

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.)
9

10 **Section 1. Applicability**

11
12 Sec. 1. These standards are requirements for the approval OF THE INITIATION, REPLACEMENT,
13 EXPANSION, ACQUISITION, OR RELOCATION OF PET SCANNER SERVICES, and THE delivery of
14 THESE services under Part 222 of the Code. PURSUANT TO Part 222 of the Code PET SCANNER
15 SERVICES ARE A COVERED CLINICAL SERVICE. The Department shall use THESE STANDARDS in
16 applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws AND
17 Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.
18

19 **Section 2. Definitions**

20
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

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

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

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

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

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

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

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

47 (M) "Patient visit" means a single session lasting no more than one day utilizing a PET scanner
48 during which 1 or more PET procedures are performed.

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

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

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

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

54 (R) "PET scanner" means an FDA-approved full or partial ring scanner or coincidence system that

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

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

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

65 (U) "SPECT" means single photon emission computed tomography.

66

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

68

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

70

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

73

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

76 (a) nuclear medicine services

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

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

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

80 (e) cardiac catheterization services

81 (f) open heart surgery,

82 (g) thoracic surgery,

83 (h) cardiology,

84 (i) oncology,

85 (j) radiation oncology,

86 (k) neurology,

87 (l) neurosurgery, and

88 (m) psychiatry.

89

90 (2) If the PROPOSED SITE does not provide any of the services listed in subsection (1) ON-SITE,
91 the applicant shall PROVIDE written contracts or agreements with a hospital(s) located within the same
92 planning area OR 20 MILES OF THE PROPOSED SITE for the services not provided at the proposed
93 site.

94

95 (3) THE APPLICANT SHALL DEMONSTRATE THE PROPOSED SITE HAS AN ON-SITE
96 SOURCE OF RADIOPHARMACEUTICALS.

97

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

101

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

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

107 (B) THE APPLICANT HAS RECEIVED:

108 (I) 1,700 PET SCANS IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE

109 DEPARTMENT FOR A HOST SITE IN A METROPOLITAN STATISTICAL AREA COUNTY, OR
110 (II) 1,500 PET SCANS IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE
111 DEPARTMENT FOR A HOST SITE IN A RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY.
112 (C) THE APPLICANT AGREES TO CEASE OPERATION AS A HOST SITE AND NOT BECOME A
113 HOST SITE FOR AT LEAST 12 MONTHS FROM THE DATE THE FIXED PET SCANNER BECOMES
114 OPERATIONAL.

115
116 (6) AN APPLICANT PROPOSING TO INITIATE A MOBILE PET SCANNER SERVICE WITH ITS
117 FIRST MOBILE PET SCANNER SHALL PROJECT 2,100 PET DATA UNITS.

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

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

124 (C) THE APPLICANT PROVIDES A ROUTE SCHEDULE FOR THE PROPOSED MOBILE PET
125 SCANNER SERVICE.

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

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

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

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

135 (D) AN APPLICANT INITIATING A HOST SITE IN HSA 8 ON A MOBILE PET SCANNER
136 SERVICE THAT OPERATES PREDOMINANTLY OUTSIDE OF MICHIGAN SHALL DEMONSTRATE
137 240 PET DATA UNITS FROM PLANNING AREA 6.

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

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

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

145 (C) THE APPLICANT HAS RECEIVED 50 PET SCANS IN THE MOST RECENT 12-MONTH
146 PERIOD VERIFIABLE BY THE DEPARTMENT FROM AN EXISTING MOBILE PET SCANNER
147 SERVICE FOR AN EXISTING HOST SITE PROPOSING TO INITIATE SERVICES ON A DIFFERENT
148 MOBILE PET SCANNER SERVICE.

149
150 **Section 4. Requirements TO REPLACE AN EXISTING PET scanner(S) OR PET SCANNER**
151 **SERVICE**

152
153 Sec. 4. REPLACING A PET SCANNER(S) MEANS A CHANGE IN THE SCANNER EQUIPMENT
154 OR RELOCATION OF THE SERVICE TO A NEW SITE. AN UPGRADE TO SOFTWARE OR
155 COMPONENTS/PARTS OF AN EXISTING SCANNER DOES NOT CONSTITUTE REPLACEMENT OF
156 A PET SCANNER. An applicant proposing to REPLACE a PET scanner(S) shall DEMONSTRATE EACH
157 OF THE FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT.

158
159 (1) An applicant proposing to REPLACE a PET scanner shall DEMONSTRATE THE
160 FOLLOWING:

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

163 (b) THE SCANNER(S) TO BE REPLACED IS FULLY DEPRECIATED ACCORDING TO
164 GENERALLY ACCEPTED ACCOUNTING PRINCIPLES OR EITHER OF THE FOLLOWING:
165 (i) The EXISTING SCANNER(S) POSES A THREAT TO THE SAFETY OF THE PATIENTS.
166 (ii) The REPLACEMENT SCANNER(S) OFFERS TECHNOLOGICAL IMPROVEMENTS THAT
167 ENHANCE QUALITY OF CARE, INCREASE EFFICIENCY, AND REDUCE OPERATING COSTS AND
168 PATIENT CHARGES.
169 (C) THE APPLICANT AGREES THAT THE PET SCANNER(S) TO BE REPLACED WILL BE
170 REMOVED FROM SERVICE ON OR BEFORE BEGINNING OPERATION OF THE REPLACEMENT
171 SCANNER(S).

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

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

178 (B) The EXISTING FIXED PET SCANNER(S) PERFORMED 600 PET SCANS PER FIXED
179 SCANNER IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE DEPARTMENT.

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

182 183 **Section 5. Requirements to expand a PET scanner service**

184
185 Sec. 5. An applicant proposing to EXPAND A PET scanner sERVICE shall demonstrate EACH OF
186 the following, AS APPLICABLE TO THE PROPOSED PROJECT.

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 SCANS WERE PERFORMED PER EXISTING AND APPROVED FIXED PET
191 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 SCANS WERE PERFORMED PER EXISTING AND APPROVED FIXED PET
194 SCANNER(S) IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE DEPARTMENT FOR
195 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 SCANS WERE PERFORMED PER EXISTING AND APPROVED MOBILE
201 SCANNER(S)

202 IN the most recent 12-month period VERIFIABLE BY the Department FOR AN APPLICANT SERVING
203 AT LEAST ONE EXISTING HOST SITE IN A METROPOLITAN STATISTICAL AREA COUNTY, OR

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

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

210 (a) The applicant is CURRENTLY A HOST SITE BEING SERVED BY ONE OR MORE mobile PET
211 scanner serviceS.

212 (b) The applicant HAS RECEIVED:

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

216 (ii) An AVERAGE OF 1,700 PET scans FOR THE HOST SITE AND EACH OF THE FIXED

217 scanners IN the most recent 12-month period VERIFIABLE BY the Department FOR A HOST SITE IN A
218 RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY.

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

222
223 (4) THIS SECTION DOES NOT APPLY TO DEDICATED RESEARCH, DEDICATED PEDIATRIC
224 OR POSITRON EMISSION MAMMOGRAPHY (PEM) SCANNERS.

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

226
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 EACH
232 OF THE 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 on OR AFTER <INSERT EFFECTIVE DATE OF STANDARDS>, THE
236 EXISTING PET SERVICE AND ITS SCANNER(S) SHALL NOT BE REQUIRED TO BE IN COMPLIANCE
237 WITH THE APPLICABLE VOLUME REQUIREMENTS SET FORTH IN THIS SECTION.

238
239 (2) An APPLICANT PROPOSING TO ACQUIRE AN EXISTING FIXED OR MOBILE PET
240 SCANNER SERVICE SHALL DEMONSTRATE THAT THE EXISTING FIXED OR MOBILE SCANNER(S)
241 PERFORMED AN AVERAGE OF 500 PET SCANS PER SCANNER IN THE MOST RECENT 12-MONTH
242 PERIOD VERIFIABLE BY THE DEPARTMENT.

243
244 (3) An applicant proposing TO ACQUIRE AN EXISTING HOST SITE shall
245 DEMONSTRATE THAT the existing HOST SITE HAS performed 50 SCANS IN the most recent 12-month
246 period VERIFIABLE BY the Department.

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

248
249
250 Sec. 7. An applicant proposing to ADD a FIXED PET scanner TO EXPAND AN EXISTING PET
251 SCANNER SERVICE FOR EXCLUSIVE RESEARCH USE shall NOT NEED TO meet the
252 REQUIREMENTS OF SECTIONS 3 AND 5 IF THE APPLICANT DEMONSTRATES EACH OF THE
253 FOLLOWING.

254
255 (1) The DEDICATED RESEARCH PET scanner SHALL OPERATE UNDER A PROTOCOL
256 APPROVED BY THE APPLICANT'S INSTITUTIONAL REVIEW BOARD, AS DEFINED BY PUBLIC LAW
257 93-348 AND REGULATED BY TITLE 45 CFR 46.

258
259 (2) The APPLICANT HAS ACCESS TO A CYCLOTRON FOR ACCELERATING CHARGED
260 PARTICLES TO HIGH ENERGIES BY MEANS OF ELECTROMAGNETIC FIELDS.

261
262 (3) The APPLICANT HAS NO MORE THAN THREE DEDICATED RESEARCH FIXED PET
263 scanners APPROVED UNDER THIS Section.

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

265
266
267 Sec. 8. An applicant proposing to INITIATE A PET scanner service, OR ADD A fixed PET
268 SCANNER TO EXPAND AN EXISTING PET SCANNER SERVICE, FOR DEDICATED PEDIATRIC PET
269 USE, shall NOT NEED TO MEET the REQUIREMENTS OF SECTION 5 IF THE APPLICANT
270 DEMONSTRATES EACH OF THE following:

271
272 (1) The APPLICANT AGREES THAT THE DEDICATED PEDIATRIC PET scanner WILL BE USED
273 PRIMARILY (70% OF THE SCANS) FOR PATIENTS UNDER 18 YEARS OF AGE.
274

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

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

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

281 (C) AT LEAST 50 NEW PEDIATRIC CANCER CASES ON ITS CANCER REGISTRY.
282

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

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

287 (B) ANESTHESIOLOGY

288 (C) CARDIOLOGY

289 (D) CRITICAL CARE

290 (E) GASTROENTEROLOGY

291 (F) HEMATOLOGY/ONCOLOGY

292 (G) NEUROLOGY

293 (H) NEUROSURGERY

294 (I) ORTHOPEDIC SURGERY

295 (J) PATHOLOGY

296 (K) PULMONOLOGY

297 (L) SURGERY

298 (M) NEONATOLOGY
299

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

302 (A) BONE MARROW TRANSPLANT PROGRAM

303 (B) SEDATION PROGRAM

304 (C) OPEN HEART PROGRAM
305

306 (5) THE APPLICANT MEETS THE REQUIREMENTS OF SECTION 3(1) THROUGH 3(4) IF THE
307 APPLICANT IS INITIATING A PET SCANNER SERVICE WITH A DEDICATED PEDIATRIC FIXED PET
308 SCANNER.
309

310 (6) THE APPLICANT HAS NO MORE THAN THREE DEDICATED PEDIATRIC FIXED PET
311 SCANNERS APPROVED UNDER THIS SECTION.
312

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

314
315 Sec. 9. An applicant proposing to ADD A PEM SCANNER TO EXPAND an existing PET SCANNER
316 service FOR EXCLUSIVE USE IN A COMPREHENSIVE DIAGNOSTIC BREAST PROGRAM shall NOT
317 NEED TO MEET the REQUIREMENTS OF SECTION 6 IF THE APPLICANT DEMONSTRATES EACH
318 OF THE following:
319

320 (1) The APPLICANT CURRENTLY OPERATES, AT THE TIME THE APPLICATION IS
321 SUBMITTED TO THE DEPARTMENT, A COMPREHENSIVE DIAGNOSTIC BREAST PROGRAM THAT
322 INCLUDES THE FOLLOWING SPECIALTIES, SERVICES, AND MEDICAL STAFF (DEPARTMENT
323 STILL DEVELOPING REQUIREMENTS):
324

325 (2) The APPLICANT has NO MORE THAN THREE PEM SCANNERS APPROVED UNDER THIS
326 SECTION.

327
328
329 **Section 10. Requirement for MEDICAID PARTICIPATION**
330

331 Sec. 10. An applicant shall PROVIDE VERIFICATION OF MEDICAID PARTICIPATION. AN
332 APPLICANT THAT IS A NEW PROVIDER NOT CURRENTLY ENROLLED IN MEDICAID SHALL
333 CERTIFY THAT PROOF OF MEDICAID PARTICIPATION WILL BE PROVIDED TO THE DEPARTMENT
334 WITHIN (6) MONTHS FROM THE OFFERING OF SERVICES IF A CON IS APPROVED.
335

336
337 **Section 11. PROJECT DELIVERY Requirements AND TERMS OF APPROVAL FOR ALL**
338 **APPLICANTS**
339

340 Sec. 11. An applicant shall AGREE THAT, IF APPROVED, the PET SCANNER SERVICES SHALL
341 BE DELIVERED IN COMPLIANCE WITH THE FOLLOWING TERMS OF APPROVAL.
342

343 (1) COMPLIANCE WITH THESE STANDARDS.
344

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

346 (a) A PET SCANNER SERVICE SHALL BE STAFFED SO THAT SCREENING OF REQUESTS
347 FOR AND INTERPRETATION OF PET PROCEDURES WILL BE CARRIED OUT BY A PHYSICIAN(S)
348 WITH APPROPRIATE TRAINING AND FAMILIARITY WITH THE APPROPRIATE DIAGNOSTIC USE
349 AND INTERPRETATION OF CROSS-SECTIONAL IMAGES OF THE ANATOMICAL REGION(S) TO BE
350 EXAMINED. FOR PURPOSES OF EVALUATING THIS SUBSECTION, THE DEPARTMENT SHALL
351 CONSIDER IT PRIMA FACIE EVIDENCE AS TO THE TRAINING OF THE PHYSICIAN(S) IF THE
352 PHYSICIAN IS BOARD CERTIFIED OR BOARD QUALIFIED IN NUCLEAR MEDICINE OR NUCLEAR
353 RADIOLOGY. HOWEVER, AN APPLICANT MAY SUBMIT, AND THE DEPARTMENT MAY ACCEPT,
354 OTHER EVIDENCE THAT THE PHYSICIAN(S) IS QUALIFIED TO OPERATE THE PET
355 SERVICE/SCANNER. THE PHYSICIAN(S) MUST BE ON-SITE OR AVAILABLE THROUGH
356 TELECOMMUNICATION CAPABILITIES TO PARTICIPATE IN THE SCREENING OF PATIENTS FOR
357 PET PROCEDURES AND TO PROVIDE OTHER CONSULTATION SERVICES.

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

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

366 (D) THE APPLICANT MAINTAINS THE SERVICES AND SPECIALTIES AS SET FOR THE IN
367 SECTION 3(1) THROUGH 3(4).
368

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

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

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

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

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

379 333.16221; MSA 14.15 (16221).

380

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

382 (A) THE PET SCANNERS SHALL BE OPERATING AT AN AVERAGE OF 500 PET SCANS PER
383 SCANNER DURING THE SECOND 12 MONTHS OF OPERATIONS, AND ANNUALLY THEREAFTER.
384 THIS REQUIREMENT SHALL BE WAIVED DURING REVIEW OF APPLICATIONS UNDER SECTION
385 4(1), IF APPLICABLE.

386 (B) THE PET SCANNER SERVICE SHALL PARTICIPATE IN A DATA COLLECTION SYSTEM
387 ESTABLISHED AND ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE. THE DATA MAY
388 INCLUDE, BUT ARE NOT LIMITED TO, CLINICAL SCAN DATA, ANNUAL BUDGET AND COST
389 INFORMATION, OPERATING SCHEDULES, THROUGH-PUT SCHEDULES, DEMOGRAPHIC AND
390 DIAGNOSTIC INFORMATION, AND THE VOLUME OF CARE PROVIDED TO PATIENTS FROM ALL
391 PAYOR SOURCES. THE APPLICANT SHALL PROVIDE THE REQUIRED DATA ON A SEPARATE
392 BASIS FOR EACH SEPARATE AND DISTINCT SITE, PET SCANNER, OR PET SCANNER SERVICE
393 AS REQUIRED BY THE DEPARTMENT, IN A FORMAT ESTABLISHED BY THE DEPARTMENT. THE
394 DEPARTMENT MAY ELECT TO VERIFY THE DATA THROUGH ON-SITE REVIEW OF APPROPRIATE
395 RECORDS.

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

399

400 (5) COMPLIANCE WITH THE FOLLOWING DEDICATED RESEARCH PET SCANNER
401 REQUIREMENTS, IF APPLICABLE:

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

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

407

408 (6) COMPLIANCE WITH THE FOLLOWING DEDICATED PEDIATRIC PET SCANNER
409 REQUIREMENTS, IF APPLICABLE:

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

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

414

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

416 (A) (DEPARTMENT TO DEVELOP)

417

418 (8) COMPLIANCE WITH THE FOLLOWING MOBILE PET SCANNER REQUIREMENTS, IF
419 APPLICABLE:

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

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

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

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

433
434 (9) THE AGREEMENTS AND ASSURANCES REQUIRED BY THIS SECTION SHALL BE IN THE
435 FORM OF A CERTIFICATION AGREED TO BY THE APPLICANT OR ITS AUTHORIZED AGENT.
436

437 **Section 12. METHODOLOGY for COMPUTING THE PROJECTED PET DATA UNITS**
438

439 Sec. 12. An applicant BEING REVIEWED UNDER SECTION 4 SHALL APPLY THE
440 METHODOLOGY SET FORTH IN THIS SECTION IN COMPUTING THE PROJECTED NUMBER OF
441 PET DATA UNITS.
442

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

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

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

454 (C) MULTIPLY THE NUMBER RESULTING FROM THE CALCULATION IN SUBSECTION (1)(C)
455 BY 2.5, WHICH IS THE ESTIMATED NUMBER OF PET SCANS NEEDED FOR EACH PATIENT
456 REQUIRING A PET SCAN.
457

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

460 (a) MULTIPLY THE NUMBER OF BREAST CANCER CASES (SITE CODES C500-C509) BY
461 0.25, WHICH IS THE ESTIMATED PROBABILITY THAT A BREAST CANCER CASE WILL REQUIRE A
462 PET SCAN.

463 (b) MULTIPLY THE NUMBER RESULTING FROM THE CALCULATION IN SUBSECTION (2)(B)
464 BY 1.0, WHICH IS THE ESTIMATED NUMBER OF PET SCANS NEEDED FOR EACH PATIENT
465 REQUIRING A PET SCAN.
466

467 (3) MULTIPLY THE NUMBER OF DIAGNOSTIC CARDIAC CATHETERIZATION CASES
468 IDENTIFIED IN ACCORD WITH THE REQUIREMENTS OF SECTION 15 BY 0.1, WHICH IS THE
469 ESTIMATED PROBABILITY THAT A PATIENT HAVING A DIAGNOSTIC CARDIAC
470 CATHETERIZATION WILL REQUIRE A PET SCAN.
471

472 (4) MULTIPLY THE NUMBER OF INTRACTABLE EPILEPSY CASES (ICD-9-CM CODES 345.01,
473 345.11, 345.41, 345.51, 345.61, 345.71, 345.81, OR 345.91) IDENTIFIED IN ACCORD WITH THE
474 REQUIREMENTS OF SECTION 16 BY 1.0, WHICH IS THE ESTIMATED PROBABILITY THAT A
475 PATIENT HAVING AN INTRACTABLE EPILEPSY PROCEDURE WILL REQUIRE A PET SCAN.
476 MULTIPLY THE NUMBER RESULTING FROM THE CALCULATION IN SUBSECTION (3) BY 1.0,
477 WHICH IS THE ESTIMATED NUMBER OF PET SCANS NEEDED FOR EACH PATIENT REQUIRING A
478 PET SCAN.
479

480 (5) SUM THE NUMBERS RESULTING FROM THE CALCULATIONS IN SUBSECTIONS (1)
481 THROUGH (4) TO DETERMINE THE TOTAL NUMBER OF PROJECTED PET DATA UNITS.
482

483 (6) MULTIPLY THE RESULT CALCULATED IN SUBSECTION (5) ABOVE BY A FACTOR OF 3.0
484 IF THE APPLICANT IS PROPOSING TO SERVE ONLY PLANNING AREA 6 TO DETERMINE THE
485 TOTAL NUMBER OF PROJECTED PET DATA UNITS.
486

487 (7) MULTIPLY THE RESULT CALCULATED IN SUBSECTION (5) ABOVE BY A FACTOR OF 2.0
488 IF THE APPLICANT IS PROPOSING TO SERVE ONLY PLANNING AREA 5 TO DETERMINE THE
489 TOTAL NUMBER OF PROJECTED PET DATA UNITS.
490
491

492 **Section 13. COMMITMENT OF DIAGNOSIS-SPECIFIC NEW CANCER CASES**
493

494 Sec. 13. AN APPLICANT PROPOSING TO USE DIAGNOSIS-SPECIFIC NEW CANCER CASES
495 SHALL DEMONSTRATE ALL OF THE FOLLOWING:
496

497 (1) ONLY THOSE CANCER DIAGNOSES IDENTIFIED IN SECTION 12(1) AND 12(2) SHALL BE
498 INCLUDED.
499

500 (2) EACH ENTITY CONTRIBUTING DIAGNOSIS SPECIFIC NEW CANCER CASE DATA
501 PROVIDES, AS PART OF THE APPLICATION AT THE TIME IT IS SUBMITTED TO THE
502 DEPARTMENT, A SIGNED GOVERNING BODY RESOLUTION THAT IDENTIFIES THE NUMBER OF
503 DIAGNOSIS-SPECIFIC CANCER CASES BEING COMMITTED TO THE APPLICATION AND THAT
504 STATES NO CURRENT OR FUTURE DIAGNOSIS-SPECIFIC NEW CANCER CASE DATA WILL BE
505 USED IN SUPPORT OF ANY OTHER APPLICATION FOR A PET UNIT FOR A PERIOD OF FIVE (5)
506 YEARS FROM THE DATE OF START OF OPERATIONS OF THE APPROVED PET SCANNER
507 SERVICE FOR WHICH DATA ARE BEING COMMITTED. IF THE REQUIRED DOCUMENTATION FOR
508 THIS SUBSECTION IS NOT SUBMITTED WITH THE APPLICATION ON THE DESIGNATED
509 APPLICATION DATE, THE APPLICATION WILL BE DEEMED FILED ON THE FIRST APPLICABLE
510 DESIGNATED APPLICATION DATE AFTER ALL REQUIRED DOCUMENTATION IS RECEIVED BY
511 THE DEPARTMENT.

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

515 (B) FOR MOBILE PET SCANNER SERVICES, THE GEOGRAPHIC LOCATION OF EACH
516 ENTITY CONTRIBUTING DIAGNOSIS-SPECIFIC NEW CANCER CASE DATA IN THE PLANNING
517 AREA(S) FOR WHICH THE PROPOSED PET SERVICE CONTAINS A PROPOSED HOST SITE OR
518 WITHIN A 75-MILE RADIUS OF THE PROPOSED HOST SITE FOR RURAL AND MICROPOLITAN
519 STATISTICAL AREA COUNTIES OR 25-MILE RADIUS FOR METROPOLITAN STATISTICAL AREA
520 COUNTIES.

521 (C) NO ENTITY CONTRIBUTING DIAGNOSIS-SPECIFIC NEW CANCER CASE DATA HAS
522 PREVIOUSLY COMMITTED OR IS COMMITTING DATA TO ANOTHER SERVICE THAT IS LESS
523 THAN FIVE (5) YEARS FROM THE START OF OPERATIONS OF THAT SERVICE.
524

525 (2) NO ENTITY CURRENTLY OPERATING OR APPROVED TO OPERATE A PET SCANNER
526 SERVICE SHALL CONTRIBUTE DIAGNOSIS-SPECIFIC NEW CANCER CASES.
527

528 (3) THE DEPARTMENT MAY NOT CONSIDER A WITHDRAWAL OF DIAGNOSIS-SPECIFIC
529 NEW CANCER CASE DATA DURING THE 120-DAY APPLICATION REVIEW CYCLE FOLLOWING
530 THE DATE ON WHICH THE DEPARTMENT REVIEW OF THE APPLICATION COMMENCES OR
531 AFTER A PROPOSED DECISION TO APPROVE THE APPLICATION HAS BEEN ISSUED UNLESS
532 THE APPLICATION IS DENIED, WITHDRAWN, OR EXPIRED. THE WITHDRAWAL MUST BE
533 SUBMITTED TO THE DEPARTMENT IN THE FORM OF A GOVERNING BODY RESOLUTION THAT
534 CONTAINS THE SPECIFIC CON APPLICATION NUMBER TO WHICH THE DATA WERE ORIGINALLY
535 COMMITTED, THE LEGAL APPLICANT ENTITY, THE COMMITTING ENTITY, THE TYPE OF DATA,
536 THE DATE OF THE MEETING IN WHICH THE GOVERNING BODY AUTHORIZED THE WITHDRAWAL
537 OF THE DATA, THE GOVERNING BODY PRESIDENT'S SIGNATURE, AND THE DATE OF THE
538 SIGNATURE.
539

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

541
542 Sec. 14. AN APPLICANT REQUIRED TO DOCUMENT VOLUMES OF DIAGNOSIS-SPECIFIC
543 NEW CANCER CASES SHALL SUBMIT, AS PART OF ITS APPLICATION AT THE TIME IT IS
544 SUBMITTED TO THE DEPARTMENT, DOCUMENTATION FROM THE DIVISION FOR VITAL
545 RECORDS AND HEALTH STATISTICS VERIFYING THE NUMBER OF DIAGNOSIS-SPECIFIC NEW
546 CANCER CASES PROVIDED IN SUPPORT OF THE APPLICATION FOR THE MOST RECENT
547 CALENDAR YEAR FOR WHICH VERIFIABLE DATA ARE AVAILABLE FROM THE STATE
548 REGISTRAR. IF THE REQUIRED DOCUMENTATION FOR THIS SUBSECTION IS NOT SUBMITTED
549 WITH THE APPLICATION ON THE DESIGNATED APPLICATION DATE, THE APPLICATION WILL BE
550 DEEMED FILED ON THE FIRST APPLICABLE DESIGNATED APPLICATION DATE AFTER ALL
551 REQUIRED DOCUMENTATION IS RECEIVED BY THE DEPARTMENT. DIAGNOSIS-SPECIFIC NEW
552 CANCER CASE DATA SUPPORTING AN APPLICATION UNDER THESE STANDARDS SHALL BE
553 SUBMITTED TO THE DIVISION FOR VITAL RECORDS AND HEALTH STATISTICS USING A FORMAT
554 AND MEDIA SPECIFIED IN INSTRUCTIONS FROM THE DEPARTMENT OF COMMUNITY HEALTH.
555

556
557 **Section 15. COMMITMENT AND DOCUMENTATION OF DIAGNOSTIC CARDIAC**
558 **CATHETERIZATION DATA**

559
560 Sec. 15. AN APPLICANT PROPOSING TO USE DIAGNOSTIC CARDIAC CATHETERIZATION
561 DATA SHALL DEMONSTRATE ALL OF THE FOLLOWING:
562

563 (1) EACH ENTITY CONTRIBUTING DIAGNOSTIC CARDIAC CATHETERIZATION DATA
564 PROVIDES, AS PART OF THE APPLICATION AT THE TIME IT IS SUBMITTED TO THE
565 DEPARTMENT, A SIGNED GOVERNING BODY RESOLUTION THAT IDENTIFIES THE NUMBER OF
566 DIAGNOSTIC CARDIAC CATHETERIZATION CASES (SESSIONS) COMMITTED TO THE
567 APPLICATION AND THAT STATES NO CURRENT OR FUTURE DIAGNOSTIC CARDIAC
568 CATHETERIZATION DATA WILL BE USED IN SUPPORT OF ANY OTHER APPLICATION FOR A PET
569 UNIT FOR THE DURATION OF THE PET SERVICE FOR WHICH DATA ARE BEING COMMITTED
570 FOR A PERIOD OF FIVE (5) YEARS FROM THE DATE OF START OF OPERATIONS OF THE
571 APPROVED PET SERVICE FOR WHICH DATA ARE BEING COMMITTED. IF THE REQUIRED
572 DOCUMENTATION FOR THIS SUBSECTION IS NOT SUBMITTED WITH THE APPLICATION ON THE
573 DESIGNATED APPLICATION DATE, THE APPLICATION WILL BE DEEMED FILED ON THE FIRST
574 APPLICABLE DESIGNATED APPLICATION DATE AFTER ALL REQUIRED DOCUMENTATION IS
575 RECEIVED BY THE DEPARTMENT.

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

579 (B) FOR MOBILE PET SCANNER SERVICES, THE GEOGRAPHIC LOCATION OF EACH
580 ENTITY CONTRIBUTING DIAGNOSIS SPECIFIC NEW CANCER CASE DATA IN THE PLANNING
581 AREA(S) FOR WHICH THE PROPOSED PET SERVICE CONTAINS A PROPOSED HOST SITE OR
582 WITHIN A 75-MILE RADIUS OF THE PROPOSED HOST SITE FOR RURAL AND MICROPOLITAN
583 STATISTICAL AREA COUNTIES OR 25-MILE RADIUS FOR METROPOLITAN STATISTICAL AREA
584 COUNTIES.

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

588 (D) THE DIAGNOSTIC CARDIAC CATHETERIZATION CASE DATA IS FROM THE MOST
589 RECENTLY COMPLETED REPORT(S) OF THE ANNUAL SURVEY PRODUCED BY THE
590 DEPARTMENT, AND THE CONTRIBUTING ENTITY HAS CON APPROVAL TO PROVIDE
591 DIAGNOSTIC CARDIAC CATHETERIZATION SERVICES.
592

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

595
596 (3) THE DEPARTMENT MAY NOT CONSIDER A WITHDRAWAL OF DIAGNOSTIC CARDIAC
597 CATHETERIZATION CASE DATA DURING THE 120-DAY APPLICATION REVIEW CYCLE
598 FOLLOWING THE DATE ON WHICH THE DEPARTMENT REVIEW OF THE APPLICATION
599 COMMENCES OR AFTER A PROPOSED DECISION TO APPROVE THE APPLICATION HAS BEEN
600 DENIED UNLESS THE APPLICATION IS DENIED, WITHDRAWN, OR EXPIRED. THE WITHDRAWAL
601 MUST BE SUBMITTED TO THE DEPARTMENT IN THE FORM OF A GOVERNING BODY
602 RESOLUTION THAT CONTAINS THE SPECIFIC CON APPLICATION NUMBER TO WHICH THE DATA
603 WERE ORIGINALLY COMMITTED, THE LEGAL APPLICANT ENTITY, THE COMMITTING ENTITY,
604 THE TYPE OF DATA, THE DATE OF THE MEETING IN WHICH THE GOVERNING BODY
605 AUTHORIZED THE WITHDRAWAL OF THE DATA, THE GOVERNING BODY PRESIDENT'S
606 SIGNATURE, AND THE DATE OF THE SIGNATURE.
607

608 **Section 16. COMMITMENT AND DOCUMENTATION OF INTRACTABLE EPILEPSY DATA**
609

610 Sec. 16. AN APPLICANT PROPOSING TO USE INTRACTABLE EPILEPSY CASES SHALL
611 DEMONSTRATE ALL OF THE FOLLOWING:
612

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

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

628 (B) FOR MOBILE PET SCANNER SERVICES, THE GEOGRAPHIC LOCATION OF EACH
629 ENTITY CONTRIBUTING DIAGNOSIS SPECIFIC NEW CANCER CASE DATA IN THE PLANNING
630 AREA(S) FOR WHICH THE PROPOSED PET SCANNER SERVICE CONTAINS A PROPOSED HOST
631 SITE OR WITHIN A 75-MILE RADIUS OF THE PROPOSED HOST SITE FOR RURAL AND
632 MICROPOLITAN STATISTICAL AREA COUNTIES OR 25-MILE RADIUS FOR METROPOLITAN
633 STATISTICAL AREA COUNTIES.

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

637 (D) THE INTRACTABLE EPILEPSY CASE DATA IS FROM THE MOST RECENT MICHIGAN
638 INPATIENT DATA BASE (MIDB) AVAILABLE TO THE DEPARTMENT.
639

640 (2) NO ENTITY CURRENTLY OPERATING OR APPROVED TO OPERATE A SCANNER SHALL
641 CONTRIBUTE INTRACTABLE EPILEPSY CASE DATA.
642

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

649 APPLICATION NUMBER TO WHICH THE DATA WERE ORIGINALLY COMMITTED, THE LEGAL
650 APPLICANT ENTITY, THE COMMITTING ENTITY, THE TYPE OF DATA, THE DATE OF THE
651 MEETING IN WHICH THE GOVERNING BODY AUTHORIZED THE WITHDRAWAL OF THE DATA,
652 THE GOVERNING BODY PRESIDENT'S SIGNATURE, AND THE DATE OF THE SIGNATURE.
653

654 **Section 17. DEPARTMENT INVENTORY OF PET SCANNERS**
655

656 Sec. 17. THE DEPARTMENT SHALL MAINTAIN AND PUBLICLY POST ON ITS WEB SITE A LIST
657 OF PET SCANNER SERVICES ANNUALLY.
658

659 **Section 18. COMPARATIVE REVIEWS; EFFECT ON PRIOR PLANNING POLICIES**
660

661 Sec. 18. PROPOSED PROJECTS REVIEWED UNDER THESE STANDARDS SHALL NOT BE
662 SUBJECT TO COMPARATIVE REVIEW. THESE CON REVIEW STANDARDS SUPERSEDE AND
663 REPLACE THE CON STANDARDS FOR PET SCANNER SERVICES APPROVED BY THE CON
664 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:

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