K) PULMONOLOGY

530 (L) SURGERY

531 (M) NEONATOLOGY

532
533 (4) THE APPLICANT SHALL HAVE IN OPERATION THE FOLLOWING PEDIATRIC SPECIALTY
534 PROGRAMS AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT:

535 (A) BONE MARROW TRANSPLANT PROGRAM

536 (B) SEDATION PROGRAM

537 (C) OPEN HEART PROGRAM

538
539 (5) THE APPLICANT MEETS THE REQUIREMENTS OF SECTION 3, SUBSECTIONS (1)
540 THROUGH (4), IF THE APPLICANT IS INITIATING A PET SCANNER SERVICE WITH A

541 DEDICATED PEDIATRIC FIXED PET SCANNER.

542
543 (6) THE APPLICANT HAS NO MORE THAN THREE DEDICATED PEDIATRIC FIXED PET
544 SCANNERS APPROVED UNDER THIS SECTION.

545
546 **Section 9. Requirements for ~~approval for applicants proposing to relocate an existing PET A~~**
547 **POSITRON EMISSION MAMMOGRAPHY (PEM) scanner service or its unit(s)**
548

549 Sec. 9. ~~(1) An applicant proposing to relocate~~ ADD A PEM SCANNER TO EXPAND an existing
550 ~~fixed PET SCANNER service~~ FOR EXCLUSIVE USE IN A COMPREHENSIVE DIAGNOSTIC BREAST
551 PROGRAM and all its existing unit(s) shall NOT NEED TO MEET ~~demonstrate that it meets all of the~~
552 REQUIREMENTS OF SECTION 6 IF THE APPLICANT DEMONSTRATES EACH OF THE following:
553

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

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

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

562 ~~(d) The proposed project will not result in an increase in the number of PET scanner(s) operated~~
563 ~~by the applicant at the proposed site unless the applicant demonstrates that the requirements of Section~~
564 ~~5, as applicable, have also been met.~~

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

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

570
571 ~~(2) An applicant proposing to relocate a PET scanner of an existing PET service shall demonstrate~~
572 ~~that it meets all of the following:~~

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

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

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

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

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

581
582 **Section 10. Requirements for ~~approval for applicants proposing a dedicated research fixed PET~~**
583 **scanner** MEDICAID PARTICIPATION
584

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

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

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

595 ~~_____ (c) The applicant has access to a cyclotron.~~

596

597 ~~_____ (2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the~~
598 ~~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~~
599 ~~these standards.~~

600

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

603

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

607

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

610

611 ~~_____ (b2) The applicant shall experience at least 5,000 pediatric (< 18 years old) surgeries in the most~~
612 ~~recent year of operation~~ COMPLIANCE WITH THE FOLLOWING QUALITY ASSURANCE
613 REQUIREMENTS:-

614

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

628

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

634

635 ~~(i) pediatric radiology (at least two staff members)~~

636

637 ~~_____ (ii) pediatric anesthesiology~~

638

639 ~~_____ (iii) pediatric cardiology~~

640

641 ~~_____ (iv) pediatric critical care~~

642

643 ~~_____ (v) pediatric gastroenterology~~

644

645 ~~_____ (vi) pediatric hematology/oncology~~

646

647 ~~_____ (vii) pediatric neurology~~

648

649 ~~_____ (viii) pediatric neurosurgery~~

650

651 ~~_____ (ix) pediatric orthopedic surgery~~

652

653 ~~_____ (x) pediatric pathology~~

654

655 ~~_____ (xi) pediatric pulmonology~~

656

657 ~~_____ (xii) pediatric surgery~~

658

659 ~~_____ (xiii) neonatology~~

660

661 ~~(eC) The applicant shall have in operation the following pediatric specialty programs at the time the~~
662 ~~application is submitted to~~ PET SCANNER SERVICE SHALL HAVE A PHYSICIAN ON-SITE OR

649 IMMEDIATELY AVAILABLE TO THE PET SCANNER SERVICE AT ALL TIMES WHEN PATIENTS ARE
650 UNDERGOING PET PROCEDURES~~the Department;~~

- 651 ~~(i) pediatric bone marrow transplant program~~
- 652 ~~(ii) established pediatric sedation program~~
- 653 ~~(iii) pediatric open heart program~~

654
655 ~~(23) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the~~
656 ~~requirements of Section 4 or Section 5 of these standards but must meet Section 6.~~ COMPLIANCE WITH
657 THE FOLLOWING ACCESS TO CARE REQUIREMENTS:

658 ~~(3A) The dedicated pediatric PET scanner SERVICE shall be excluded.~~ ACCEPT REFERRALS FOR
659 PET SCANNER SERVICES from the adult count for ALL APPROPRIATELY LICENSED
660 PRACTITIONERS~~the facility.~~

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

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

666 (D) THE OPERATION OF AND REFERRAL OF PATIENTS TO THE PET SERVICE SHALL BE IN
667 CONFORMANCE WITH 1978 PA 368, SEC. 16221, AS AMENDED BY 1986 PA 319; MCL
668 333.16221; MSA 14.15 (16221).

669
670 (4) COMPLIANCE WITH THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:

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

675 (B) THE PET SCANNER SERVICE SHALL PARTICIPATE IN A DATA COLLECTION SYSTEM
676 ESTABLISHED AND ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE. THE
677 DATA MAY INCLUDE, BUT ARE NOT LIMITED TO, CLINICAL SCAN DATA, ANNUAL
678 BUDGET AND COST INFORMATION, OPERATING SCHEDULES, THROUGH-PUT
679 SCHEDULES, DEMOGRAPHIC AND DIAGNOSTIC INFORMATION, AND THE VOLUME OF
680 CARE PROVIDED TO PATIENTS FROM ALL PAYOR SOURCES. THE APPLICANT SHALL
681 PROVIDE THE REQUIRED DATA ON A SEPARATE BASIS FOR EACH SEPARATE AND
682 DISTRICT SITE, PET SCANNER, OR PET SERVICE AS REQUIRED BY THE DEPARTMENT,
683 IN A FORMAT ESTABLISHED BY THE DEPARTMENT. THE DEPARTMENT MAY ELECT TO
684 VERIFY THE DATA THROUGH ON-SITE REVIEW OF APPROPRIATE RECORDS.

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

688
689 (5) COMPLIANCE WITH THE FOLLOWING DEDICATED RESEARCH PET SCANNER
690 REQUIREMENTS, IF APPLICABLE:

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

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

696
697 (6) COMPLIANCE WITH THE FOLLOWING DEDICATED PEDIATRIC PET SCANNER
698 REQUIREMENTS, IF APPLICABLE:

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

701 (B) SHALL MAINTAIN ACTIVE MEDICAL STAFF IN THE APPLICABLE PEDIATRIC
702 SPECIALTIES AND PEDIATRIC SPECIALTY PROGRAMS AS SET FORTH IN THE

703 SECTION.

704
705 (7) COMPLIANCE WITH THE FOLLOWING PEM SCANNER REQUIREMENTS, IF APPLICABLE:

706 (A) ~~(DEPARTMENT TO DEVELOP)~~

707
708 (8) COMPLIANCE WITH THE FOLLOWING MOBILE PET SCANNER REQUIREMENTS, IF
709 APPLICABLE:

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

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

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

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

725
726 (9) THE AGREEMENTS AND ASSURANCES REQUIRED BY THIS SECTION SHALL BE IN
727 THE FORM OF A CERTIFICATION AGREED TO BY THE APPLICANT OR ITS AUTHORIZED
728 AGENT.

729
730 **Section 12. ~~Additional requirements~~METHODOLOGY for mobile**COMPUTING THE PROJECTED****
731 **PET service**DATA UNITS****

732
733 Sec. 12. ~~(1) An applicant proposing to begin operation of a mobile PET service shall demonstrate all~~
734 ~~of the following~~BEING REVIEWED UNDER SECTION 4 SHALL APPLY THE METHODOLOGY SET
735 FORTH IN THIS SECTION IN COMPUTING THE PROJECTED NUMBER OF PET DATA UNITS:

736
737 ~~____(a1) A separate CON application has been submitted by the central service coordinator and each~~
738 ~~proposed host site~~IDENTIFY THE NUMBER OF DIAGNOSIS-SPECIFIC NEW CANCER CASES
739 DOCUMENTED IN ACCORDANCE WITH THE REQUIREMENTS OF SECTION 13.

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

748
749 ~~(eB) The requirements of sections 3, 4, 5, and 6, as applicable, have been met. Multiply the number~~
750 ~~resulting from the calculation in "combined" cancer cases identified in subsection (1)(b) by 0.8, which is~~
751 ~~the estimated probability that a "combined" cancer case will require a PET scan.~~

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

754
755
756 ~~(2) An applicant proposing to become a host site on an existing mobile PET scanner service shall~~

757 ~~demonstrate that it meets all of the following:~~ Identify the number of diagnosis-specific new cancer cases
758 documented in accord with the requirements of Section 13.

759 (a) ~~Approval of the application will not result in an increase in the number of mobile PET scanners~~
760 ~~listed on the "Department Inventory of PET Scanners" unless the requirements of Section 5 have been~~
761 ~~met. Multiply the number of breast cancer cases (site codes C500-C509) by 0.25, which is the estimated~~
762 probability that a breast cancer case will require a PET scan.

763 (b) ~~A proposed regular route schedule, the procedures for handling emergency situations, and~~
764 ~~copies of all proposed contracts related to the mobile PET scanner have been included in the CON~~
765 ~~application. Multiply the number resulting from the calculation in subsection (2)(b) by 1.0, which is the~~
766 estimated number of PET scans needed for each patient requiring a PET scan.

767
768 (3) Multiply the number of diagnostic cardiac catheterization cases identified in accord with the
769 requirements of Section 15 by 0.1, which is the estimated probability that a patient having a diagnostic
770 cardiac catheterization will require a PET scan.

771 (4) Multiply the number of intractable epilepsy cases (ICD-9-CM Codes 345.01, 345.11, 345.41,
772 345.51, 345.61, 345.71, 345.81, OR 345.91) identified in accord with the requirements of Section 16 by
773 1.0, which is the estimated probability that a patient having an intractable epilepsy procedure will require
774 a PET scan. Multiply the number resulting from the calculation in subsection (3) by 1.0, which is the
775 estimated number of PET scans needed for each patient requiring a PET scan.

776
777
778
779 (5) Sum the numbers resulting from the calculations in subsections (1) through (4) to determine the
780 total number of projected PET data units.

781
782 (6) Multiply the result calculated in subsection (5) above by a factor of 3.0 if the applicant is
783 proposing to serve only Planning Area 6 to determine the total number of projected PET data units.

784
785 (7) Multiply the result calculated in subsection (5) above by a factor of 2.0 if the applicant is
786 proposing to serve only Planning Area 5 to determine the total number of projected PET data units.

787
788
789 **Section 13. ~~Requirements for approval for all applicants~~ COMMITMENT OF DIAGNOSIS-SPECIFIC**
790 **NEW CANCER CASES**

791
792 ~~Sec. 13. An applicant shall provide verification of Medicaid participation at the time the application is~~
793 ~~submitted to the Department. If the required documentation is not submitted with the application on the~~
794 ~~designated application date, the application will be deemed filed on the first applicable designated~~
795 ~~application date after all required documentation is received by the Department.) An applicant proposing~~
796 ~~to use diagnosis specific new cancer cases shall demonstrate all of the following:~~

797
798 (1) Only those cancer diagnoses identified in Section 12(1) and 12(2) shall be included.

799
800 (2) Each entity contributing diagnosis specific new cancer case data provides, as part of the
801 application at the time it is submitted to the Department, a signed governing body resolution that identifies
802 the number of diagnosis- specific cancer cases being committed to the application and that states no
803 current or future diagnosis- specific new cancer case data will be used in support of any other application
804 for a PET unit for a period of five (5) years from the date of start of operations of the approved PET
805 service for which data are being committed. If the required documentation for this subsection is not
806 submitted with the application on the designated application date, the application will be deemed filed on
807 the first applicable designated application date after all required documentation is received by the
808 Department.

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

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

815 (C) No entity contributing diagnosis- specific new cancer case data has previously committed or is
816 committing data to another service that is less than five (5) years from the start of operations of that
817 service and is listed on the "Department Inventory of Pet Scanners."

818
819 (2) No entity currently operating or approved to operate a PET scanner SERVICE shall contribute
820 diagnosis specific new cancer cases.

821
822 (3) The Department may not consider a withdrawal of diagnosis-specific new cancer case data
823 during the 120-day application review cycle following the date on which the Department review of the
824 application commences or after a proposed decision to approve the application has been issued unless
825 the application is denied, withdrawn, or expired. The withdrawal must be submitted to the Department in
826 the form of a governing body resolution that contains the specific CON application number to which the
827 data were originally committed, the legal applicant entity, the committing entity, the type of data, the date
828 of the meeting in which the governing body authorized the withdrawal of the data, the governing body
829 president's signature, and the date of the signature.

830
831 **Section 14. Project delivery requirements and terms of approval for all applicants**
832 **DOCUMENTATION OF DIAGNOSIS- SPECIFIC NEW CANCER CASE DATA**

833
834 Sec. 14. An applicant required to document volumes of diagnosis specific new cancer cases shall
835 submit, as part of its application at the time it is submitted to the Department, documentation from the
836 Division for Vital Records and Health Statistics verifying the number of diagnosis- specific new cancer
837 cases provided in support of the application for the most recent calendar year for which verifiable data are
838 available from the State Registrar. If the required documentation for this subsection is not submitted with
839 the application on the designated application date, the application will be deemed filed on the first
840 applicable designated application date after all required documentation is received by the Department.
841 Diagnosis- specific new cancer case data supporting an application under these standards shall be
842 submitted to the Division for Vital Records and Health Statistics using a format and media specified in
843 instructions from the Department of Community Health.

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

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

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

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

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

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

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

865 ~~— (iv) An applicant shall establish a PET service team. A PET service team shall be responsible for~~
866 ~~(A) developing criteria for procedure performance, (B) developing protocols for procedure performance,~~
867 ~~(C) developing a clinical data base for utilization review and quality assurance purposes, (D) transmitting~~
868 ~~requested data to the Department, (E) screening of patients to assure appropriate utilization of the PET~~
869 ~~scanner, (F) taking and interpreting scans, and (G) coordinating PET activity at a PET host site(s) for a~~
870 ~~mobile pet service(s)/scanner(s).~~
871 ~~— (v) At a minimum, the PET service team shall include the following personnel, employed directly by~~
872 ~~the applicant or on a contractual basis: (A) a team leader, (B) technologists with training in PET~~
873 ~~scanning, (C) radiation safety personnel, and (D) a physicist(s). The physicist(s) must be board certified~~
874 ~~or eligible for certification by the American Board of Radiology or an equivalent organization. Other~~
875 ~~personnel that may be appropriate members of the PET service team, depending on the type of operation~~
876 ~~and PET procedures performed, include but are not limited to nurses, computer technicians, radio-~~
877 ~~chemists, radio-chemistry technicians, radio-pharmacists, and instrument maintenance technicians. If the~~
878 ~~team leader is not a physician, the PET service team also shall include a physician with appropriate~~
879 ~~training and familiarity with the appropriate diagnostic use and interpretation of cross-sectional images of~~
880 ~~the anatomical region(s) to be examined.~~
881 ~~— (vi) The applicant shall have, within the PET service, equipment and supplies to handle clinical~~
882 ~~emergencies that might occur within the PET service, with PET staff trained in CPR and other appropriate~~
883 ~~emergency interventions, and a physician on-site or immediately available to the PET service at all times~~
884 ~~when patients are undergoing PET procedures.~~
885 ~~— (vii) An applicant shall participate in Medicaid at least 12 consecutive months within the first two~~
886 ~~years of operation and continue to participate annually thereafter.~~
887 ~~— (viii) Fixed and mobile PET scanner units shall be operating at a minimum average annual level of~~
888 ~~utilization during the second twelve months of operation, and annually thereafter, of 1,500 PET~~
889 ~~equivalents per unit.~~
890 ~~— (d) Compliance with the following requirements:~~
891 ~~— (i) The applicant shall accept referrals for PET scanner services from all appropriately licensed~~
892 ~~practitioners.~~
893 ~~— (ii) The applicant, to assure that the PET scanner services will be utilized by all segments of the~~
894 ~~Michigan population, shall (A) not deny PET scanner services to any individual based on ability to pay or~~
895 ~~source of payment, (B) provide PET scanning services to any individual based on the clinical indications~~
896 ~~of need for the service, and (C) maintain information by payor and non-paying sources to indicate the~~
897 ~~volume of care from each source provided annually.~~
898 ~~— Compliance with selective contracting requirements shall not be construed as a violation of this~~
899 ~~term.~~
900 ~~— (iii) The applicant shall participate in a data collection network established and administered by the~~
901 ~~Department or its designee. The data may include, but are not limited to annual budget and cost~~
902 ~~information, operating schedules, through-put schedules, demographic and diagnostic information, the~~
903 ~~volume of care provided to patients from all payor sources, and other data requested by the Department~~
904 ~~or its designee. The applicant shall provide the required data on a separate basis for each separate and~~
905 ~~distinct site, PET scanner, or PET service as required by the Department, in a format established by the~~
906 ~~Department, and in a mutually agreed upon media. The Department may elect to verify the data through~~
907 ~~on-site review of appropriate records. If the applicant intends to include research PET equivalents~~
908 ~~conducted by a PET scanner other than a dedicated research PET scanner in its utilization statistics, the~~
909 ~~applicant shall submit to the Department a copy of the research protocol with evidence of approval by the~~
910 ~~Institutional Review Board. The applicant shall submit this at the time the applicant intends to include~~
911 ~~research procedures in its utilization statistics. The applicant shall separately report to the Department~~
912 ~~any PET equivalents conducted by a dedicated research PET scanner.~~
913 ~~— (iv) PET equipment to be replaced shall be removed from service on or before beginning operation~~
914 ~~of the replacement equipment, including the use of temporary scanners as part of the replacement~~
915 ~~project.~~
916 ~~— (v) The applicant shall provide the Department with a notice stating the first date on which the PET~~
917 ~~scanner became operational, and such notice shall be submitted to the Department consistent with~~
918 ~~applicable statute and promulgated rules.~~

919
920 ~~_____ (2) An applicant for a dedicated research PET scanner under Section 10 shall agree that the~~
921 ~~services provided by the PET scanner approved pursuant to Section 10 shall be delivered in compliance~~
922 ~~with the following terms of CON approval:~~

923 ~~_____ (a) The capital and operating costs relating to the dedicated research PET scanner approved~~
924 ~~pursuant to Section 8 shall be charged only to a specific research account(s) and not to any patient or~~
925 ~~third-party payor.~~

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

929
930 ~~_____ (3) The operation of and referral of patients to the PET service shall be in conformance with 1978~~
931 ~~PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).~~

932
933 ~~_____ (4) The agreements and assurances required by this section shall be in the form of a certification~~
934 ~~authorized by the governing body of the applicant or its authorized agent.~~

935
936 **Section 15. ~~Project delivery requirements and additional terms of approval for applicants~~**
937 **~~involving mobile PET services~~COMMITMENT AND DOCUMENTATION OF DIAGNOSTIC CARDIAC**
938 **CATHETERIZATION DATA**

939
940 ~~Sec. 15--~~AN applicant proposing to use diagnostic cardiac catheterization data shall demonstrate all
941 of the following:

942
943 _____ (1) Each entity contributing diagnostic cardiac catheterization data provides, as part of the
944 application at the time it is submitted to the Department, a signed governing body resolution that identifies
945 the number of diagnostic cardiac catheterization cases (sessions) committed to the application and that
946 states no current or future diagnostic cardiac catheterization data will be used in support of any other
947 application for a PET unit for the duration of the PET service for which data are being committed for a
948 period of five (5) years from the date of start of operations of the approved PET service for which data are
949 being committed. If the required documentation for this subsection is not submitted with the application on
950 the designated application date, the application will be deemed filed on the first applicable designated
951 application date after all required documentation is received by the Department.

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

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

958 _____ (C) No entity contributing diagnostic cardiac catheterization data has previously committed or is
959 committing data to another service that is less than five (5) years from the start of operations of that
960 service.

961 _____ (D) The diagnostic cardiac catheterization case data is from the most recently completed report(s)
962 of the ANNUAL SURVEY produced by the Department, and the contributing entity has CON approval to
963 provide diagnostic cardiac catheterization services.

964
965 _____ (2) No entity currently operating or approved to operate a PET scanner PET scanner SERVICE
966 shall contribute diagnostic cardiac catheterization case data.

967
968 _____ (3) The Department may not consider a withdrawal of diagnostic cardiac catheterization case data
969 during the 120-day application review cycle following the date on which the Department review of the
970 application commences or after a proposed decision to approve the application has been denied unless
971 the application is denied, withdrawn, or expired. The withdrawal must be submitted to the Department in
972 the form of a governing body resolution that contains the specific CON application number to which the

973 data were originally committed, the legal applicant entity, the committing entity, the type of data, the date
974 of the meeting in which the governing body authorized the withdrawal of the data, the governing body
975 president's signature, and the date of the signature.

976
977
978 ~~(1) In addition to the provisions of Section 14, an applicant for a mobile PET services shall agree that the~~
979 ~~services provided by the mobile PET scanner(s) shall be delivered in compliance with the following terms~~
980 ~~of CON approval:~~

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

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

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

994 ~~— (d) The central service coordinator shall arrange for emergency repair services to be available 24~~
995 ~~hours each day for the mobile PET scanner equipment as well as the vehicle transporting the equipment.~~
996 ~~In addition, to preserve image quality and minimize PET scanner downtime, calibration checks shall be~~
997 ~~performed on the PET scanner unit at least once each work day or in accordance with the manufacturer's~~
998 ~~requirements. Routine maintenance services shall be provided on a regularly scheduled basis, at least~~
999 ~~once a week or in accordance with the manufacturer's requirements, during hours not normally used for~~
1000 ~~patient procedures.~~

1001 ~~— (e) Each host site shall provide a properly prepared parking pad, for the mobile PET scanner unit,~~
1002 ~~of sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for~~
1003 ~~patients to enter the vehicle without going outside (such as an enclosed canopy or an enclosed corridor).~~
1004 ~~Each host site also must provide the capability for processing the film and maintaining the confidentiality~~
1005 ~~of patient records. A communication system must be provided between the mobile vehicle and each host~~
1006 ~~site to provide for immediate notification of emergency medical situations.~~

1007 ~~— (f) A mobile PET scanner service shall operate under a contractual agreement that includes the~~
1008 ~~provision of PET services at each host site on a regularly scheduled basis.~~

1009 ~~— (g) The volume of utilization at each host site shall be reported to the Department by the central~~
1010 ~~service coordinator under the terms of Section 14(1)(d)(iii).~~

1011
1012 ~~— (2) The agreements and assurances required by this section shall be in the form of a certification~~
1013 ~~authorized by the owner or the governing body of the applicant or its authorized agent.~~

1014
1015 **Section 16. Determination of PET equivalents****COMMITMENT AND DOCUMENTATION OF**
1016 **INTACTABLE EPILEPSY DATA**

1017
1018 Sec. 16. An applicant proposing to use intractable epilepsy cases shall demonstrate all of the
1019 following:

1020
1021 (1) Each entity contributing intractable epilepsy data provides, as part of the application at the time
1022 it is submitted to the Department, a signed governing body resolution that identifies the number of
1023 intractable epilepsy cases committed to the application and that states no current or future intractable
1024 epilepsy case data will be used in support of any other application for a PET unit for the duration of the
1025 PET service for which the data are being committed for a period of five (5) years from the date of start of
1026 operations of the approved PET service for which data are being committed. If the required

1027 documentation for this subsection is not submitted with the application on the designated application
1028 date, the application will be deemed filed on the first applicable designated application date after all
1029 required documentation is received by the Department.

1030 (A) For fixed PET scanner services, the geographic location of each entity contributing intractable
1031 epilepsy case data is in the same planning area as the proposed PET unit/service.

1032 (B) For mobile PET scanner services, the geographic location of each entity contributing diagnosis
1033 specific new cancer case data in the planning area(s) for which the proposed PET service contains a
1034 proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical
1035 area counties or 25-mile radius for metropolitan statistical area counties.

1036 (C) No entity contributing intractable epilepsy case data has previously committed or is committing
1037 data to another service that is less than five (5) years from the start of operations of that service.

1038 (D) The intractable epilepsy case data is from the most recent Michigan Inpatient Data Base
1039 (MIDB) available to the Department.

1040
1041 (2) No entity currently operating or approved to operate a scanner shall contribute intractable
1042 epilepsy case data.

1043
1044 (3) The Department may not consider a withdrawal of intractable epilepsy case data during the
1045 120-day application review cycle following the date on which the Department review of the application
1046 commences or after a proposed decision to approve the application unless the application is denied,
1047 withdrawn, or expired. The withdrawal must be submitted to the Department in the form of a governing
1048 body resolution that contains the specific CON application number to which the data were originally
1049 committed, the legal applicant entity, the committing entity, the type of data, the date of the meeting in
1050 which the governing body authorized the withdrawal of the data, the governing body president's
1051 signature, and the date of the signature.

1052 For purposes of these standards, PET equivalents shall be calculated as follows:

1053 (a) Each actual patient visit performed during the time period specified in the applicable section(s)
1054 of these standards shall be assigned a number of PET equivalents based on the sum of the applicable
1055 values set forth in subsections (i) through (vii).

1056 (i) A single patient visit _____ 1.0

1057 (ii) Number of chemically different tracers
1058 used during a single patient visit.

1059 1 tracers = 0

1060 >2 tracers = 0.8

1061 (iii) Number of tracer injections performed
1062 during a single patient visit.

1063 1 tracer injection = 0

1064 2 tracer injections = 0.3

1065 >3 tracer injections = 0.6

1066 (iv) Dynamic scan(s) performed during a single _____ 0.5
1067 patient visit.

1068 (v) Number of bed positions used during a single
1069 patient visit.

1070 1 bed position = 0

1071 >2 bed positions = 0.2 for each additional position

1072 (vi) Arterial sampling performed during a single _____ 0.5
1073 patient visit.

1074 (vii) Transmission scan _____ .1 per bed position

1075 **Total PET Equivalents for a Single Patient Visit**

1076 (b) For each pediatric patient visit, the PET equivalent(s) determined pursuant to subdivision (a)
1077 shall be multiplied as follows:

1078 patient < 5 years of age multiply by 4.0

1079 patient >5<10 years of age multiply by 3.0

1080 patient >10<17 years of age multiply by 2.0

1081 ~~——(c) For each radiation therapy patient visit, the PET equivalent(s) determined pursuant to~~
1082 ~~subdivision (a) shall be multiplied by 1.5.~~
1083 ~~——(d) The PET equivalents for each patient visit determined pursuant to subdivisions (a), (b) and (c)~~
1084 ~~shall be summed to determine the total PET equivalents for the time period specified in the applicable~~
1085 ~~section(s) of these standards.~~

1086
1087 **Section 17. Methodology for computing the projected number of PET data units**

1088 DEPARTMENT INVENTORY OF PET SCANNERS

1089 Sec. 17. The Department shall maintain and PUBLICLY POST on ITS WEB SITE A LIST OF PET
1090 SCANNER SERVICES ANNUALLY.

1091 ~~The applicant being reviewed under Section 4 shall apply the methodology set forth in this section in~~
1092 ~~computing the projected number of PET data units.~~

1093
1094 ~~(1)(a) Identify the number of diagnosis specific new cancer cases documented in accord with the~~
1095 ~~requirements of Section 18.~~

1096 ~~——(b) Combine the number of cancer cases for lung (site codes C340-C349), esophagus (site codes~~
1097 ~~C150-C159), colorectal (site codes C180-C209), lymphoma (morphology codes 9590-9729), melanoma~~
1098 ~~(morphology codes 8720-8790), and head & neck [site codes C000-C148, C300-C329, C410, C411,~~
1099 ~~C470 OR C490 excluding C440-C444 (skin of head and neck), and additional codes approved by~~
1100 ~~National Coverage Determination]. Use the name “combined” for this grouping.~~

1101 ~~(c) Multiply the number resulting from the calculation in “combined” cancer cases identified in~~
1102 ~~subsection (1)(b) by 0.8, which is the estimated probability that a “combined” cancer case will require a~~
1103 ~~PET scan.~~

1104 ~~(d) Multiply the number resulting from the calculation in subsection (1)(c) by 2.5, which is the~~
1105 ~~estimated number of PET scans needed for each patient requiring a PET scan.~~

1106
1107 ~~(2)(a) Identify the number of diagnosis specific new cancer cases documented in accord with the~~
1108 ~~requirements of Section 18.~~

1109 ~~(b) Multiply the number of breast cancer cases (site codes C500-C509) by 0.25, which is the~~
1110 ~~estimated probability that a breast cancer case will require a PET scan.~~

1111 ~~(c) Multiply the number resulting from the calculation in subsection (2)(b) by 1.0, which is the~~
1112 ~~estimated number of PET scans needed for each patient requiring a PET scan.~~

1113
1114 ~~(3)(a) Multiply the number of diagnostic cardiac catheterization cases identified in accord with the~~
1115 ~~requirements of Section 20 by 0.1, which is the estimated probability that a patient having a diagnostic~~
1116 ~~cardiac catheterization will require a PET scan.~~

1117 ~~——(b) Multiply the number resulting from the calculation in subsection (3)(a) by 1.0, which is the~~
1118 ~~estimated number of PET scans needed for each patient requiring a PET scan.~~

1119
1120 ~~(4)(a)(b) Multiply the number resulting from the calculation in subsection (4)(a) by 1.0, which is the~~
1121 ~~estimated number of PET scans needed for each patient requiring a PET scan.~~

1122
1123 ~~(5) Sum the numbers resulting from the calculations in subsections (1) through (4) to determine the~~
1124 ~~total number of projected PET data units.~~

1125
1126 ~~(6) Multiply the result calculated in subsection (5) above by a factor of 3.0 if the applicant is~~
1127 ~~proposing to serve only Planning Area 6 to determine the total number of projected PET data units.~~

1128
1129 ~~——(7) Multiply the result calculated in subsection (5) above by a factor of 2.0 if the applicant is~~
1130 ~~proposing to serve only Planning Area 5 to determine the total number of projected PET data units.~~

1131

1132 **Section 18. ~~Commitment of diagnosis specific new cancer cases~~ COMPARATIVE REVIEWS;**
1133 **EFFECT ON PRIOR PLANNING POLICIES**

1134
1135 Sec. 18. Proposed projects reviewed under these standards shall not be subject to comparative
1136 review. These CON review standards supersede and replace the CON Standards for PET SCANNER
1137 SERVICES approved by the CON Commission on DECEMBER 12, 2006 and effective MARCH 8, 2007.

1138
1139 (1) ~~An applicant proposing to use diagnosis specific new cancer cases shall demonstrate all of the~~
1140 ~~following:~~

1141 ~~— (a) Only those cancer diagnoses identified in Section 17(1) and 17(2) shall be included.~~

1142 ~~— (b) Each entity contributing diagnosis specific new cancer case data provides, as part of the~~
1143 ~~application at the time it is submitted to the Department, a signed governing body resolution that identifies~~
1144 ~~the number of diagnosis specific cancer cases being committed to the application and that states no~~
1145 ~~current or future diagnosis specific new cancer case data will be used in support of any other application~~
1146 ~~for a PET unit for a period of five (5) years from the date of start of operations of the approved PET~~
1147 ~~service for which data are being committed. If the required documentation for this subsection is not~~
1148 ~~submitted with the application on the designated application date, the application will be deemed filed on~~
1149 ~~the first applicable designated application date after all required documentation is received by the~~
1150 ~~Department.~~

1151 ~~— (c) For fixed PET scanner services, the geographic location of each entity contributing diagnosis~~
1152 ~~specific new cancer case data is in the same planning area as the proposed PET service.~~

1153 ~~— (d) For mobile PET scanner services, the geographic location of each entity contributing diagnosis~~
1154 ~~specific new cancer case data in the planning area(s) for which the proposed PET service contains a~~
1155 ~~proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical~~
1156 ~~area counties or 25-mile radius for metropolitan statistical area counties.~~

1157 ~~— (e) No entity contributing diagnosis specific new cancer case data has previously committed or is~~
1158 ~~committing data to another service that is less than five (5) years from the start of operations of that~~
1159 ~~service and is listed on the "Department Inventory of Pet Scanners."~~

1160
1161 ~~— (2) No entity currently operating or approved to operate a scanner, whether fixed or mobile, listed~~
1162 ~~on the "Department Inventory of PET Scanners" shall contribute diagnosis specific new cancer cases.~~

1163
1164 ~~— (3)(a) The Department may not consider a withdrawal of diagnosis specific new cancer case data~~
1165 ~~during the 120-day application review cycle following the date on which the Department review of the~~
1166 ~~application commences or after a proposed decision to approve the application has been issued unless~~
1167 ~~the application is denied, withdrawn, or expired.~~

1168 ~~— (b) The withdrawal must be submitted to the Department in the form of a governing body resolution~~
1169 ~~that contains the specific CON application number to which the data were originally committed, the legal~~
1170 ~~applicant entity, the committing entity, the type of data, the date of the meeting in which the governing~~
1171 ~~body authorized the withdrawal of the data, the governing body president's signature, and the date of the~~
1172 ~~signature.~~

1173
1174 **Section 19. Documentation of diagnosis specific new cancer case data**

1175
1176 Sec. 19. ~~(1) An applicant required to document volumes of diagnosis specific new cancer cases~~
1177 ~~shall submit, as part of its application at the time it is submitted to the Department, documentation from~~
1178 ~~the Division for Vital Records and Health Statistics verifying the number of diagnosis specific new cancer~~
1179 ~~cases provided in support of the application for the most recent calendar year for which verifiable data are~~
1180 ~~available from the State Registrar. If the required documentation for this subsection is not submitted with~~
1181 ~~the application on the designated application date, the application will be deemed filed on the first~~
1182 ~~applicable designated application date after all required documentation is received by the Department.~~

1183
1184 ~~— (2) Diagnosis specific new cancer case data supporting an application under these standards shall~~
1185 ~~be submitted to the Division for Vital Records and Health Statistics using a format and media specified in~~

1186 | instructions from the Department of Community Health.

1187 |
1188 | **Section 20. ~~Commitment and documentation of diagnostic cardiac catheterization data~~**

1189 |
1190 | ~~Sec. 20. (1) An applicant proposing to use diagnostic cardiac catheterization data shall demonstrate~~
1191 | ~~all of the following:~~

1192 | ~~(a) Each entity contributing diagnostic cardiac catheterization data [pursuant to Section 17(3)(a)]~~
1193 | ~~provides, as part of the application at the time it is submitted to the Department, a signed governing body~~
1194 | ~~resolution that identifies the number of diagnostic cardiac catheterization cases (sessions) committed to~~
1195 | ~~the application and that states no current or future diagnostic cardiac catheterization data will be used in~~
1196 | ~~support of any other application for a PET unit for the duration of the PET service for which data are~~
1197 | ~~being committed for a period of five (5) years from the date of start of operations of the approved PET~~
1198 | ~~service for which data are being committed. If the required documentation for this subsection is not~~
1199 | ~~submitted with the application on the designated application date, the application will be deemed filed on~~
1200 | ~~the first applicable designated application date after all required documentation is received by the~~
1201 | ~~Department.~~

1202 | ~~— (b) For fixed PET scanner services, the geographic location of each entity contributing diagnostic~~
1203 | ~~cardiac catheterization data is in the same planning area as the proposed PET unit/service.~~

1204 | ~~— (c) For mobile PET scanner services, the geographic location of each entity contributing diagnosis~~
1205 | ~~specific new cancer case data in the planning area(s) for which the proposed PET service contains a~~
1206 | ~~proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical~~
1207 | ~~area counties or 25-mile radius for metropolitan statistical area counties.~~

1208 | ~~— (d) No entity contributing diagnostic cardiac catheterization data has previously committed or is~~
1209 | ~~committing data to another service that is less than five (5) years from the start of operations of that~~
1210 | ~~service and is listed on the "Department Inventory of Pet Scanners."~~

1211 | ~~— (e) The diagnostic cardiac catheterization case data is from the most recently completed report(s)~~
1212 | ~~of the "Annual Hospital Statistical Questionnaire" produced by the Department, and the contributing entity~~
1213 | ~~has CON Approval to provide diagnostic cardiac catheterization services.~~

1214 |
1215 | ~~— (2) No entity currently operating or approved to operate a PET scanner, whether fixed or mobile,~~
1216 | ~~listed on the "Department Inventory of PET Scanners" shall contribute diagnostic cardiac catheterization~~
1217 | ~~case data.~~

1218 |
1219 | ~~— (3)(a) The Department may not consider a withdrawal of diagnostic cardiac catheterization case data~~
1220 | ~~during the 120-day application review cycle following the date on which the Department review of the~~
1221 | ~~application commences or after a proposed decision to approve the application has been denied unless~~
1222 | ~~the application is denied, withdrawn, or expired.~~

1223 | ~~— (b) The withdrawal must be submitted to the Department in the form of a governing body resolution~~
1224 | ~~that contains the specific CON application number to which the data were originally committed, the legal~~
1225 | ~~applicant entity, the committing entity, the type of data, the date of the meeting in which the governing~~
1226 | ~~body authorized the withdrawal of the data, the governing body president's signature, and the date of the~~
1227 | ~~signature.~~

1228 |
1229 | **Section 21. ~~Commitment and documentation of intractable epilepsy data~~**

1230 |
1231 | ~~— Sec. 21. (1) An applicant proposing to use intractable epilepsy cases shall demonstrate all of the~~
1232 | ~~following:~~

1233 | ~~— (a) Each entity contributing intractable epilepsy data [pursuant to Section 17(4)(a)] provides, as~~
1234 | ~~part of the application at the time it is submitted to the Department, a signed governing body resolution~~
1235 | ~~that identifies the number of intractable epilepsy cases committed to the application and that states no~~
1236 | ~~current or future intractable epilepsy case data will be used in support of any other application for a PET~~
1237 | ~~unit for the duration of the PET service for which the data are being committed for a period of five (5)~~
1238 | ~~years from the date of start of operations of the approved PET service for which data are being~~
1239 | ~~committed. If the required documentation for this subsection is not submitted with the application on the~~

1240 ~~designated application date, the application will be deemed filed on the first applicable designated~~
1241 ~~application date after all required documentation is received by the Department.~~
1242 ~~—— (b) For fixed PET scanner services, the geographic location of each entity contributing intractable~~
1243 ~~epilepsy case data is in the same planning area as the proposed PET unit/service.~~
1244 ~~—— (c) For mobile PET scanner services, the geographic location of each entity contributing diagnosis~~
1245 ~~specific new cancer case data in the planning area(s) for which the proposed PET service contains a~~
1246 ~~proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical~~
1247 ~~area counties or 25-mile radius for metropolitan statistical area counties.~~
1248 ~~—— (d) No entity contributing intractable epilepsy case data has previously committed or is committing~~
1249 ~~data to another service that is less than five (5) years from the start of operations of that service and is~~
1250 ~~listed on the "Department Inventory of Pet Scanners."~~
1251 ~~—— (e) The intractable epilepsy case data is from the most recent Michigan Inpatient Data Base~~
1252 ~~(MIDB) available to the Department.~~
1253
1254 ~~—— (2) No entity currently operating or approved to operate a scanner, whether fixed or mobile, listed~~
1255 ~~on the "Department Inventory of Pet Scanners" shall contribute intractable epilepsy case data.~~
1256
1257 ~~—— (3)(a) The Department may not consider a withdrawal of intractable epilepsy case data during the~~
1258 ~~120-day application review cycle following the date on which the Department review of the application~~
1259 ~~commences or after a proposed decision to approve the application unless the application is denied,~~
1260 ~~withdrawn, or expired.~~
1261 ~~—— (b) The withdrawal must be submitted to the Department in the form of a governing body resolution~~
1262 ~~that contains the specific CON application number to which the data were originally committed, the legal~~
1263 ~~applicant entity, the committing entity, the type of data, the date of the meeting in which the governing~~
1264 ~~body authorized the withdrawal of the data, the governing body president's signature, and the date of the~~
1265 ~~signature.~~
1266

1267 | **Section 22-APPENDIX A Health Service Areas**

1268

1269 | Sec. 22. Counties assigned to each health service area are as follows:

1270

1271 | **HEALTH SERVICE AREA**

COUNTIES

1272

1273	1	Livingston	Monroe	St. Clair
1274		Macomb	Oakland	Washtenaw
1275		Wayne		

1276

1277	2	Clinton	Hillsdale	Jackson
1278		Eaton	Ingham	Lenawee

1279

1280	3	Barry	Calhoun	St. Joseph
1281		Berrien	Cass	Van Buren
1282		Branch	Kalamazoo	

1283

1284	4	Allegan	Mason	Newaygo
1285		Ionia	Mecosta	Oceana
1286		Kent	Montcalm	Osceola
1287		Lake	Muskegon	Ottawa

1288

1289	5	Genesee	Lapeer	Shiawassee
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1290

1291	6	Arenac	Huron	Roscommon
1292		Bay	Iosco	Saginaw
1293		Clare	Isabella	Sanilac
1294		Gladwin	Midland	Tuscola
1295		Gratiot	Ogemaw	

1296

1297	7	Alcona	Crawford	Missaukee
1298		Alpena	Emmet	Montmorency
1299		Antrim	Gd Traverse	Oscoda
1300		Benzie	Kalkaska	Otsego
1301		Charlevoix	Leelanau	Presque Isle
1302		Cheboygan	Manistee	Wexford

1303

1304	8	Alger	Gogebic	Mackinac
1305		Baraga	Houghton	Marquette
1306		Chippewa	Iron	Menominee
1307		Delta	Keweenaw	Ontonagon
1308		Dickinson	Luce	Schoolcraft

1309

1310 | [Section 23. Planning Areas](#) **APPENDIX B**

1311

1312 | [Sec. 23. COUNTIES BY](#) Health service areas assigned to each planning area are as follows:

1313

1314 | **PLANNING AREA 1**

COUNTIES

1315

1316 | HSA 1

Livingston
Macomb
Wayne

Monroe
Oakland

St. Clair
Washtenaw

1317

1318

1319

1320 | **PLANNING AREA 2**

1321

1322 | HSA 2

Clinton
Eaton

Hillsdale
Ingham

Jackson
Lenawee

1323

1324 | HSA 3

Barry
Berrien
Branch

Calhoun
Cass
Kalamazoo

St. Joseph
Van Buren

1325

1326

1327

1328 | **PLANNING AREA 3**

1329

1330 | HSA 4

Allegan
Ionia
Kent
Lake

Mason
Mecosta
Montcalm
Muskegon

Newaygo
Oceana
Osceola
Ottawa

1331

1332

1333

1334

1335 | **PLANNING AREA 4**

1336

1337 | HSA 5

Genesee

Lapeer

Shiawassee

1338 | HSA 6

Arenac
Bay
Clare
Gladwin
Gratiot

Huron
Iosco
Isabella
Midland
Ogemaw

Roscommon
Saginaw
Sanilac
Tuscola

1339

1340

1341

1342

1343

1344 | **PLANNING AREA 5**

1345

1346 | HSA 7

Alcona
Alpena
Antrim
Benzie
Charlevoix
Cheboygan

Crawford
Emmet
Gd Traverse
Kalkaska
Leelanau
Manistee

Missaukee
Montmorency
Oscoda
Otsego
Presque Isle
Wexford

1347

1348

1349

1350

1351

1352

1353 | **PLANNING AREA 6**

1354

1355 | HSA 8

Alger
Baraga
Chippewa
Delta
Dickinson

Gogebic
Houghton
Iron
Keweenaw
Luce

Mackinac
Marquette
Menominee
Ontonagon
Schoolcraft

1356

1357

1358

1359

1360

1361 **Section 24. Department Inventory of PET Scanners**

1362
1363 ~~— Sec. 24. The Department shall maintain and provide upon request a listing of the Department~~
1364 ~~Inventory of Pet Scanners as of the effective date of these standards.~~

1365
1366 **Section 25. Comparative reviews; effect on prior planning policies**

1367
1368 ~~Sec. 25. (1) Proposed projects reviewed under these standards shall not be subject to comparative~~
1369 ~~review except for applicants under Section 4(4) that may be subject to comparative review.~~

1370
1371 ~~—(2)(a) These CON review standards supersede and replace the CON Standards for Positron~~
1372 ~~Emission Tomography approved by the CON Commission on March 9, 2004 and effective June 4, 2004.~~

1373
1374 **APPENDIX AC**

1375
1376 **CON REVIEW STANDARDS**
1377 **FOR PET SCANNER SERVICES**

1378
1379 Rural Michigan counties are as follows:

1380

1381 Alcona	Hillsdale	Ogemaw
1382 Alger	Huron	Ontonagon
1383 Antrim	Iosco	Osceola
1384 Arenac	Iron	Oscoda
1385 Baraga	Lake	Otsego
1386 Charlevoix	Luce	Presque Isle
1387 Cheboygan	Mackinac	Roscommon
1388 Clare	Manistee	Sanilac
1389 Crawford	Mason	Schoolcraft
1390 Emmet	Montcalm	Tuscola
1391 Gladwin	Montmorency	
1392 Gogebic	Oceana	

1393
1394 Micropolitan statistical area Michigan counties are as follows:

1395

1396 Allegan	Gratiot	Mecosta
1397 Alpena	Houghton	Menominee
1398 Benzie	Isabella	Midland
1399 Branch	Kalkaska	Missaukee
1400 Chippewa	Keweenaw	St. Joseph
1401 Delta	Leelanau	Shiawassee
1402 Dickinson	Lenawee	Wexford
1403 Grand Traverse	Marquette	

1404
1405 Metropolitan statistical area Michigan counties are as follows:

1406

1407 Barry	Ionia	Newaygo
1408 Bay	Jackson	Oakland
1409 Berrien	Kalamazoo	Ottawa
1410 Calhoun	Kent	Saginaw
1411 Cass	Lapeer	St. Clair
1412 Clinton	Livingston	Van Buren
1413 Eaton	Macomb	Washtenaw
1414 Genesee	Monroe	Wayne

1415 Ingham Muskegon
1416
1417 Source:
1418
1419 65 F.R., p. 82238 (December 27, 2000)
1420 Statistical Policy Office
1421 Office of Information and Regulatory Affairs
1422 United States Office of Management and Budget
1423