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**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH**

**CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR  
POSITRON EMISSION TOMOGRAPHY (PET) SCANNER SERVICES**

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207 and 24.208 of the Michigan Compiled Laws.)

**Section 1. Applicability**

Sec. 1. These standards are requirements for the approval OF THE INITIATION, REPLACEMENT, EXPANSION, OR ACQUISITION OF PET SCANNER SERVICES, and THE delivery of THESE services under Part 222 of the Code. PURSUANT TO Part 222 of the Code PET SCANNER SERVICES ARE A COVERED CLINICAL SERVICE. The Department shall use THESE STANDARDS in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws AND Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

**Section 2. Definitions**

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

(a) "Central service coordinator" means the legal entity that has operational responsibility for a mobile PET scanner service.

(B) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

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

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

(E) "Existing PET scanner service" means aN operational PET scanner SERVICE providing PET SCANNER services at one site in the case of a fixed PET service or at each host site in the case of a mobile PET service on the date an application is submitted to the Department.

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

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

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

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

(J) "Michigan Inpatient Data Base" or "MIDB" means the data base compiled by the Michigan Health and Hospital Association or successor organization. The data base consists of inpatient discharge records from all Michigan hospitals and Michigan residents discharged from hospitals in border states for a specific calendar year.

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

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

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

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

(O) "PET data unit" means the result of the methodology as used in Section 12.

(P) "PET equivalent" means the number calculated in accordance with Section 17 for a single patient visit.

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

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

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

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

65 (U) "Planning area" means the GROUPS OF health service area(s) LISTED in APPENDIX B.

66 (V) "SPECT" means single photon emission computed tomography.

67  
68 (2) The definitions in Part 222 shall apply to these standards.  
69

### 70 **Section 3. Requirements TO INITIATE A PET SCANNER SERVICE**

71  
72 Sec. 3. An applicant proposing to INITIATE PET scanner services shall DEMONSTRATE the  
73 following, AS APPLICABLE TO THE PROPOSED PROJECT.  
74

75 (1) THE APPLICANT SHALL DEMONSTRATE THE PROPOSED SITE PROVIDES THE  
76 FOLLOWING SERVICES AND SPECIALTIES:

77 (a) nuclear medicine services AS DOCUMENTED BY A CERTIFICATE FROM THE US NUCLEAR  
78 REGULATORY COMMISSION,

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

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

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

82 (e) cardiac catheterization services,

83 (f) open heart surgery,

84 (g) thoracic surgery,

85 (h) cardiology,

86 (i) oncology,

87 (j) radiation oncology,

88 (k) neurology,

89 (l) neurosurgery, and

90 (m) psychiatry.  
91

92 (2) If the PROPOSED SITE does not provide any of the services listed in subsection (1) ON-SITE,  
93 the applicant shall PROVIDE written contracts or agreements with a hospital(s) located within the same  
94 planning area OR 25-MILE RADIUS OF THE PROPOSED SITE for the services not provided at the  
95 proposed site.  
96

97 (3) THE APPLICANT SHALL DEMONSTRATE THE PROPOSED SITE HAS AN ON-SITE  
98 SOURCE OF RADIOPHARMACEUTICALS.  
99

100 (4) If THE proposed SITE does not PROVIDE an on-site source of radiopharmaceuticals, THE  
101 applicant SHALL provide a written contract or agreement that demonstrates a reliable supply of  
102 radiopharmaceuticals  
103

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

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

- 109 (B) THE APPLICANT HAS RECEIVED:  
110 (I) 1,700 PET EQUIVALENTS IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY  
111 THE DEPARTMENT FOR A HOST SITE IN A METROPOLITAN STATISTICAL AREA COUNTY, OR  
112 (II) 1,500 PET EQUIVALENTS IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY  
113 THE DEPARTMENT FOR A HOST SITE IN A RURAL OR MICROPOLITAN STATISTICAL AREA  
114 COUNTY.  
115 (C) THE APPLICANT AGREES TO CEASE OPERATION AS A HOST SITE AND NOT BECOME A  
116 HOST SITE FOR AT LEAST 12 MONTHS FROM THE DATE THE FIXED PET SCANNER BECOMES  
117 OPERATIONAL.  
118  
119 (6) AN APPLICANT PROPOSING TO INITIATE A MOBILE PET SCANNER SERVICE WITH ITS  
120 FIRST MOBILE PET SCANNER SHALL PROJECT 2,100 PET DATA UNITS.  
121 (A) OF THE 2,100 PET DATA UNITS, THE APPLICANT SHALL PROJECT A MINIMUM OF 360  
122 PET DATA UNITS WITHIN A 20-MILE RADIUS OF EACH PROPOSED HOST SITE FOR PLANNING  
123 AREA 1, OR 240 PET DATA UNITS PER HOST SITE FOR ANY OTHER PLANNING AREA, FOR THE  
124 PROPOSED SERVICE.  
125 (B) THE APPLICATION FOR THE MOBILE PET SCANNER SERVICE IS ACCOMPANIED BY AT  
126 LEAST TWO HOST SITE APPLICATIONS.  
127 (C) EACH APPLICANT PROVIDES A ROUTE SCHEDULE FOR THE PROPOSED MOBILE PET  
128 SCANNER SERVICE.  
129 (D) THE APPLICANT PROVIDES A DRAFT CONTRACT FOR SERVICES BETWEEN THE  
130 PROPOSED HOST SITE AND CENTRAL SERVICE COORDINATOR.  
131  
132 (7) AN APPLICANT PROPOSING TO INITIATE A HOST SITE ON A PROPOSED OR EXISTING  
133 MOBILE PET SCANNER SERVICE SHALL DEMONSTRATE THE FOLLOWING:  
134 (A) THE APPLICANT PROVIDES A PROPOSED ROUTE SCHEDULE.  
135 (B) THE APPLICANT PROVIDES A DRAFT CONTRACT FOR SERVICES BETWEEN THE  
136 PROPOSED HOST SITE AND CENTRAL SERVICE COORDINATOR.  
137 (C) THE APPLICANT HAS NOT INITIATED FIXED PET SCANNER SERVICES UNDER  
138 SUBSECTION 3(5) WITHIN THE MOST RECENT 12-MONTH PERIOD AS OF THE DATE THE  
139 APPLICATION IS SUBMITTED TO THE DEPARTMENT.  
140 (D) AN APPLICANT INITIATING A HOST SITE IN HSA 8 ON A MOBILE PET SCANNER  
141 SERVICE THAT OPERATES PREDOMINANTLY OUTSIDE OF MICHIGAN SHALL DEMONSTRATE  
142 240 PET DATA UNITS FROM PLANNING AREA 6.  
143  
144 (8) AN APPLICANT PROPOSING TO INITIATE PET SCANNER SERVICES AS AN EXISTING  
145 HOST SITE ON A DIFFERENT MOBILE PET SCANNER SERVICE SHALL DEMONSTRATE THE  
146 FOLLOWING:  
147 (A) THE APPLICANT PROVIDES A PROPOSED ROUTE SCHEDULE.  
148 (B) THE APPLICANT PROVIDES A DRAFT CONTRACT FOR SERVICES BETWEEN THE  
149 PROPOSED HOST SITE AND CENTRAL SERVICE COORDINATOR.  
150 (C) 50 PET EQUIVALENTS WERE PERFORMED IN THE MOST RECENT 12-MONTH PERIOD  
151 VERIFIABLE BY THE DEPARTMENT FROM AN EXISTING MOBILE PET SCANNER SERVICE FOR  
152 AN EXISTING HOST SITE PROPOSING TO INITIATE SERVICES ON A DIFFERENT MOBILE PET  
153 SCANNER SERVICE.

154  
155 **Section 4. Requirements TO REPLACE AN EXISTING PET scanner(S) OR PET SCANNER**  
156 **SERVICE**

157  
158 Sec. 4. REPLACING A PET SCANNER(S) MEANS A CHANGE IN THE SCANNER EQUIPMENT  
159 OR RELOCATION OF THE SERVICE TO A NEW SITE. AN UPGRADE TO SOFTWARE OR  
160 COMPONENTS/PARTS OF AN EXISTING SCANNER DOES NOT CONSTITUTE REPLACEMENT OF  
161 A PET SCANNER.  
162

163 (1) An applicant proposing to REPLACE a PET scanner(S) shall DEMONSTRATE EACH OF THE  
164 FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT:

165 (a) THE REPLACEMENT SCANNER(S) IS THE SAME TYPE (FIXED OR MOBILE) AS THE  
166 SCANNER(S) TO BE REPLACED.

167 (b) THE SCANNER(S) TO BE REPLACED IS FULLY DEPRECIATED ACCORDING TO  
168 GENERALLY ACCEPTED ACCOUNTING PRINCIPLES OR EITHER OF THE FOLLOWING:

169 (i) The EXISTING SCANNER(S) POSES A THREAT TO THE SAFETY OF THE PATIENTS.

170 (ii) The REPLACEMENT SCANNER(S) OFFERS TECHNOLOGICAL IMPROVEMENTS THAT  
171 ENHANCE QUALITY OF CARE, INCREASE EFFICIENCY, AND REDUCE OPERATING COSTS AND  
172 PATIENT CHARGES.

173 (C) THE APPLICANT AGREES THAT THE PET SCANNER(S) TO BE REPLACED WILL BE  
174 REMOVED FROM SERVICE ON OR BEFORE BEGINNING OPERATION OF THE REPLACEMENT  
175 SCANNER(S).

176  
177 (2) AN APPLICANT PROPOSING TO REPLACE A FIXED PET SCANNER SERVICE TO A NEW  
178 SITE SHALL DEMONSTRATE THE FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT:

179 (A) The PROPOSED SITE IS WITHIN A 10-MILE RADIUS OF THE EXISTING SITE FOR A  
180 METROPOLITAN STATISTICAL AREA COUNTY OR A 25-MILE RADIUS FOR A RURAL OR  
181 MICROPOLITAN STATISTICAL AREA COUNTY.

182 (B) The EXISTING FIXED PET SCANNER(S) PERFORMED 500 PET SCANS PER FIXED  
183 SCANNER IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE DEPARTMENT.

184 (C) THE EXISTING FIXED PET SCANNER SERVICE HAS BEEN IN OPERATION FOR AT  
185 LEAST 36 MONTHS AS OF THE DATE OF THE APPLICATION SUBMITTED TO THE DEPARTMENT.

186  
187 **Section 5. Requirements to expand a PET scanner service**

188  
189 Sec. 5. An applicant proposing to EXPAND A PET scanner SERVICE shall demonstrate EACH OF  
190 the following, AS APPLICABLE TO THE PROPOSED PROJECT.

191  
192 (1) An applicant PROPOSING TO ADD A FIXED PET SCANNER(S) TO AN EXISTING FIXED  
193 PET SCANNER SERVICE SHALL DEMONSTRATE THE FOLLOWING:

194 (A) 1,900 PET EQUIVALENTS WERE PERFORMED PER EXISTING AND APPROVED FIXED  
195 PET SCANNER(S) IN the most recent 12-month period VERIFIABLE BY THE DEPARTMENT FOR AN  
196 APPLICANT IN A METROPOLITAN STATISTICAL AREA COUNTY, OR

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

200 (c) THE ADDITIONAL PET SCANNER(S) SHALL BE LOCATED AT THE SAME SITE.

201  
202 (2) An applicant proposing to ADD A mobile PET scanner(s) TO AN EXISTING MOBILE PET  
203 SCANNER SERVICE shall demonstrate the following:

204 (a) 2,000 PET EQUIVALENTS WERE PERFORMED PER EXISTING AND APPROVED MOBILE  
205 SCANNER(S) IN the most recent 12-month period VERIFIABLE BY the Department FOR AN  
206 APPLICANT SERVING AT LEAST ONE EXISTING HOST SITE IN A METROPOLITAN STATISTICAL  
207 AREA COUNTY, OR

208 (b) 1,800 PET EQUIVALENTS WERE PERFORMED PER EXISTING AND APPROVED  
209 SCANNER(S) IN the most recent 12-month period VERIFIABLE BY the Department FOR AN  
210 APPLICANT SERVING ONLY HOST SITES IN RURAL OR MICROPOLITAN STATISTICAL AREA  
211 COUNTIES.

212  
213 (3) An applicant PROPOSING TO ADD A FIXED PET SCANNER TO AN EXISTING FIXED PET  
214 SCANNER SERVICE that ALSO RECEIVES MOBILE PET SCANNER SERVICES SHALL  
215 DEMONSTRATE the following:

216 (a) The applicant is CURRENTLY A HOST SITE BEING SERVED BY ONE OR MORE mobile PET

217 scanner serviceS.

218 (b) The applicant HAS PERFORMED:

219 (i) AN AVERAGE OF 1,900 PET EQUIVALENTS FOR THE HOST SITE AND EACH OF THE  
220 EXISTING AND APPROVED FIXED SCANNER IN THE MOST RECENT 12-MONTH PERIOD  
221 VERIFIABLE BY THE DEPARTMENT FOR A HOST SITE IN A METROPOLITAN STATISTICAL AREA  
222 COUNTY, OR

223 (ii) An AVERAGE OF 1,700 PET EQUIVALENTS FOR THE HOST SITE AND EACH OF THE  
224 EXISTING AND APPROVED FIXED scanners IN the most recent 12-month period VERIFIABLE BY the  
225 Department FOR A HOST SITE IN A RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY.  
226

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

231 (4) THIS SECTION DOES NOT APPLY TO DEDICATED RESEARCH, DEDICATED PEDIATRIC,  
232 OR POSITRON EMISSION MAMMOGRAPHY (PEM) SCANNERS.  
233

### 234 **Section 6. Requirements to ACQUIRE a PET scanner SERVICE OR SCANNER(S)**

235  
236 Sec. 6. ACQUIRING A PET SCANNER SERVICE AND ITS scanner(s) MEANS OBTAINING  
237 POSSESSION AND CONTROL BY CONTRACT, OWNERSHIP, LEASE, OR OTHER COMPARABLE  
238 ARRANGEMENT AND RENEWAL OF LEASE FOR AN EXISTING fixed OR MOBILE PET scanner. AN  
239 APPLICANT PROPOSING TO ACQUIRE A PET SCANNER SERVICE SHALL DEMONSTRATE EACH  
240 OF THE FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT.  
241

242 (1) FOR THE FIRST APPLICATION proposing to ACQUIRE an existing FIXED, mobile, OR HOST  
243 SITE PET scanner SERVICE, OTHER THAN A RENEWAL OF LEASE, **on OR AFTER <INSERT**  
244 **EFFECTIVE DATE OF STANDARDS>**, THE EXISTING PET SERVICE AND ITS SCANNER(S) SHALL  
245 NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE APPLICABLE VOLUME REQUIREMENTS  
246 SET FORTH IN THIS SECTION.  
247

248 (2) An APPLICANT PROPOSING TO ACQUIRE AN EXISTING FIXED OR MOBILE PET  
249 SCANNER SERVICE SHALL DEMONSTRATE THAT THE EXISTING FIXED OR MOBILE SCANNER(S)  
250 PERFORMED AN AVERAGE OF 500 PET EQUIVALENTS PER SCANNER IN THE MOST RECENT 12-  
251 MONTH PERIOD VERIFIABLE BY THE DEPARTMENT.  
252

253 (3) An applicant proposing TO ACQUIRE AN EXISTING HOST SITE shall DEMONSTRATE THAT  
254 the existing HOST SITE HAS PERFORMED 50 PET EQUIVALENTS IN the most recent 12-month period  
255 VERIFIABLE BY the Department.  
256

257 (4) An applicant proposing to RENEW A LEASE FOR AN EXISTING FIXED OR MOBILE PET  
258 scanner(s) **shall demonstrate THAT THE LEASE IS COST EFFECTIVE** AND THE EXISTING  
259 EQUIPMENT DOES NOT POSE A THREAT TO THE SAFETY OF THE PATIENT.  
260

### 261 **Section 7. Requirements for A DEDICATED RESEARCH FIXED PET scanner**

262  
263 Sec. 7. An applicant proposing to ADD a FIXED PET scanner TO AN EXISTING PET SCANNER  
264 SERVICE FOR EXCLUSIVE RESEARCH USE shall demonstrate EACH OF THE FOLLOWING:  
265

266 (1) THE APPLICANT AGREES THAT THE DEDICATED RESEARCH PET SCANNER WILL BE  
267 USED PRIMARILY (70% OR MORE OF THE SCANS) FOR RESEARCH PURPOSES ONLY.  
268

269 (2) The DEDICATED RESEARCH PET scanner SHALL OPERATE UNDER A PROTOCOL  
270 APPROVED BY THE APPLICANT'S INSTITUTIONAL REVIEW BOARD, AS DEFINED BY PUBLIC LAW

271 93-348 AND REGULATED BY TITLE 45 CFR 46.

272

273 (3) The APPLICANT HAS ACCESS TO A CYCLOTRON FOR ACCELERATING CHARGED  
274 PARTICLES TO HIGH ENERGIES BY MEANS of ELECTROMAGNETIC FIELDS.

275

276 (4) The PROPOSED SITE CAN HAVE NO MORE THAN THREE DEDICATED RESEARCH  
277 FIXED PET scanners APPROVED UNDER THIS Section.

278

279 **Section 8. Requirements for A DEDICATED PEDIATRIC PET scanner**

280

281 Sec. 8. An applicant proposing to INITIATE A PET scanner service, OR ADD A fixed PET  
282 SCANNER TO EXPAND AN EXISTING PET SCANNER SERVICE, FOR DEDICATED PEDIATRIC PET  
283 USE, shall NOT NEED TO MEET the REQUIREMENTS OF SECTION 5 IF THE APPLICANT  
284 DEMONSTRATES EACH OF THE following:

285

286 (1) The APPLICANT AGREES THAT THE DEDICATED PEDIATRIC PET scanner WILL BE USED  
287 PRIMARILY (70% OR MORE OF THE SCANS) FOR PATIENTS UNDER 18 YEARS OF AGE.

288

289 (2) The APPLICANT SHALL DEMONSTRATE the EXISTING SITE of THE PET scanner SERVICE  
290 PROVIDED the FOLLOWING FOR THE MOST RECENT CALENDAR YEAR OR A CONTINUOUS 12-  
291 MONTH PERIOD AT THE TIME THE APPLICATION IS SUBMITTED TO THE Department:

292 (A) AT LEAST 7,000 PEDIATRIC (< 18 YEARS OLD) DISCHARGES, EXCLUDING NORMAL  
293 NEWBORNS,

294 (B) AT LEAST 5,000 PEDIATRIC (< 18 YEARS OLD) SURGERIES, AND

295 (C) AT LEAST 50 NEW PEDIATRIC CANCER CASES ON ITS CANCER REGISTRY.

296

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

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

301 (B) ANESTHESIOLOGY

302 (C) CARDIOLOGY

303 (D) CRITICAL CARE

304 (E) GASTROENTEROLOGY

305 (F) HEMATOLOGY/ONCOLOGY

306 (G) NEUROLOGY

307 (H) NEUROSURGERY

308 (I) ORTHOPEDIC SURGERY

309 (J) PATHOLOGY

310 (K) PULMONOLOGY

311 (L) SURGERY

312 (M) NEONATOLOGY

313

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

316 (A) BONE MARROW TRANSPLANT PROGRAM

317 (B) SEDATION PROGRAM

318 (C) OPEN HEART PROGRAM

319

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

323

324 (6) THE PROPOSED SITE CAN HAVE NO MORE THAN TWO DEDICATED PEDIATRIC FIXED

325 PET SCANNERS APPROVED UNDER THIS SECTION.

326

327 **Section 9. Requirements for A POSITRON EMISSION MAMMOGRAPHY (PEM) scanner**

328

329 Sec. 9. AN APPLICANT PROPOSING TO ADD A PEM SCANNER SERVICE TO AN EXISTING  
330 PET SCANNER SERVICE SHALL DEMONSTRATE EACH OF THE FOLLOWING, AS APPLICABLE TO  
331 THE PROPOSED PROJECT.

332

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

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

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

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

343

344 (2) AN APPLICANT PROPOSING TO ADD A MOBILE PEM SCANNER TO AN EXISTING  
345 MOBILE PET SCANNER SERVICE SHALL NOT NEED TO MEET THE REQUIREMENTS OF SECTION  
346 5 IF THE APPLICANT DEMONSTRATES THE FOLLOWING:

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

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

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

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

357

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

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

363 (B) FOR AN EXISTING FIXED PET SCANNER SITE, THE APPLICANT HAS PERFORMED 1,000  
364 PET EQUIVALENTS PER SERVICE IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY  
365 THE DEPARTMENT, AND FOR AN EXISTING PET SCANNER HOST SITE, THE APPLICANT HAS  
366 PERFORMED 100 PET EQUIVALENTS IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY  
367 THE DEPARTMENT.

368

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

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

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

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

378 (D) THE APPLICANT PROVIDES A DRAFT CONTRACT FOR PEM SERVICES BETWEEN THE

379 HOST SITE AND CENTRAL SERVICE COORDINATOR.

380

381 **Section 10. Requirement for MEDICAID PARTICIPATION**

382

383 Sec. 10. An applicant shall PROVIDE VERIFICATION OF MEDICAID PARTICIPATION. AN  
384 APPLICANT THAT IS A NEW PROVIDER NOT CURRENTLY ENROLLED IN MEDICAID SHALL  
385 CERTIFY THAT PROOF OF MEDICAID PARTICIPATION WILL BE PROVIDED TO THE DEPARTMENT  
386 WITHIN (6) MONTHS FROM THE OFFERING OF SERVICES IF A CON IS APPROVED.

387

388 **Section 11. PROJECT DELIVERY Requirements AND TERMS OF APPROVAL FOR ALL**  
389 **APPLICANTS**

390

391 Sec. 11. An applicant shall AGREE THAT, IF APPROVED, the PET SCANNER SERVICES SHALL  
392 BE DELIVERED IN COMPLIANCE WITH THE FOLLOWING TERMS OF APPROVAL.

393

394 (1) COMPLIANCE WITH THESE STANDARDS.

395

396 (2) COMPLIANCE WITH THE FOLLOWING QUALITY ASSURANCE REQUIREMENTS:

397 (a) A PET SCANNER SERVICE SHALL BE STAFFED SO THAT SCREENING OF REQUESTS  
398 FOR AND INTERPRETATION OF PET PROCEDURES WILL BE CARRIED OUT BY A PHYSICIAN(S)  
399 WITH APPROPRIATE TRAINING AND FAMILIARITY WITH THE APPROPRIATE DIAGNOSTIC USE  
400 AND INTERPRETATION OF CROSS-SECTIONAL IMAGES OF THE ANATOMICAL REGION(S) TO BE  
401 EXAMINED. FOR PURPOSES OF EVALUATING THIS SUBSECTION, THE DEPARTMENT SHALL  
402 CONSIDER IT PRIMA FACIE EVIDENCE AS TO THE TRAINING OF THE PHYSICIAN(S) IF THE  
403 PHYSICIAN IS BOARD CERTIFIED OR BOARD QUALIFIED IN NUCLEAR MEDICINE OR NUCLEAR  
404 RADIOLOGY. HOWEVER, AN APPLICANT MAY SUBMIT, AND THE DEPARTMENT MAY ACCEPT,  
405 OTHER EVIDENCE THAT THE PHYSICIAN(S) IS QUALIFIED TO OPERATE THE PET  
406 SERVICE/SCANNER. THE PHYSICIAN(S) MUST BE ON-SITE OR AVAILABLE THROUGH  
407 TELECOMMUNICATION CAPABILITIES TO PARTICIPATE IN THE SCREENING OF PATIENTS FOR  
408 PET PROCEDURES AND TO PROVIDE OTHER CONSULTATION SERVICES.

409 (B) The PET SCANNER SERVICE SHALL include the following PERSONNEL, EMPLOYED  
410 DIRECTLY OR ON A CONTRACTUAL BASIS: A TECHNOLOGIST WITH TRAINING IN PET  
411 SCANNING AND A PHYSICIST. THE PHYSICIST MUST BE BOARD CERTIFIED OR ELIGIBLE FOR  
412 CERTIFICATION BY THE AMERICAN BOARD OF RADIOLOGY OR AN EQUIVALENT  
413 ORGANIZATION.

414 (C) The PET SCANNER SERVICE SHALL HAVE A PHYSICIAN ON-SITE OR IMMEDIATELY  
415 AVAILABLE TO THE PET SCANNER SERVICE AT ALL TIMES WHEN PATIENTS ARE UNDERGOING  
416 PET PROCEDURES.

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

419

420 (3) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:

421 (A) The PET scanner SERVICE shall ACCEPT REFERRALS FOR PET SCANNER SERVICES  
422 from ALL APPROPRIATELY LICENSED PRACTITIONERS.

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

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

428 (D) THE OPERATION OF AND REFERRAL OF PATIENTS TO THE PET SCANNER SERVICE  
429 SHALL BE IN CONFORMANCE WITH 1978 PA 368, SEC. 16221, AS AMENDED BY 1986 PA 319; MCL  
430 333.16221; MSA 14.15 (16221).

431

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



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

441 (B) THE PET SCANNER SERVICE SHALL PARTICIPATE IN A DATA COLLECTION SYSTEM  
442 ESTABLISHED AND ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE. THE DATA MAY  
443 INCLUDE, BUT ARE NOT LIMITED TO, CLINICAL SCAN DATA, ANNUAL BUDGET AND COST  
444 INFORMATION, OPERATING SCHEDULES, THROUGH-PUT SCHEDULES, DEMOGRAPHIC AND  
445 DIAGNOSTIC INFORMATION, AND THE VOLUME OF CARE PROVIDED TO PATIENTS FROM ALL  
446 PAYOR SOURCES. THE APPLICANT SHALL PROVIDE THE REQUIRED DATA ON A SEPARATE  
447 BASIS FOR EACH SEPARATE AND DISTINCT SITE, PET SCANNER, OR PET SCANNER SERVICE  
448 AS REQUIRED BY THE DEPARTMENT, IN A FORMAT ESTABLISHED BY THE DEPARTMENT. THE  
449 DEPARTMENT MAY ELECT TO VERIFY THE DATA THROUGH ON-SITE REVIEW OF APPROPRIATE  
450 RECORDS.

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

454  
455 (5) COMPLIANCE WITH THE FOLLOWING DEDICATED RESEARCH PET SCANNER  
456 REQUIREMENTS, IF APPLICABLE:

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

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

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

464  
465 (6) COMPLIANCE WITH THE FOLLOWING DEDICATED PEDIATRIC PET SCANNER  
466 REQUIREMENTS, IF APPLICABLE:

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

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

471  
472 (7) COMPLIANCE WITH THE FOLLOWING PEM SCANNER REQUIREMENTS, IF APPLICABLE:

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

475  
476 (8) COMPLIANCE WITH THE FOLLOWING MOBILE PET SCANNER REQUIREMENTS, IF  
477 APPLICABLE:

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

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

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

487 ENCLOSED CORRIDOR).  
488 (D) A MOBILE PET SCANNER SERVICE SHALL OPERATE UNDER A CONTRACTUAL  
489 AGREEMENT THAT INCLUDES THE PROVISION OF PET SERVICES AT EACH HOST SITE ON A  
490 REGULARLY SCHEDULED BASIS.

491  
492 (9) THE AGREEMENTS AND ASSURANCES REQUIRED BY THIS SECTION SHALL BE IN THE  
493 FORM OF A CERTIFICATION AGREED TO BY THE APPLICANT OR ITS AUTHORIZED AGENT.

494 **Section 12. METHODOLOGY for COMPUTING THE PROJECTED PET DATA UNITS**

495  
496  
497 Sec. 12. An applicant BEING REVIEWED UNDER SECTION 3 SHALL APPLY THE  
498 METHODOLOGY SET FORTH IN THIS SECTION IN COMPUTING THE PROJECTED NUMBER OF  
499 PET DATA UNITS.

500  
501 (1) IDENTIFY THE NUMBER OF DIAGNOSIS-SPECIFIC NEW CANCER CASES DOCUMENTED  
502 IN ACCORDANCE WITH THE REQUIREMENTS OF SECTION 13.

503 (A) COMBINE THE NUMBER OF CANCER CASES FOR LUNG (SITE CODES C340-C349),  
504 ESOPHAGUS (SITE CODES C150-C159), COLORECTAL (SITE CODES C180-C209), LYMPHOMA  
505 (MORPHOLOGY CODES (9590-9729), MELANOMA (MORPHOLOGY CODES 8720-8790), AND HEAD  
506 & NECK [SITE CODES C000-C148, C300-C329, C410, C411, C470 OR C490 EXCLUDING C440-C444  
507 (SKIN OF HEAD AND NECK), AND ADDITIONAL CODES APPROVED BY NATIONAL COVERAGE  
508 DETERMINATION]. USE THE NAME "COMBINED" FOR THIS GROUPING.

509 (B) MULTIPLY THE NUMBER RESULTING FROM THE CALCULATION IN "COMBINED"  
510 CANCER CASES IDENTIFIED IN SUBSECTION (1)(B) BY 0.8, WHICH IS THE ESTIMATED  
511 PROBABILITY THAT A "COMBINED" CANCER CASE WILL REQUIRE A PET SCAN.

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

515  
516 (2) IDENTIFY THE NUMBER OF DIAGNOSIS-SPECIFIC NEW CANCER CASES  
517 DOCUMENTED IN ACCORD WITH THE REQUIREMENTS OF SECTION 13.

518 (a) MULTIPLY THE NUMBER OF BREAST CANCER CASES (SITE CODES C500-C509) BY  
519 0.25, WHICH IS THE ESTIMATED PROBABILITY THAT A BREAST CANCER CASE WILL REQUIRE A  
520 PET SCAN.

521 (b) MULTIPLY THE NUMBER RESULTING FROM THE CALCULATION IN SUBSECTION (2)(B)  
522 BY 1.0, WHICH IS THE ESTIMATED NUMBER OF PET SCANS NEEDED FOR EACH PATIENT  
523 REQUIRING A PET SCAN.

524  
525 (3) MULTIPLY THE NUMBER OF DIAGNOSTIC CARDIAC CATHETERIZATION CASES  
526 IDENTIFIED IN ACCORD WITH THE REQUIREMENTS OF SECTION 15 BY 0.1, WHICH IS THE  
527 ESTIMATED PROBABILITY THAT A PATIENT HAVING A DIAGNOSTIC CARDIAC  
528 CATHETERIZATION WILL REQUIRE A PET SCAN.

529  
530 (4) MULTIPLY THE NUMBER OF INTRACTABLE EPILEPSY CASES (ICD-9-CM CODES 345.01,  
531 345.11, 345.41, 345.51, 345.61, 345.71, 345.81, OR 345.91) IDENTIFIED IN ACCORD WITH THE  
532 REQUIREMENTS OF SECTION 16 BY 1.0, WHICH IS THE ESTIMATED PROBABILITY THAT A  
533 PATIENT HAVING AN INTRACTABLE EPILEPSY PROCEDURE WILL REQUIRE A PET SCAN.  
534 MULTIPLY THE NUMBER RESULTING FROM THE CALCULATION IN SUBSECTION (3) BY 1.0,  
535 WHICH IS THE ESTIMATED NUMBER OF PET SCANS NEEDED FOR EACH PATIENT REQUIRING A  
536 PET SCAN.

537  
538 (5) SUM THE NUMBERS RESULTING FROM THE CALCULATIONS IN SUBSECTIONS (1)  
539 THROUGH (4) TO DETERMINE THE TOTAL NUMBER OF PROJECTED PET DATA UNITS.

540

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

544  
545 (7) MULTIPLY THE RESULT CALCULATED IN SUBSECTION (5) ABOVE BY A FACTOR OF 2.0  
546 IF THE APPLICANT IS PROPOSING TO SERVE ONLY PLANNING AREA 5 TO DETERMINE THE  
547 TOTAL NUMBER OF PROJECTED PET DATA UNITS.

548  
549 **Section 13. COMMITMENT OF DIAGNOSIS-SPECIFIC NEW CANCER CASES**

550  
551 Sec. 13. AN APPLICANT PROPOSING TO USE DIAGNOSIS-SPECIFIC NEW CANCER CASES  
552 SHALL DEMONSTRATE ALL OF THE FOLLOWING:

553  
554 (1) ONLY THOSE CANCER DIAGNOSES IDENTIFIED IN SECTION 12(1) AND 12(2) SHALL BE  
555 INCLUDED.

556  
557 (2) EACH ENTITY CONTRIBUTING DIAGNOSIS SPECIFIC NEW CANCER CASE DATA  
558 PROVIDES, AS PART OF THE APPLICATION AT THE TIME IT IS SUBMITTED TO THE  
559 DEPARTMENT, A SIGNED GOVERNING BODY RESOLUTION THAT IDENTIFIES THE NUMBER OF  
560 DIAGNOSIS-SPECIFIC CANCER CASES BEING COMMITTED TO THE APPLICATION AND THAT  
561 STATES NO CURRENT OR FUTURE DIAGNOSIS-SPECIFIC NEW CANCER CASE DATA WILL BE  
562 USED IN SUPPORT OF ANY OTHER APPLICATION FOR A PET UNIT FOR A PERIOD OF FIVE (5)  
563 YEARS FROM THE DATE OF START OF OPERATIONS OF THE APPROVED PET SCANNER  
564 SERVICE FOR WHICH DATA ARE BEING COMMITTED. IF THE REQUIRED DOCUMENTATION FOR  
565 THIS SUBSECTION IS NOT SUBMITTED WITH THE APPLICATION ON THE DESIGNATED  
566 APPLICATION DATE, THE APPLICATION WILL BE DEEMED FILED ON THE FIRST APPLICABLE  
567 DESIGNATED APPLICATION DATE AFTER ALL REQUIRED DOCUMENTATION IS RECEIVED BY  
568 THE DEPARTMENT.

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

572 (B) FOR MOBILE PET SCANNER SERVICES, THE GEOGRAPHIC LOCATION OF EACH  
573 ENTITY CONTRIBUTING DIAGNOSIS-SPECIFIC NEW CANCER CASE DATA IN THE PLANNING  
574 AREA(S) FOR WHICH THE PROPOSED PET SERVICE CONTAINS A PROPOSED HOST SITE OR  
575 WITHIN A 75-MILE RADIUS OF THE PROPOSED HOST SITE FOR RURAL AND MICROPOLITAN  
576 STATISTICAL AREA COUNTIES OR 25-MILE RADIUS FOR METROPOLITAN STATISTICAL AREA  
577 COUNTIES.

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

581  
582 (3) NO ENTITY CURRENTLY OPERATING OR APPROVED TO OPERATE A PET SCANNER  
583 SERVICE SHALL CONTRIBUTE DIAGNOSIS-SPECIFIC NEW CANCER CASES.

584  
585 (4) THE DEPARTMENT MAY NOT CONSIDER A WITHDRAWAL OF DIAGNOSIS-SPECIFIC  
586 NEW CANCER CASE DATA DURING THE 120-DAY APPLICATION REVIEW CYCLE FOLLOWING  
587 THE DATE ON WHICH THE DEPARTMENT REVIEW OF THE APPLICATION COMMENCES OR  
588 AFTER A PROPOSED DECISION TO APPROVE THE APPLICATION HAS BEEN ISSUED UNLESS  
589 THE APPLICATION IS DENIED, WITHDRAWN, OR EXPIRED. THE WITHDRAWAL MUST BE  
590 SUBMITTED TO THE DEPARTMENT IN THE FORM OF A GOVERNING BODY RESOLUTION THAT  
591 CONTAINS THE SPECIFIC CON APPLICATION NUMBER TO WHICH THE DATA WERE ORIGINALLY  
592 COMMITTED, THE LEGAL APPLICANT ENTITY, THE COMMITTING ENTITY, THE TYPE OF DATA,  
593 THE DATE OF THE MEETING IN WHICH THE GOVERNING BODY AUTHORIZED THE WITHDRAWAL  
594 OF THE DATA, THE GOVERNING BODY PRESIDENT'S SIGNATURE, AND THE DATE OF THE

595 SIGNATURE.  
596

597 **Section 14. DOCUMENTATION OF DIAGNOSIS-SPECIFIC NEW CANCER CASE DATA**  
598

599 Sec. 14. AN APPLICANT REQUIRED TO DOCUMENT VOLUMES OF DIAGNOSIS-SPECIFIC  
600 NEW CANCER CASES SHALL SUBMIT, AS PART OF ITS APPLICATION AT THE TIME IT IS  
601 SUBMITTED TO THE DEPARTMENT, DOCUMENTATION FROM THE DIVISION FOR VITAL  
602 RECORDS AND HEALTH STATISTICS VERIFYING THE NUMBER OF DIAGNOSIS-SPECIFIC NEW  
603 CANCER CASES PROVIDED IN SUPPORT OF THE APPLICATION FOR THE MOST RECENT  
604 CALENDAR YEAR FOR WHICH VERIFIABLE DATA ARE AVAILABLE FROM THE STATE  
605 REGISTRAR. IF THE REQUIRED DOCUMENTATION FOR THIS SUBSECTION IS NOT SUBMITTED  
606 WITH THE APPLICATION ON THE DESIGNATED APPLICATION DATE, THE APPLICATION WILL BE  
607 DEEMED FILED ON THE FIRST APPLICABLE DESIGNATED APPLICATION DATE AFTER ALL  
608 REQUIRED DOCUMENTATION IS RECEIVED BY THE DEPARTMENT. DIAGNOSIS-SPECIFIC NEW  
609 CANCER CASE DATA SUPPORTING AN APPLICATION UNDER THESE STANDARDS SHALL BE  
610 SUBMITTED TO THE DIVISION FOR VITAL RECORDS AND HEALTH STATISTICS USING A FORMAT  
611 AND MEDIA SPECIFIED IN INSTRUCTIONS FROM THE DEPARTMENT OF COMMUNITY HEALTH.  
612

613 **Section 15. COMMITMENT AND DOCUMENTATION OF DIAGNOSTIC CARDIAC**  
614 **CATHETERIZATION DATA**  
615

616 Sec. 15. AN APPLICANT PROPOSING TO USE DIAGNOSTIC CARDIAC CATHETERIZATION  
617 DATA SHALL DEMONSTRATE ALL OF THE FOLLOWING:  
618

619 (1) EACH ENTITY CONTRIBUTING DIAGNOSTIC CARDIAC CATHETERIZATION DATA  
620 PROVIDES, AS PART OF THE APPLICATION AT THE TIME IT IS SUBMITTED TO THE  
621 DEPARTMENT, A SIGNED GOVERNING BODY RESOLUTION THAT IDENTIFIES THE NUMBER OF  
622 DIAGNOSTIC CARDIAC CATHETERIZATION CASES (SESSIONS) COMMITTED TO THE  
623 APPLICATION AND THAT STATES NO CURRENT OR FUTURE DIAGNOSTIC CARDIAC  
624 CATHETERIZATION DATA WILL BE USED IN SUPPORT OF ANY OTHER APPLICATION FOR A PET  
625 UNIT FOR THE DURATION OF THE PET SERVICE FOR WHICH DATA ARE BEING COMMITTED  
626 FOR A PERIOD OF FIVE (5) YEARS FROM THE DATE OF START OF OPERATIONS OF THE  
627 APPROVED PET SERVICE FOR WHICH DATA ARE BEING COMMITTED. IF THE REQUIRED  
628 DOCUMENTATION FOR THIS SUBSECTION IS NOT SUBMITTED WITH THE APPLICATION ON THE  
629 DESIGNATED APPLICATION DATE, THE APPLICATION WILL BE DEEMED FILED ON THE FIRST  
630 APPLICABLE DESIGNATED APPLICATION DATE AFTER ALL REQUIRED DOCUMENTATION IS  
631 RECEIVED BY THE DEPARTMENT.

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

635 (B) FOR MOBILE PET SCANNER SERVICES, THE GEOGRAPHIC LOCATION OF EACH  
636 ENTITY CONTRIBUTING DIAGNOSTIC CARDIAC CATHETERIZATION CASE DATA IN THE  
637 PLANNING AREA(S) FOR WHICH THE PROPOSED PET SERVICE CONTAINS A PROPOSED HOST  
638 SITE OR WITHIN A 75-MILE RADIUS OF THE PROPOSED HOST SITE FOR RURAL AND  
639 MICROPOLITAN STATISTICAL AREA COUNTIES OR 25-MILE RADIUS FOR METROPOLITAN  
640 STATISTICAL AREA COUNTIES.

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

644 (D) THE DIAGNOSTIC CARDIAC CATHETERIZATION CASE DATA IS FROM THE MOST  
645 RECENTLY COMPLETED REPORT(S) OF THE ANNUAL SURVEY PRODUCED BY THE  
646 DEPARTMENT, AND THE CONTRIBUTING ENTITY HAS CON APPROVAL TO PROVIDE  
647 DIAGNOSTIC CARDIAC CATHETERIZATION SERVICES.  
648

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

651  
652 (3) THE DEPARTMENT MAY NOT CONSIDER A WITHDRAWAL OF DIAGNOSTIC CARDIAC  
653 CATHETERIZATION CASE DATA DURING THE 120-DAY APPLICATION REVIEW CYCLE  
654 FOLLOWING THE DATE ON WHICH THE DEPARTMENT REVIEW OF THE APPLICATION  
655 COMMENCES OR AFTER A PROPOSED DECISION TO APPROVE THE APPLICATION HAS BEEN  
656 DENIED UNLESS THE APPLICATION IS DENIED, WITHDRAWN, OR EXPIRED. THE WITHDRAWAL  
657 MUST BE SUBMITTED TO THE DEPARTMENT IN THE FORM OF A GOVERNING BODY  
658 RESOLUTION THAT CONTAINS THE SPECIFIC CON APPLICATION NUMBER TO WHICH THE DATA  
659 WERE ORIGINALLY COMMITTED, THE LEGAL APPLICANT ENTITY, THE COMMITTING ENTITY,  
660 THE TYPE OF DATA, THE DATE OF THE MEETING IN WHICH THE GOVERNING BODY  
661 AUTHORIZED THE WITHDRAWAL OF THE DATA, THE GOVERNING BODY PRESIDENT'S  
662 SIGNATURE, AND THE DATE OF THE SIGNATURE.  
663

664 **Section 16. COMMITMENT AND DOCUMENTATION OF INTRACTABLE EPILEPSY DATA**  
665

666 Sec. 16. AN APPLICANT PROPOSING TO USE INTRACTABLE EPILEPSY CASES SHALL  
667 DEMONSTRATE ALL OF THE FOLLOWING:  
668

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

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

684 (B) FOR MOBILE PET SCANNER SERVICES, THE GEOGRAPHIC LOCATION OF EACH  
685 ENTITY CONTRIBUTING INTRACTABLE EPILEPSY CASE DATA IN THE PLANNING AREA(S) FOR  
686 WHICH THE PROPOSED PET SCANNER SERVICE CONTAINS A PROPOSED HOST SITE OR  
687 WITHIN A 75-MILE RADIUS OF THE PROPOSED HOST SITE FOR RURAL AND MICROPOLITAN  
688 STATISTICAL AREA COUNTIES OR 25-MILE RADIUS FOR METROPOLITAN STATISTICAL AREA  
689 COUNTIES.

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

693 (D) THE INTRACTABLE EPILEPSY CASE DATA IS FROM THE MOST RECENT MICHIGAN  
694 INPATIENT DATA BASE (MIDB) AVAILABLE TO THE DEPARTMENT.  
695

696 (2) NO ENTITY CURRENTLY OPERATING OR APPROVED TO OPERATE A SCANNER SHALL  
697 CONTRIBUTE INTRACTABLE EPILEPSY CASE DATA.  
698

699 (3) THE DEPARTMENT MAY NOT CONSIDER A WITHDRAWAL OF INTRACTABLE EPILEPSY  
700 CASE DATA DURING THE 120-DAY APPLICATION REVIEW CYCLE FOLLOWING THE DATE ON  
701 WHICH THE DEPARTMENT REVIEW OF THE APPLICATION COMMENCES OR AFTER A  
702 PROPOSED DECISION TO APPROVE THE APPLICATION UNLESS THE APPLICATION IS DENIED,  
703 WITHDRAWN, OR EXPIRED. THE WITHDRAWAL MUST BE SUBMITTED TO THE DEPARTMENT IN  
704 THE FORM OF A GOVERNING BODY RESOLUTION THAT CONTAINS THE SPECIFIC CON

705 APPLICATION NUMBER TO WHICH THE DATA WERE ORIGINALLY COMMITTED, THE LEGAL  
706 APPLICANT ENTITY, THE COMMITTING ENTITY, THE TYPE OF DATA, THE DATE OF THE  
707 MEETING IN WHICH THE GOVERNING BODY AUTHORIZED THE WITHDRAWAL OF THE DATA,  
708 THE GOVERNING BODY PRESIDENT'S SIGNATURE, AND THE DATE OF THE SIGNATURE.

709

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

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713

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

<b>TABLE1 PET EQUIVALENTS</b>	
<b>Scan Category</b>	<b>Weight</b>
Simple <sup>1</sup>	0.75
Standard	1.0
Complex <sup>2</sup>	1.5

<sup>1</sup> Brain and single cardiac scans.  
<sup>2</sup> Inpatient radiation treatment when patient position device is used, cardiac rest/stress perfusion and metabolism, standard study with additional limited scan, and all pediatric scans.

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**Section 18. DEPARTMENT INVENTORY OF PET SCANNERS**

717 Sec. 18. THE DEPARTMENT SHALL MAINTAIN AND PUBLICLY POST ON ITS WEB SITE A LIST  
718 OF PET SCANNER SERVICES ANNUALLY.

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721

**Section 19. COMPARATIVE REVIEWS; EFFECT ON PRIOR PLANNING POLICIES**

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725

Sec. 19. PROPOSED PROJECTS REVIEWED UNDER THESE STANDARDS SHALL NOT BE  
SUBJECT TO COMPARATIVE REVIEW. THESE CON REVIEW STANDARDS SUPERSEDE AND  
REPLACE THE CON STANDARDS FOR PET SCANNER SERVICES APPROVED BY THE CON  
COMMISSION ON DECEMBER 12, 2006 AND EFFECTIVE MARCH 8, 2007.

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Counties assigned to each health service area are as follows:

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



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

**PLANNING AREA 1**

**COUNTIES**

HSA 1

Livingston	Monroe	St. Clair
Macomb	Oakland	Washtenaw
Wayne		

**PLANNING AREA 2**

HSA 2

Clinton	Hillsdale	Jackson
Eaton	Ingham	Lenawee

HSA 3

Barry	Calhoun	St. Joseph
Berrien	Cass	Van Buren
Branch	Kalamazoo	

**PLANNING AREA 3**

HSA 4

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

**PLANNING AREA 4**

HSA 5

Genesee	Lapeer	Shiawassee
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HSA 6

Arenac	Huron	Roscommon
Bay	Iosco	Saginaw
Clare	Isabella	Sanilac
Gladwin	Midland	Tuscola
Gratiot	Ogemaw	

**PLANNING AREA 5**

HSA 7

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

**PLANNING AREA 6**

HSA 8

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

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Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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Office of Information and Regulatory Affairs  
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