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

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

Section 1. Applicability

Sec. 1. (1) These standards are requirements for the approval of the initiation, replacement, expansion, or acquisition of PET scanner services, and the delivery of these services for all projects approved and Certificates of Need issued under Part 222 of the Code that involve PET scanner services.

(2) PET is a covered clinical service for purposes of PURSUANT TO Part 222 of the Code. A PET scanner previously approved pursuant to Section 10 of these standards and recognized by the Department as a dedicated research PET scanner listed in the Department Inventory of PET Scanners, and now seeking approval to operate pursuant to sections 3, 4, or 5, shall be considered as a person requesting CON approval to initiate or expand, as applicable, a PET scanner service.

(3) PET SCANNER SERVICES ARE A COVERED CLINICAL SERVICE. The Department shall use sections 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 16, 17, 18, 19, 20, and 21, as applicable, THESE STANDARDS in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(4) The Department shall use sections 14 and 15, as applicable, in applying AND Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

(5) The Department shall use Section 13, as applicable, in applying Section 22215(1)(b) of the Code, being Section 333.22215(1)(b) of the Michigan Compiled Laws.

Section 2. Definitions

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

(a) "Accelerator" means an apparatus, such as a linear accelerator or cyclotron, for accelerating charged particles to high energies by means of electromagnetic fields.

(b) "Acquisition of an existing PET scanner" means obtaining possession or control of an existing PET scanner from an existing PET scanner service by contract, ownership, lease, or other comparable arrangement.

(c) "Acquisition of an existing PET scanner service" means obtaining possession or control of an existing PET service and its unit(s) by contract, ownership, lease, or other comparable arrangement.

(d) "Arterial sampling" means the insertion of an in-dwelling intra-arterial catheter for the withdrawal of arterial blood as part of a PET procedure.

(e) "Bed position" means the anatomical site being imaged. A change in bed position occurs when a different anatomical site is imaged and the scan requires the physical relocation of the patient relative to the PET scanner.

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

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

(h) "Cyclotron" means an apparatus for accelerating charged particles to high energies by means
of electromagnetic fields.

(i) "Dedicated pediatric PET scanner" means a PET scanner approved pursuant to Section 11 of these standards, recognized by the Department as a dedicated pediatric PET scanner listed in the Department Inventory of PET Scanners, and is a PET scanner upon which at least 70% of the PET procedures are performed on patients under 18 years of age.

(k) "Dedicated research PET scanner" means a PET scanner approved pursuant to Section 10 of these standards and recognized by the Department as a dedicated research PET scanner listed in the Department Inventory of PET Scanners. The Department shall modify the Department Inventory of PET Scanners as applicable.

(C) "Department" means the state agency known as the Michigan Department of Community Health (MDCH).

(m) "Department inventory of PET scanners" or "Department Inventory" means the list, maintained by the Department on a continuous basis, of: (i) the PET scanners operating pursuant to a valid CON issued under Part 222 or former Part 221; (ii) PET scanners that are not yet operational but have a valid CON issued under Part 222; (iii) proposed PET scanners under appeal from a final Department decision or pending a hearing from a proposed decision issued under Part 222 of the Code; and (iv) proposed PET scanners that are part of a completed application under Part 222 of the Code.

(n) "Dynamic PET scan" means a PET scan that is closely timed to the administration of a radiopharmaceutical in order to capture the perfusion of the tracer.

(D) "Existing PET scanner" means an CON-approved and 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 CON-approved and operational PET scanner service(s) used to provide PET 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.

(q) "Expand a fixed PET scanner service" means increasing the number of fixed PET scanners at the same geographic location of an existing fixed PET scanner service.

(r) "Expand a mobile PET scanner service" means the addition of a mobile PET scanner that will be operated by a central service coordinator in the same planning area in which the CSC is approved primarily to operate one or more mobile PET scanners as of the date an application is submitted to the Department.

(s) "FDG" means 2-(fluorine-18) fluoro-2-deoxy-D-glucose radiopharmaceuticals.

(F) "Health service area" or "HSA" means the groups of counties listed in Section 22APPENDIX 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.

(w) "Initiate a mobile PET host site" means the provision of PET services at a host site that has not received any approved mobile PET services within 12 months from the date an application is submitted to the Department. The term does not include the renewal of a lease for the mobile PET service(s).

(x) "Initiate a PET scanner service" means begin operation of a PET scanner service, either fixed or mobile, at a geographic location that does not offer (or has not offered within the last consecutive 12-month period) approved PET scanner services and is not listed on the Department Inventory of PET Scanners on the date on which an application is submitted to the Department.

(y) "Institutional review board" or "IRB" means an institutional review board as defined by Public Law 93-348 which is regulated by Title 45 CFR 46.

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

(aa) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

(bb) "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

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discharge records from all Michigan hospitals and Michigan residents discharged from hospitals in border states for a specific calendar year.

---(cc) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

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

---(eefL) "Mobile PET scanner network" means the route (i.e., all host sites) that the central service coordinator is authorized to serve under CON. The mobile PET unit shall operate under a contractual agreement for the provision of PET services on a regularly scheduled basis at each host site, with a minimum of one visit per year.

---(ff) "Out-state Michigan" means health service areas two (2) through eight (8).

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

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

---(iiiO) "PET data unit" means the result of the methodology as used in Section 1712.

---(jjP) "PET equivalent" means the number calculated in accordance with Section 16-17 for a single patient visit.

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

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

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

---(nnSIR) "PET scanner services" or "PET services" means either the CON-approved utilization of a PET unit(s) at one site in the case of a fixed PET service or at each host site in the case of a mobile PET service.

---(ooTU) "Planning area" means the health service area(s), as applicable, and identified in Section .

---(pp) "Radionuclide generator" means the source of radioactive material, other than an accelerator or nuclear reactor, used to produce radiopharmaceuticals.

---(qq) "Radiopharmaceutical" means a radioactive pharmaceutical used for diagnostic or therapeutic purposes.

---(rr) "Relocate a fixed PET scanner" means a change in the location of a fixed PET scanner(s) from the existing site to a different site within the relocation zone.

---(ss) "Relocate an existing fixed PET scanner service" means a change in the location of a fixed PET scanner service and its unit(s) from the existing site to a different site within the relocation zone.

---(tt) "Relocation zone" means a proposed site that is within a 10-mile radius of the existing fixed PET scanner service for a metropolitan statistical area county and a 25-mile radius of the existing fixed PET scanner service for a rural or micropolitan statistical area county, based upon documentation acceptable and verified by the Department.

---(uu) "Replace a PET scanner" means an equipment change, other than an upgrade, involving a PET scanner that results in that applicant operating the same number of PET scanners before and after project completion.

---(vv) "Rural county" means a county not located in a metropolitan statistical area or micropolitan statistical area as those terms are defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as...
"SPECT" means single photon emission computed tomography.

“Static PET scan” means any PET scan that is not dynamic.

“Tracer” means a radiopharmaceutical developed for use in PET scanner services which allows the quantification and/or qualitative images of chemistry, metabolism, and/or perfusion in vivo.

"Transmission scan" means transmission computed tomography using a sealed radioactive photon source or x-ray tube photon source applied to the attenuation correction of the emission scan data.

"Upgrade an existing PET scanner" means any equipment change that:

(i) does not involve a change in, or replacement of, the scanner;
(ii) does not result in an increase in the number of PET scanners;
(iii) does not result in a change in the type of PET scanner (e.g., changing a mobile PET scanner to a fixed PET scanner) or a change in manufacturer; and
(iv) involves a capital expenditure of less than $500,000 in any consecutive 24-month period.

The definitions in Part 222 shall apply to these standards.

Section 3. Requirements for approval for all fixed services and mobile host sites TO INITIATE A PET SCANNER SERVICE

Sec. 3. (1) An applicant proposing to initiate PET scanner services shall demonstrate the following services and medical specialties, as applicable to the proposed project:

(a) nuclear medicine services as documented by a certificate from the US Nuclear Regulatory Commission, as documented on the certificate issued by the Department of Environmental Quality,
(b) single photon emission computed tomography (SPECT) services,
(c) computed tomography (CT) scanning services,
(d) magnetic resonance imaging (MRI) services,
(e) cardiac catheterization services,
(f) open heart surgery,
(g) thoracic surgery,
(h) cardiology,
(i) oncology,
(j) radiation oncology,
(k) neurology,
(l) neurosurgery, and
(m) psychiatry.

(2) If the applicant does not provide any of the services listed in subsection (1) at the same site at which the proposed PET scanner service will be located, the applicant shall include in the application written contracts or agreements with a hospital(s) located within the same planning area or 25-mile radius of the proposed site for the services not provided at the proposed PET scanner service site.

(3) The applicant shall demonstrate the proposed site has an on-site source of radiopharmaceuticals.

(4) If the proposed PET scanner service does not involve an on-site source of radiopharmaceuticals, the applicant must provide in the application a written contract or
agreement that demonstrates that a reliable supply of radiopharmaceuticals will be available to the proposed PET scanner service.

(54) An applicant proposing to initiate a fixed PET scanner service with its first PET scanner shall project 2,600 PET data units or shall demonstrate all of the following:

(a) The applicant is currently a host site being served by one or more mobile PET scanner services.

(b) The applicant has performed:

(i) 1,700 PET equivalents in the most recent 12-month period verifiable by the department for a host site in a metropolitan statistical area county, or

(ii) 1,500 PET equivalents in the most recent 12-month period verifiable by the department for a host site in a rural or micropolitan statistical area county.

(c) The applicant agrees to cease operation as a host site and not become a host site for at least 12 months from the date the fixed PET scanner becomes operational.

(55) An applicant proposing to initiate a mobile PET scanner service with its first mobile PET scanner shall project 2,100 PET data units.

(a) Of the 2,100 PET data units, the applicant shall project a minimum of 360 PET data units within a 20-mile radius of each proposed host site for Planning Area 1, or 240 PET data units per host site for any other planning area, for the proposed service.

(b) The application for the mobile PET scanner service is accompanied by at least two host site applications.

(c) Each applicant provides a route schedule for the proposed mobile PET scanner service.

(d) The applicant provides a draft contract for services between the proposed host site and central service coordinator.

(56) An applicant proposing to initiate a host site on a proposed or existing mobile PET scanner service shall demonstrate the following:

(a) The applicant provides a proposed route schedule.

(b) The applicant provides a draft contract for services between the proposed host site and central service coordinator.

(c) The applicant has not initiated fixed PET scanner services under subsection 3(54) within the most recent 12-month period as of the date the application is submitted to the department.

(d) An applicant initiating a host site in HSA 8 on a mobile PET scanner service that operates predominantly outside of Michigan shall demonstrate 240 PET data units from Planning Area 6.

(57) An applicant proposing to initiate PET scanner services as an existing host site on a different mobile PET scanner service shall demonstrate the following:

(a) The applicant provides a proposed route schedule.

(b) The applicant provides a draft contract for services between the proposed host site and central service coordinator.

(c) 50 PET equivalents were performed in the most recent 12-month period verifiable by the department from an existing mobile PET scanner service at the for an existing host site.
Section 4. Requirements for approval for applicants proposing to initiate TO REPLACE AN EXISTING PET scanner service(S) OR PET SCANNER SERVICE

Sec. 4. REPLACING A PET SCANNER(S) MEANS A CHANGE IN THE SCANNER EQUIPMENT OR RELOCATION OF THE SERVICE TO A NEW SITE. AN UPGRADE TO SOFTWARE OR COMPONENTS OF AN EXISTING SCANNER DOES NOT CONSTITUTE REPLACEMENT OF A PET SCANNER. AN APPLICANT PROPOSING TO REPLACE AN EXISTING PET SCANNER(S) OR PET SCANNER SERVICE SHALL DEMONSTRATE THE FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT.(1) An applicant proposing to initiate a fixed PET scanner(S) service shall project an operating level of at least 2,600 PET data units for each proposed PET scanner based on the methodology used in Section 17.

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

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

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

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

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

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

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

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

(cB) The application is submitted to the Department prior to the provision of PET services on that network EXISTING FIXED PET SCANNER(S) PERFORMED 500 PET EQUIVALENTS PER FIXED SCANNER IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE DEPARTMENT.

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

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

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

(4) An applicant that meets all of the following requirements shall not be required to be in
compliance with subsection (1):

(a) The applicant is proposing to initiate a fixed PET scanner service.

(b) The applicant is currently a host site being served by one or more mobile PET scanners.

(c) The applicant has received, in aggregate, the following:

(i) At least 4,500 PET equivalents, for an applicant in a metropolitan statistical area county, during
the most recent 12-month period for which the Department has verifiable data.

(ii) At least 4,000 PET equivalents, for an applicant in a rural or micropolitan statistical area
county, during the most recent 12-month period for which the Department has verifiable data.

(d) The applicant shall install the fixed PET unit at the same site as the existing approved host site.

(e) The applicant shall cease operation as a host site and not become a host site for at least 12
months from the date the fixed PET scanner, including any temporary scanner used during the transition
from mobile to fixed, becomes operational.

Section 5. Requirements for approval for applicants proposing to expand a PET scanner service

Sec. 5. (1) An applicant proposing to expand a PET scanner service

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

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

(2) An applicant proposing to expand a mobile PET scanner(s) TO AN
EXISTING MOBILE PET SCANNER SERVICE (second, third, etc.) shall demonstrate the following:

(a) 2,000 PET EQUIVALENTS WERE PERFORMED PER EXISTING AND APPROVED MOBILE
PET SCANNER(S) IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE DEPARTMENT FOR AN APPLICANT IN A METROPOLITAN STATISTICAL AREA COUNTY, OR

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

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

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SCANNER(S)

For an applicant proposing to replace an existing fixed PET scanner service or mobile PET scanner service, the following requirements shall be met:

(1) An applicant proposing to replace an existing PET scanner service or scanner(s) means obtaining possession and control by contract, ownership, lease, or other comparable arrangement and renewal of lease for an existing scanner. The Department shall demonstrate that all of the applicant’s approved and operating PET scanners, whether fixed or mobile, have performed an average of at least 5,500 PET equivalents per scanner during the most recent 12-month period verifiable by the Department for which the Department has verifiable data for an applicant serving at least one existing host site in a metropolitan statistical area county, or

(b) 1,800 PET EQUIVALENTS WERE PERFORMED PER EXISTING AND APPROVED PET SCANNER(S) FOR AN APPLICANT SERVING ONLY HOST SITES IN RURAL OR MICROPOLITAN STATISTICAL AREA COUNTIES.

(3) An applicant proposing to add a fixed PET scanner to an existing fixed PET scanner service that also receives mobile PET scanner services shall demonstrate all of the following requirements shall not be required to be in compliance with subsection (1):

(a) The applicant is proposing currently a host site being served by one or more mobile PET scanner services.

(b) The applicant is currently a fixed PET scanner service has performed an average of at least 5,000 PET equivalents per fixed scanner service, subject to Section 4(3).

(c) The applicant has demonstrated the following: an average of 1,900 PET equivalents for the host site and each of the existing and approved fixed scanner in the most recent 12-month period verifiable by the Department for a host site in a metropolitan statistical area county, or

(ii) For an applicant in a metropolitan statistical area county, all of the applicant’s approved fixed PET scanners have performed an average of at least 5,500 PET equivalents per PET scanner during the most recent 12-month period for which the Department has verifiable data for a host site in a rural or micropolitan statistical area county.

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

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

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

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

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

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

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

Sec. 6. (1) An applicant proposing to replace an existing fixed PET SCANNER SERVICE AND ITS scanner(s) means obtaining possession and control by contract, ownership, lease, or other comparable arrangement and renewal of lease for an existing scanner. AN APPLICANT PROPOSING TO ACQUIRE a have performed an average of at least
4,500 PET scanner service equivalents shall demonstrate the following, as applicable to the proposed project per PET scanner during the most recent 12-month period for which the Department has verifiable data.

(21) For the first application proposing to replace an existing fixed, mobile, or host site PET scanner service, other than a renewal of lease, shall demonstrate that all of the applicant’s approved and operating mobile PET scanners on or after the effective date of standards, the existing mobile route have performed an average of at least 3,000 PET equivalents per PET scanner service and its scanner(s) shall not be required to be in compliance with the applicable volume requirements set forth in this section during the most recent 12-month period for which the Department has verifiable data.

(32) An exemption to subsections (1) and (2) may be made by the Department if an applicant demonstrates to the satisfaction of the Department, the following: Proposing to acquire an existing fixed or mobile PET scanner service shall demonstrate that the existing fixed or mobile scanner(s) performed an average of 500 PET equivalents per scanner in the most recent 12-month period verifiable by the Department.

(a3) The existing PET scanner is technologically incapable of performing the applicable minimum number of PET equivalents. An applicant proposing to acquire an existing host site under this subsection shall provide documentation to demonstrate that the Department, from a person or an organization with recognized professional expertise regarding that type of equipment, other than the applicant or a representative of a manufacturer or vendor of that type of equipment, indicating the number of PET equivalents the existing host site equipment is technologically capable of performing. The applicant also shall provide documentation, satisfactory to the Department, that the number of PET equivalents performed during the most recent 12-month period, for which verifiable by the Department has verifiable data, was the number the equipment is technologically capable of performing.

(4) An applicant proposing to renew a lease for an existing fixed or mobile PET scanner, whether fixed or mobile, shall demonstrate that the renewal of the lease is more cost effective than replacing the scanner(s).

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

(b) either of the following:

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

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

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

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

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

(6) In the case of a fixed PET scanner, the proposed PET scanner will be located at the same site as the applicant’s existing fixed PET scanner to be replaced. If the proposed scanner will not be located at the same site, the applicant must meet the requirements to relocate a PET scanner at the proposed site, in accordance with Section 9.
Section 7. Requirements for approval for applicants proposing to acquire an existing A DEDICATED RESEARCH FIXED PET scanner

Sec. 7. An applicant proposing to acquire ADD an existing FIXED PET scanner, whether fixed or mobile, scanner TO AN EXISTING PET SCANNER SERVICE FOR EXCLUSIVE RESEARCH USE shall demonstrate that it meets all of the following THE FOLLOWING:

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

(a2) The project is limited solely to the acquisition of an existing DEDICATED RESEARCH PET scanner SHALL OPERATE UNDER A PROTOCOL APPROVED BY THE APPLICANT’S INSTITUTIONAL REVIEW BOARD, AS DEFINED BY PUBLIC LAW 93-348 AND REGULATED BY TITLE 45 CFR 46.

(b3) The project APPLICANT HAS ACCESS TO A CYCLOTRON FOR ACCELERATING CHARGED PARTICLES TO HIGH ENERGIES BY MEANS will not change the number of PET scanners listed on the Department Inventory of PET Scanners ELECTROMAGNETIC FIELDS.

(c4) The project PROPOSED SITE CAN HAVE NO MORE THAN THREE DEDICATED RESEARCH FIXED will not result in the replacement of the PET scanners APPROVED UNDER THIS to be acquired unless the applicant demonstrates that the requirements of Section 6 also have been met.

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

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

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

Sec. 8. An applicant proposing to acquire INITIATE an existing A PET scanner service, whether OR ADD A fixed PET SCANNER TO EXPAND AN EXISTING PET SCANNER SERVICE, FOR DEDICATED PEDIATRIC PET USE , or mobile, shall demonstrate that it meets all of the DEMONSTRATE THE following:

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

(b2) The project APPLICANT SHALL DEMONSTRATE will not change the number EXISTING SITE of Pet_scanners PROVIDED listed on the FOLLOWING FOR THE MOST RECENT CALENDAR YEAR OR A CONTINUOUS 12-MONTH PERIOD AT THE TIME THE APPLICATION IS SUBMITTED TO THE Department Inventory of PET Scanners:

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

(dB) AT LEAST 5,000 PEDIATRIC (< 18 YEARS OLD) SURGERIES. All PET scanners to be acquired are listed on the Department Inventory of PET Scanners on the date the application is submitted to the Department AND
(eC) AT LEAST 50 NEW PEDIATRIC CANCER CASES ON ITS CANCER REGISTRY. The applicant agrees to operate the PET scanner service in accordance with all applicable project delivery requirements set forth in Section 14.

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

(A) RADIOLOGY (AT LEAST TWO STAFF MEMBERS)
(B) ANESTHESIOLOGY
(C) CARDIOLOGY
(D) CRITICAL CARE
(E) GASTROENTEROLOGY
(F) HEMATOLOGY/ONCOLOGY
(G) NEUROLOGY
(H) NEUROSURGERY
(I) ORTHOPEDIC SURGERY
(J) PATHOLOGY
(K) PULMONOLOGY
(L) SURGERY
(M) NEONATOLOGY

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

(A) BONE MARROW TRANSPLANT PROGRAM
(B) SEDATION PROGRAM
(C) OPEN HEART PROGRAM

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

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

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

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 a 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.

(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.

(1) An applicant proposing to relocate an existing fixed PET service and all its existing unit(s) shall demonstrate that it meets all of the following:

(a) The service and all its existing units to be relocated are fixed PET scanners.

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

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

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

(e) The proposed project will not result in the replacement of the PET scanner(s) of the service to be relocated unless the applicant demonstrates that the requirements of Section 6, as applicable, have also been met.
The applicant agrees to operate the PET service and all its units in accordance with all applicable project delivery requirements set forth in Section 15 of these standards.

An applicant proposing to relocate a PET scanner of an existing PET service shall demonstrate that it meets all of the following:

(a) The PET scanner to be relocated is a fixed PET scanner.
(b) The existing fixed PET service from which the PET scanner is to be relocated has been in operation for at least 36 months as of the date of the application submitted to the Department.
(c) The proposed new site for the PET scanner to be relocated is in the relocation zone.
(d) The proposed project will not result in the replacement of the PET scanner(s) to be relocated unless the applicant demonstrates that the requirements of Section 6, as applicable, have also been met.
(e) The applicant agrees to operate the PET scanner at the proposed site in accordance with all applicable project delivery requirements set forth in Section 15.

Section 10. Requirements for approval for applicants proposing a dedicated research fixed PET scanner MEDICAID PARTICIPATION

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

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

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

(a1) The applicant shall experience at least 7,000 pediatric (< 18 years old) discharges, excluding normal newborns, in the most recent year of operation. COMPLIANCE WITH THESE STANDARDS.
(b2) The applicant shall experience at least 5,000 pediatric (< 18 years old) surgeries in the most recent year of operation. COMPLIANCE WITH THE FOLLOWING QUALITY ASSURANCE REQUIREMENTS:
(Ca) The applicant shall experience at least 50 new pediatric cancer cases on its cancer registry in the most recent year of operation. A PET SCANNER SERVICE SHALL BE STAFFED SO THAT SCREENING OF REQUESTS FOR AND INTERPRETATION OF PET PROCEDURES WILL BE CARRIED OUT BY A PHYSICIAN(S) WITH APPROPRIATE TRAINING AND FAMILIARITY WITH THE APPROPRIATE DIAGNOSTIC USE AND INTERPRETATION OF CROSS-SECTIONAL IMAGES OF THE ANATOMICAL REGION(S) TO BE EXAMINED. FOR PURPOSES OF EVALUATING THIS SUBSECTION, THE DEPARTMENT SHALL CONSIDER IT PRIMA FACIE EVIDENCE AS TO THE TRAINING OF THE PHYSICIAN(S) IF THE PHYSICIAN IS BOARD CERTIFIED OR BOARD QUALIFIED IN NUCLEAR MEDICINE OR NUCLEAR RADIOLOGY. HOWEVER, AN APPLICANT MAY SUBMIT, AND THE DEPARTMENT MAY ACCEPT, OTHER EVIDENCE THAT THE PHYSICIAN(S) IS QUALIFIED TO OPERATE THE PET SERVICE/SCANNER. THE PHYSICIAN(S) MUST BE ON-SITE OR AVAILABLE THROUGH TELECOMMUNICATION CAPABILITIES TO PARTICIPATE IN THE SCREENING OF PATIENTS FOR PET PROCEDURES AND TO PROVIDE OTHER CONSULTATION SERVICES.
(dB) The applicant shall have an active medical staff at the time the application is submitted to the Department that PET SCANNER SERVICE SHALL includes, but is not limited to, physicians who are...
fellowship trained in the following pediatric specialties:  
PERSONNEL, EMPLOYED DIRECTLY OR ON A
CONTRACTUAL BASIS: A TECHNOLOGIST WITH TRAINING IN PET SCANNING AND A PHYSICIST.
THE PHYSICIST MUST BE BOARD CERTIFIED OR ELIGIBLE FOR CERTIFICATION BY THE
AMERICAN BOARD OF RADIOLOGY OR AN EQUIVALENT ORGANIZATION.

(i) pediatric radiology (at least two staff members)
(ii) pediatric anesthesiology
(iii) pediatric cardiology
(iv) pediatric critical care
(v) pediatric gastroenterology
(vi) pediatric hematology/oncology
(vii) pediatric neurology
(viii) pediatric neurosurgery
(ix) pediatric orthopedic surgery
(x) pediatric pathology
(xi) pediatric pulmonology
(xii) pediatric surgery
(xiii) neonatology

The applicant shall have in operation the following pediatric specialty programs at the time the
application is submitted to PET SCANNER SERVICE SHALL HAVE A PHYSICIAN ON-SITE OR
IMMEDIATELY AVAILABLE TO THE PET SCANNER SERVICE AT ALL TIMES WHEN PATIENTS ARE
UNDERGOING PET PROCEDURES, the Department:

(i) pediatric bone marrow transplant program
(ii) established pediatric sedation program
(iii) pediatric open heart program

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

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

(A) The dedicated pediatric PET scanner SERVICE shall be excluded.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 12. Additional requirements

METHODOLOGY for mobile COMPUTING THE PROJECTED
Sec. 12. (1) An applicant proposing to begin operation of a mobile PET service shall demonstrate all of the following:

A separate CON application has been submitted by the central service coordinator and each proposed host site. Identify the number of diagnosis-specific new cancer cases documented in accordance with the requirements of Section 13.

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

(b) A proposed regular route schedule, the procedures for handling emergency situations, and copies of all proposed contracts related to the mobile PET service have been included in the CON application. Multiply the number resulting from the calculation in subsection (1)(b) by 1.0, which is the estimated number of PET scans needed for each patient requiring a PET scan.

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

(2) An applicant proposing to become a host site on an existing mobile PET scanner service shall demonstrate that it meets all of the following:

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

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

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

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

(5) Sum the numbers resulting from the calculations in subsections (1)
THROUGH (4) TO DETERMINE THE TOTAL NUMBER OF PROJECTED PET DATA UNITS.

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

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

Section 13. Requirements for approval for all applicants

COMMITMENT OF DIAGNOSIS-SPECIFIC NEW CANCER CASES

Sec. 13. An applicant shall provide verification of Medicaid participation at the time the application is submitted to the Department. If the required documentation is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

An applicant proposing to use diagnosis-specific new cancer cases shall demonstrate all of the following:

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

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

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

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

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

(3) NO ENTITY CURRENTLY OPERATING OR APPROVED TO OPERATE A PET Scanner SERVICE SHALL CONTRIBUTE DIAGNOSIS-SPECIFIC NEW CANCER CASE DATA DURING THE 120-DAY APPLICATION REVIEW CYCLE FOLLOWING
Section 14. Project delivery requirements and terms of approval for all applicants

DOCUMENTATION OF DIAGNOSIS-SPECIFIC NEW CANCER CASE DATA

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

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

(a) Compliance with these standards.

(b) Compliance with applicable safety and operating standards.

(c) Compliance with the following quality assurance standards:

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

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

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

(iv) An applicant shall establish a PET service team. A PET service team shall be responsible for
(A) developing criteria for procedure performance, (B) developing protocols for procedure performance,
(C) developing a clinical data base for utilization review and quality assurance purposes, (D) transmitting
requested data to the Department, (E) screening of patients to assure appropriate utilization of the PET
scanner, (F) taking and interpreting scans, and (G) coordinating PET activity at a PET host site(s) for a
mobile pet service(s)/scanner(s).
(v) At a minimum, the PET service team shall include the following personnel, employed directly by the applicant or on a contractual basis: (A) a team leader, (B) technologists with training in PET scanning, (C) radiation safety personnel, and (D) a physicist(s). The physicist(s) must be board certified or eligible for certification by the American Board of Radiology or an equivalent organization. Other personnel that may be appropriate members of the PET service team, depending on the type of operation and PET procedures performed, include but are not limited to nurses, computer technicians, radiochemists, radiochemistry technicians, radio-pharmacists, and instrument maintenance technicians. If the team leader is not a physician, the PET service team also shall include a physician with appropriate training and familiarity with the appropriate diagnostic use and interpretation of cross-sectional images of the anatomical region(s) to be examined.

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

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

(viii) Fixed and mobile PET scanner units shall be operating at a minimum average annual level of utilization during the second twelve months of operation, and annually thereafter, of 1,500 PET equivalents per unit.

(d) Compliance with the following requirements:

(i) The applicant shall accept referrals for PET scanner services from all appropriately licensed practitioners.

(ii) The applicant, to assure that the PET scanner services will be utilized by all segments of the Michigan population, shall (A) not deny PET scanner services to any individual based on ability to pay or source of payment, (B) provide PET scanning services to any individual based on the clinical indications of need for the service, and (C) maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

Compliance with selective contracting requirements shall not be construed as a violation of this term.

(iii) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but are not limited to annual budget and cost information, operating schedules, through-put schedules, demographic and diagnostic information, the volume of care provided to patients from all payor sources, and other data requested by the Department or its designee. The applicant shall provide the required data on a separate basis for each separate and distinct site, PET scanner, or PET service as required by the Department, in a format established by the Department, and in a mutually agreed upon media. The Department may elect to verify the data through site review of appropriate records. If the applicant intends to include research PET equivalents conducted by a PET scanner other than a dedicated research PET scanner in its utilization statistics, the applicant shall submit to the Department a copy of the research protocol with evidence of approval by the Institutional Review Board. The applicant shall submit this at the time the applicant intends to include research procedures in its utilization statistics. The applicant shall separately report to the Department any PET equivalents conducted by a dedicated research PET scanner.

(iv) PET equipment to be replaced shall be removed from service on or before beginning operation of the replacement equipment, including the use of temporary scanners as part of the replacement project.

(v) The applicant shall provide the Department with a notice stating the first date on which the PET scanner became operational, and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

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

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

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

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

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

Section 15. Project delivery requirements and additional terms of approval for applicants involving mobile PET services

COMMITMENT AND DOCUMENTATION OF DIAGNOSTIC CARDIAC CATHETERIZATION DATA

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

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

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

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

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

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

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

(3) THE DEPARTMENT MAY NOT CONSIDER A WITHDRAWAL OF DIAGNOSTIC CARDIAC
CATHETERIZATION CASE DATA DURING THE 120-DAY APPLICATION REVIEW CYCLE

FOLLOWING THE DATE ON WHICH THE DEPARTMENT REVIEW OF THE APPLICATION

COMMENCES OR AFTER A PROPOSED DECISION TO APPROVE THE APPLICATION HAS BEEN

DENIED UNLESS THE APPLICATION IS DENIED, WITHDRAWN, OR EXPIRED. THE WITHDRAWAL

MUST BE SUBMITTED TO THE DEPARTMENT IN THE FORM OF A GOVERNING BODY

RESOLUTION THAT CONTAINS THE SPECIFIC CON APPLICATION NUMBER TO WHICH THE DATA

WERE ORIGINALLY COMMITTED, THE LEGAL APPLICANT ENTITY, THE COMMITTING ENTITY,

THE TYPE OF DATA, THE DATE OF THE MEETING IN WHICH THE GOVERNING BODY

AUTHORIZED THE WITHDRAWAL OF THE DATA, THE GOVERNING BODY PRESIDENT’S

SIGNATURE, AND THE DATE OF THE SIGNATURE.

-1- In addition to the provisions of Section 14, an applicant for a mobile PET services shall agree that the

services provided by the mobile PET scanner(s) shall be delivered in compliance with the following terms of

CON approval:

(a) The central service coordinator for a mobile PET service, with an approved CON, shall notify

the administrative unit of the Department of Community Health responsible for administering the CON

program 30 days prior to dropping an existing host site.

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

nuclear medicine or nuclear radiology on its medical staff. The physician(s) shall be responsible for (i)

establishing patient examination and infusion protocol and (ii) providing for the interpretation of scans

performed by the mobile PET service/scanner.

(c) Each mobile PET scanner service shall have an operations committee with members

representing each host site, the central service coordinator, and the medical director. This committee

shall oversee the effective and efficient use of the PET scanner, establish the regular route schedule,

identify the process by which changes are to be made to the schedule, develop procedures for handling

emergency situations, and review the ongoing operations of the mobile PET scanner service on at least a

quarterly basis.

(d) The central service coordinator shall arrange for emergency repair services to be available 24

hours each day for the mobile PET scanner equipment as well as the vehicle transporting the equipment.

In addition, to preserve image quality and minimize PET scanner downtime, calibration checks shall be

performed on the PET scanner unit at least once each work day or in accordance with the manufacturer’s

requirements. Routine maintenance services shall be provided on a regularly scheduled basis, at least

once a week or in accordance with the manufacturer’s requirements, during hours not normally used for

patient procedures.

(e) Each host site shall provide a properly prepared parking pad, for the mobile PET scanner unit,
of sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for

patients to enter the vehicle without going outside (such as an enclosed canopy or an enclosed corridor).

Each host site also must provide the capability for processing the film and maintaining the confidentiality

of patient records. A communication system must be provided between the mobile vehicle and each host

site to provide for immediate notification of emergency medical situations.

(f) A mobile PET scanner service shall operate under a contractual agreement that includes the

provision of PET services at which changes are to be made to the schedule, with an approved

operations committee under the terms of Section 14(1)(d)(iii).

(g) The volume of utilization at each host site shall be reported to the Department by the central

service coordinator under the terms of Section 14(1)(d)(iii).

(2) The agreements and assurances required by this section shall be in the form of a certification

authorized by the owner or the governing body of the applicant or its authorized agent.

Section 16. Determination of PET equivalents

COMMITMENT AND DOCUMENTATION OF

INTRACTABLE EPILEPSY DATA

Sec. 16. AN APPLICANT PROPOSING TO USE INTRACTABLE EPILEPSY CASES SHALL

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

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

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

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

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

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

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

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

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

(i) A single patient visit

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

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

1 tracer injection = 0
2 tracer injections = 0.3
3 tracer injections = 0.6

(iv) Dynamic scan(s) performed during a single patient visit.

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

1 bed position = 0
2 bed positions = 0.2 for each additional position

(vi) Arterial sampling performed during a single patient visit.

(vii) Transmission scan = 1 per bed position

Total PET Equivalents for a Single Patient Visit

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

patient < 5 years of age multiply by 4.0
patient > 5 ≤ 10 years of age multiply by 3.0
patient > 10 ≤ 17 years of age multiply by 2.0

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

(d) The PET equivalents for each patient visit determined pursuant to subdivisions (a), (b) and (c) shall be summed to determine the total PET equivalents for the time period specified in the applicable section(s) of these standards.

SECTION 17. METHODOLOGY FOR COMPUTING PET EQUIVALENTS

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

<table>
<thead>
<tr>
<th>Scan Category</th>
<th>Weight</th>
</tr>
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<tr>
<td>Simple</td>
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</tr>
<tr>
<td>Standard</td>
<td>1.0</td>
</tr>
<tr>
<td>Complex</td>
<td>1.5</td>
</tr>
</tbody>
</table>

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.

Section 17.8. Methodology for computing the projected number of PET data units

DEPARTMENT INVENTORY OF PET SCANNERS

Sec. 17.8. THE DEPARTMENT SHALL MAINTAIN AND PUBLICLY POST ON ITS WEB SITE A LIST OF PET SCANNER SERVICES ANNUALLY.

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

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

(b) Combine the number of cancer cases for lung (site codes C340-C349), esophagus (site codes
Section 1819. Commitment of diagnosis specific new cancer cases COMPARATIVE REVIEWS; EFFECT ON PRIOR PLANNING POLICIES

Sec. 1819. 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.

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

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

(b) Each entity contributing diagnosis specific new cancer case data provides, as part of the application at the time it is submitted to the Department, a signed governing body resolution that identifies the number of diagnosis specific cancer cases being committed to the application and that states no current or future diagnosis specific new cancer case data will be used in support of any other application for a PET unit for a period of five (5) years from the date of start of operations of the approved PET service for which data are being committed. If the required documentation for this subsection is not

CON Review Standards for Positron Emission Tomography Scanner Services CON-227
For CON Commission Final Action on September 22, 2011
submitted with the application on the designated application date, the application will be deemed filed on
the first applicable designated application date after all required documentation is received by the
Department.

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

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

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

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

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

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

Section 19. Documentation of diagnosis specific new cancer case data

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

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

Section 20. Commitment and documentation of diagnostic cardiac catheterization data

(1) An applicant proposing to use diagnostic cardiac catheterization data shall demonstrate
all of the following:

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

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

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

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

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

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

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

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

Section 21. Commitment and documentation of intractable epilepsy data

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

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

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

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

— (d) No entity contributing intractable epilepsy case data has previously committed or is committing data to another service that is less than five (5) years from the start of operations of that service and is listed on the "Department Inventory of PET Scanners."

— (e) The intractable epilepsy case data is from the most recent Michigan Inpatient Data Base (MIDB) available to the Department.
(2) No entity currently operating or approved to operate a scanner, whether fixed or mobile, listed on the "Department Inventory of Pet Scanners" shall contribute intractable epilepsy case data.

(3)(a) The Department may not consider a withdrawal of intractable epilepsy case data during the 120-day application review cycle following the date on which the Department review of the application commences or after a proposed decision to approve the application unless the application is denied, withdrawn, or expired.

(b) The withdrawal must be submitted to the Department in the form of a governing body resolution that contains the specific CON application number to which the data were originally committed, the legal applicant entity, the committing entity, the type of data, the date of the meeting in which the governing body authorized the withdrawal of the data, the governing body president’s signature, and the date of the signature.
## Section 22. Health Service Areas

### APPENDIX A

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

<table>
<thead>
<tr>
<th>HEALTH SERVICE AREA</th>
<th>COUNTIES</th>
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<tbody>
<tr>
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<td>Wayne</td>
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<td>Cheboygan  Manistee  Wexford</td>
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<td>Baraga  Houghton  Marquette</td>
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<tr>
<td></td>
<td>Chippewa  Iron  Menominee</td>
</tr>
<tr>
<td></td>
<td>Delta  Keweenaw  Ontonagon</td>
</tr>
<tr>
<td></td>
<td>Dickinson  Luce  Schoolcraft</td>
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### Appendix B: Counties by Health Service Areas

#### Planning Areas

**Planning Area 1**

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<thead>
<tr>
<th>HSA 1</th>
<th>Counties</th>
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<tbody>
<tr>
<td>Livingston</td>
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<td>Macomb</td>
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**Planning Area 2**

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**Planning Area 6**

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<tr>
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<tr>
<td>Cheboygan</td>
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</tr>
<tr>
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<td>Manistee</td>
<td>Sanilac</td>
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<td>Mason</td>
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<td>Gladwin</td>
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<tr>
<td>Gogebic</td>
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### Micropolitan statistical area Michigan counties are as follows:

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<tr>
<th>County</th>
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<th>County</th>
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</thead>
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<td>Mecosta</td>
</tr>
<tr>
<td>Alpena</td>
<td>Houghton</td>
<td>Menominee</td>
</tr>
<tr>
<td>Benzie</td>
<td>Isabella</td>
<td>Midland</td>
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<tr>
<td>Branch</td>
<td>Kalkaska</td>
<td>Missaukee</td>
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<tr>
<td>Chippewa</td>
<td>Keweenaw</td>
<td>St. Joseph</td>
</tr>
<tr>
<td>Delta</td>
<td>Leelanau</td>
<td>Shiawassee</td>
</tr>
<tr>
<td>Dickinson</td>
<td>Lenawee</td>
<td>Wexford</td>
</tr>
<tr>
<td>Grand Traverse</td>
<td>Marquette</td>
<td></td>
</tr>
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<table>
<thead>
<tr>
<th>County</th>
<th>County</th>
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</thead>
<tbody>
<tr>
<td>Barry</td>
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<td>Newaygo</td>
</tr>
<tr>
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<td>Jackson</td>
<td>Oakland</td>
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<tr>
<td>Berrien</td>
<td>Kalamazoo</td>
<td>Ottawa</td>
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<td>Calhoun</td>
<td>Kent</td>
<td>Saginaw</td>
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<td>St. Clair</td>
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<td>Van Buren</td>
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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