

1 MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
2
3 CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR
4 POSITRON EMISSION TOMOGRAPHY (PET) SCANNER SERVICES
5

6 (By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of
7 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being
8 sections 333.22215, 24.207 and 24.208 of the Michigan Compiled Laws.)
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10 **Section 1. Applicability**

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12 Sec. 1. These standards are requirements for the approval OF THE INITIATION, REPLACEMENT,
13 EXPANSION, OR ACQUISITION OF PET SCANNER SERVICES, and THE delivery of THESE services
14 under Part 222 of the Code. PURSUANT TO Part 222 of the Code PET SCANNER SERVICES ARE A
15 COVERED CLINICAL SERVICE. The Department shall use THESE STANDARDS in applying Section
16 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws AND Section
17 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.
18

19 **Section 2. Definitions**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

52 (Q) "PET scanner" means an FDA-approved full or partial ring scanner or coincidence system that
53 has a crystal at least 5/8-inch thick, techniques to minimize or correct for scatter and/or randoms, and

54 digital detectors and iterative reconstruction. Further, the term does include PET/CT scanner hybrids. If
55 the PET/CT scanner will be used for computed tomography (CT) scans only in conjunction with the PET
56 scan, then no separate CON is required for that CT use. The term does not include single-photon
57 emission computed tomography systems (SPECT), x-ray CT systems, magnetic resonance, ultrasound
58 computed tomographic systems, gamma cameras modified for either non-coincidence or coincidence
59 imaging, or similar technology.

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

62 (S) "SPECT" means single photon emission computed tomography.

63

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

65

66 **Section 3. Requirements TO INITIATE A PET SCANNER SERVICE**

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68 Sec. 3. An applicant proposing to INITIATE PET scanner services shall DEMONSTRATE the
69 following, AS APPLICABLE TO THE PROPOSED PROJECT.

70

71 (1) THE APPLICANT SHALL DEMONSTRATE THE PROPOSED SITE PROVIDES THE
72 FOLLOWING SERVICES AND SPECIALTIES:

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

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

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

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

78 (e) cardiac catheterization services,

79 (f) open heart surgery,

80 (g) thoracic surgery,

81 (h) cardiology,

82 (i) oncology,

83 (j) radiation oncology,

84 (k) neurology,

85 (l) neurosurgery, and

86 (m) psychiatry.

87

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

91

92 (3) THE APPLICANT SHALL DEMONSTRATE THE PROPOSED SITE HAS AN ON-SITE
93 SOURCE OF RADIOPHARMACEUTICALS. If THE proposed SITE does not PROVIDE an on-site source
94 of radiopharmaceuticals, THE applicant SHALL provide a written contract or agreement that
95 demonstrates a reliable supply of radiopharmaceuticals

96

97 (4) AN APPLICANT PROPOSING TO INITIATE A FIXED PET SCANNER SERVICE WITH ITS
98 FIRST PET SCANNER SHALL PROJECT 2,600 PET DATA UNITS OR SHALL DEMONSTRATE ALL
99 OF THE FOLLOWING:

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

102 (B) THE APPLICANT HAS PERFORMED:

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

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

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

111
112 (5) AN APPLICANT PROPOSING TO INITIATE A MOBILE PET SCANNER SERVICE WITH ITS
113 FIRST MOBILE PET SCANNER SHALL PROJECT 2,100 PET DATA UNITS.

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

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

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

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

124
125 (6) AN APPLICANT PROPOSING TO INITIATE A HOST SITE ON A PROPOSED OR EXISTING
126 MOBILE PET SCANNER SERVICE SHALL DEMONSTRATE THE FOLLOWING:

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

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

130 (C) THE APPLICANT HAS NOT INITIATED FIXED PET SCANNER SERVICES UNDER
131 SUBSECTION 3(4) WITHIN THE MOST RECENT 12-MONTH PERIOD AS OF THE DATE THE
132 APPLICATION IS SUBMITTED TO THE DEPARTMENT.

133 (D) AN APPLICANT INITIATING A HOST SITE IN HSA 8 ON A MOBILE PET SCANNER
134 SERVICE THAT OPERATES PREDOMINANTLY OUTSIDE OF MICHIGAN SHALL DEMONSTRATE
135 240 PET DATA UNITS FROM PLANNING AREA 6.

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137 (7) AN APPLICANT PROPOSING TO INITIATE PET SCANNER SERVICES AS AN EXISTING
138 HOST SITE ON A DIFFERENT MOBILE PET SCANNER SERVICE SHALL DEMONSTRATE THE
139 FOLLOWING:

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

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

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

146
147 **Section 4. Requirements TO REPLACE AN EXISTING PET scanner(S) OR PET SCANNER**
148 **SERVICE**

149
150 Sec. 4. REPLACING A PET SCANNER(S) MEANS A CHANGE IN THE SCANNER EQUIPMENT
151 OR RELOCATION OF THE SERVICE TO A NEW SITE. AN UPGRADE TO SOFTWARE OR
152 COMPONENTS OF AN EXISTING SCANNER DOES NOT CONSTITUTE REPLACEMENT OF A PET
153 SCANNER. AN APPLICANT PROPOSING TO REPLACE AN EXISTING PET SCANNER(S) OR PET
154 SCANNER SERVICE SHALL DEMONSTRATE THE FOLLOWING, AS APPLICABLE TO THE
155 PROPOSED PROJECT.

156
157 (1) An applicant proposing to REPLACE a PET scanner(S) shall DEMONSTRATE EACH OF THE
158 FOLLOWING:

159 (a) THE REPLACEMENT SCANNER(S) IS THE SAME TYPE (FIXED OR MOBILE) AS THE

160 SCANNER(S) TO BE REPLACED.

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

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

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

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

170
171 (2) AN APPLICANT PROPOSING TO REPLACE A FIXED PET SCANNER SERVICE TO A NEW
172 SITE SHALL DEMONSTRATE THE FOLLOWING:

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

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

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

180

181 **Section 5. Requirements to expand a PET scanner service**

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183 Sec. 5. An applicant proposing to EXPAND A PET scanner SERVICE shall demonstrate the following,
184 AS APPLICABLE TO THE PROPOSED PROJECT. THIS SECTION DOES NOT APPLY TO
185 DEDICATED RESEARCH, DEDICATED PEDIATRIC, OR POSITRON EMISSION MAMMOGRAPHY
186 (PEM) SCANNERS.

187

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

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

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

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

197

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

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

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

208

209 (3) An applicant PROPOSING TO ADD A FIXED PET SCANNER TO AN EXISTING FIXED PET
210 SCANNER SERVICE that ALSO RECEIVES MOBILE PET SCANNER SERVICES SHALL
211 DEMONSTRATE the following:

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

213 scanner services.

214 (b) The applicant HAS PERFORMED:

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

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

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

225

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

227

228 Sec. 6. ACQUIRING A PET SCANNER SERVICE AND ITS scanner(s) MEANS OBTAINING
229 POSSESSION AND CONTROL BY CONTRACT, OWNERSHIP, LEASE, OR OTHER COMPARABLE
230 ARRANGEMENT AND RENEWAL OF LEASE FOR AN EXISTING fixed OR MOBILE PET scanner. AN
231 APPLICANT PROPOSING TO ACQUIRE A PET SCANNER SERVICE SHALL DEMONSTRATE THE
232 FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT.

233

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

239

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

244

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

248

249 (4) An applicant proposing to RENEW A LEASE FOR AN EXISTING FIXED OR MOBILE PET
250 scanner(s) shall demonstrate THAT THE RENEWAL OF THE LEASE IS MORE COST EFFECTIVE
251 THAN REPLACING THE SCANNER(S).

252

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

254

255 Sec. 7. An applicant proposing to ADD a FIXED PET scanner TO AN EXISTING PET SCANNER
256 SERVICE FOR EXCLUSIVE RESEARCH USE shall demonstrate THE FOLLOWING:

257

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

260

261 (2) The DEDICATED RESEARCH PET scanner SHALL OPERATE UNDER A PROTOCOL
262 APPROVED BY THE APPLICANT'S INSTITUTIONAL REVIEW BOARD, AS DEFINED BY PUBLIC LAW
263 93-348 AND REGULATED BY TITLE 45 CFR 46.

264

265 (3) The APPLICANT HAS ACCESS TO A CYCLOTRON FOR ACCELERATING CHARGED

266 PARTICLES TO HIGH ENERGIES BY MEANS of ELECTROMAGNETIC FIELDS.

267

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

270

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

272

273 Sec. 8. An applicant proposing to INITIATE A PET scanner service, OR ADD A fixed PET
274 SCANNER TO EXPAND AN EXISTING PET SCANNER SERVICE, FOR DEDICATED PEDIATRIC PET
275 USE shall DEMONSTRATE THE following:

276

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

279

280 (2) The APPLICANT SHALL DEMONSTRATE the EXISTING SITE PROVIDED the FOLLOWING
281 FOR THE MOST RECENT CALENDAR YEAR OR A CONTINUOUS 12-MONTH PERIOD AT THE TIME
282 THE APPLICATION IS SUBMITTED TO THE Department:

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

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

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

287

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

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

292 (B) ANESTHESIOLOGY

293 (C) CARDIOLOGY

294 (D) CRITICAL CARE

295 (E) GASTROENTEROLOGY

296 (F) HEMATOLOGY/ONCOLOGY

297 (G) NEUROLOGY

298 (H) NEUROSURGERY

299 (I) ORTHOPEDIC SURGERY

300 (J) PATHOLOGY

301 (K) PULMONOLOGY

302 (L) SURGERY

303 (M) NEONATOLOGY

304

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

307 (A) BONE MARROW TRANSPLANT PROGRAM

308 (B) SEDATION PROGRAM

309 (C) OPEN HEART PROGRAM

310

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

314

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

317

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

383
384 **Section 11. PROJECT DELIVERY Requirements AND TERMS OF APPROVAL FOR ALL**
385 **APPLICANTS**

386
387 Sec. 11. An applicant shall AGREE THAT, IF APPROVED, the PET SCANNER SERVICES SHALL
388 BE DELIVERED IN COMPLIANCE WITH THE FOLLOWING TERMS OF APPROVAL.

389
390 (1) COMPLIANCE WITH THESE STANDARDS.

391
392 (2) COMPLIANCE WITH THE FOLLOWING QUALITY ASSURANCE REQUIREMENTS:

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

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

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

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

415
416 (3) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:

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

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

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

424 (D) THE OPERATION OF AND REFERRAL OF PATIENTS TO THE PET SCANNER SERVICE

425 SHALL BE IN CONFORMANCE WITH 1978 PA 368, SEC. 16221, AS AMENDED BY 1986 PA 319; MCL
426 333.16221; MSA 14.15 (16221).

427

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

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

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

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

450
451 (5) COMPLIANCE WITH THE FOLLOWING DEDICATED RESEARCH PET SCANNER
452 REQUIREMENTS, IF APPLICABLE:

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

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

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

460
461 (6) COMPLIANCE WITH THE FOLLOWING DEDICATED PEDIATRIC PET SCANNER
462 REQUIREMENTS, IF APPLICABLE:

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

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

467
468 (7) COMPLIANCE WITH THE FOLLOWING PEM SCANNER REQUIREMENTS, IF APPLICABLE:

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

471
472 (8) COMPLIANCE WITH THE FOLLOWING MOBILE PET SCANNER REQUIREMENTS, IF
473 APPLICABLE:

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

476 (B) EACH HOST SITE MUST HAVE AT LEAST ONE PHYSICIAN WHO IS BOARD CERTIFIED
477 OR BOARD ELIGIBLE IN NUCLEAR MEDICINE OR NUCLEAR RADIOLOGY ON ITS MEDICAL STAFF.

478 THE PHYSICIAN(S) SHALL BE RESPONSIBLE FOR ESTABLISHING PATIENT EXAMINATION AND
479 INFUSION PROTOCOL, AND PROVIDING FOR THE INTERPRETATION OF SCANS PERFORMED.

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

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

487
488 (9) THE AGREEMENTS AND ASSURANCES REQUIRED BY THIS SECTION SHALL BE IN THE
489 FORM OF A CERTIFICATION AGREED TO BY THE APPLICANT OR ITS AUTHORIZED AGENT.

490

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

492

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

496

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

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

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

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

511

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

514 (a) MULTIPLY THE NUMBER OF BREAST CANCER CASES (SITE CODES C500-C509) BY
515 0.25, WHICH IS THE ESTIMATED PROBABILITY THAT A BREAST CANCER CASE WILL REQUIRE A
516 PET SCAN.

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

520

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

525

526 (4) MULTIPLY THE NUMBER OF INTRACTABLE EPILEPSY CASES (ICD-9-CM CODES 345.01,
527 345.11, 345.41, 345.51, 345.61, 345.71, 345.81, OR 345.91) IDENTIFIED IN ACCORD WITH THE
528 REQUIREMENTS OF SECTION 16 BY 1.0, WHICH IS THE ESTIMATED PROBABILITY THAT A
529 PATIENT HAVING AN INTRACTABLE EPILEPSY PROCEDURE WILL REQUIRE A PET SCAN.
530 MULTIPLY THE NUMBER RESULTING FROM THE CALCULATION IN SUBSECTION (3) BY 1.0,

531 WHICH IS THE ESTIMATED NUMBER OF PET SCANS NEEDED FOR EACH PATIENT REQUIRING A
532 PET SCAN.

533

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

536

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

540

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

544

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

546

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

549

550 (1) ONLY THOSE CANCER DIAGNOSES IDENTIFIED IN SECTION 12(1) AND 12(2) SHALL BE
551 INCLUDED.

552

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

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

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

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

577

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

580

581 (4) THE DEPARTMENT MAY NOT CONSIDER A WITHDRAWAL OF DIAGNOSIS-SPECIFIC
582 NEW CANCER CASE DATA DURING THE 120-DAY APPLICATION REVIEW CYCLE FOLLOWING
583 THE DATE ON WHICH THE DEPARTMENT REVIEW OF THE APPLICATION COMMENCES OR

584 AFTER A PROPOSED DECISION TO APPROVE THE APPLICATION HAS BEEN ISSUED UNLESS
585 THE APPLICATION IS DENIED, WITHDRAWN, OR EXPIRED. THE WITHDRAWAL MUST BE
586 SUBMITTED TO THE DEPARTMENT IN THE FORM OF A GOVERNING BODY RESOLUTION THAT
587 CONTAINS THE SPECIFIC CON APPLICATION NUMBER TO WHICH THE DATA WERE ORIGINALLY
588 COMMITTED, THE LEGAL APPLICANT ENTITY, THE COMMITTING ENTITY, THE TYPE OF DATA,
589 THE DATE OF THE MEETING IN WHICH THE GOVERNING BODY AUTHORIZED THE WITHDRAWAL
590 OF THE DATA, THE GOVERNING BODY PRESIDENT'S SIGNATURE, AND THE DATE OF THE
591 SIGNATURE.

592

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

594

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

608

609 **Section 15. COMMITMENT AND DOCUMENTATION OF DIAGNOSTIC CARDIAC** 610 **CATHETERIZATION DATA**

611

612 Sec. 15. AN APPLICANT PROPOSING TO USE DIAGNOSTIC CARDIAC CATHETERIZATION
613 DATA SHALL DEMONSTRATE ALL OF THE FOLLOWING:

614

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

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

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

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

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

644

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

647

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

659

660 **Section 16. COMMITMENT AND DOCUMENTATION OF INTRACTABLE EPILEPSY DATA**

661

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

664

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

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

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

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

689 (D) THE INTRACTABLE EPILEPSY CASE DATA IS FROM THE MOST RECENT MICHIGAN

690 INPATIENT DATA BASE (MIDB) AVAILABLE TO THE DEPARTMENT.

691

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

694

695 (3) THE DEPARTMENT MAY NOT CONSIDER A WITHDRAWAL OF INTRACTABLE EPILEPSY
696 CASE DATA DURING THE 120-DAY APPLICATION REVIEW CYCLE FOLLOWING THE DATE ON
697 WHICH THE DEPARTMENT REVIEW OF THE APPLICATION COMMENCES OR AFTER A
698 PROPOSED DECISION TO APPROVE THE APPLICATION UNLESS THE APPLICATION IS DENIED,
699 WITHDRAWN, OR EXPIRED. THE WITHDRAWAL MUST BE SUBMITTED TO THE DEPARTMENT IN
700 THE FORM OF A GOVERNING BODY RESOLUTION THAT CONTAINS THE SPECIFIC CON
701 APPLICATION NUMBER TO WHICH THE DATA WERE ORIGINALLY COMMITTED, THE LEGAL
702 APPLICANT ENTITY, THE COMMITTING ENTITY, THE TYPE OF DATA, THE DATE OF THE
703 MEETING IN WHICH THE GOVERNING BODY AUTHORIZED THE WITHDRAWAL OF THE DATA,
704 THE GOVERNING BODY PRESIDENT’S SIGNATURE, AND THE DATE OF THE SIGNATURE.

705

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

707

708 Sec. 17. PET equivalents shall be calculated as follows:

709

TABLE1 PET EQUIVALENTS	
Scan Category	Weight
Simple ¹	0.75
Standard ²	1.0
Complex ³	1.5
¹ BRAIN AND SINGLE CARDIAC SCANS. ² MID-SKULL TO MID-THIGH SCANS. ³ INPATIENT, RADIATION TREATMENT WHEN PATIENT POSITION DEVICE IS USED, CARDIAC REST/STRESS PERFUSION AND METABOLISM, STANDARD STUDY WITH ADDITIONAL LIMITED SCAN, PEDIATRIC ,AND TOTAL BODY SCANS.	

710

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

712

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

715

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

717

718 Sec. 19. PROPOSED PROJECTS REVIEWED UNDER THESE STANDARDS SHALL NOT BE
719 SUBJECT TO COMPARATIVE REVIEW. THESE CON REVIEW STANDARDS SUPERSEDE AND
720 REPLACE THE CON STANDARDS FOR PET SCANNER SERVICES APPROVED BY THE CON
721 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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