MICHIGAN DEPARTMENT OF ~~COMMUNITY HEALTH~~ HEALTH AND HUMAN SERVICES

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

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

Section 1. Applicability

Sec. 1. These standards are requirements for the approval of the initiation, replacement, expansion, or acquisition of PET scanner services, and the delivery of these services under Part 222 of the Code. Pursuant to Part 222 of the Code PET scanner services are a covered clinical service. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

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

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

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

(c) “Comprehensive fixed PET referral service” means a PET scanner service that is located in the same or in a contiguous building as a fixed cyclotron-equipped radiopharmacy capable of producing a broad spectrum of radioisotopes, including those with short half-lives, and includes at least one of the following FDA-approved PET scanners:

(i) fixed whole-body PET/CT,

(ii) fixed digital PET/CT scanner, or

(iii) fixed PET/MRI scanner hybrid.

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

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

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

(g) “Fixed cyclotron” means a fixed particle accelerator used for the production of multiple medical isotopes.

(h) “Fixed digital PET/CT scanner” means a fixed PET/CT hybrid with silicon photomultipliers (SIPM) with digital readout for high-resolution image reconstruction.

(i) “Fixed whole body PET/CT scanner” means a fixed PET/CT scanner with an axial field of view of >130cm.

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

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

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

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

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

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

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

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

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

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

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

(u) "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/computed tomography (CT) and FDA-approved PET/magnetic resonance imagining (MRI) scanner hybrids. If the PET/CT scanner hybrid will be used for CT scans only in conjunction with the PET scan, then no separate CON is required for that CT use. If the FDA-approved PET/MRI scanner hybrid will be used for MRI scans only in conjunction with the PET scan, then no separate CON is required for that MRI 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.

(v) "PET scanner services" or "PET services" means either the 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.

(w) "SPECT" means single photon emission computed tomography.

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

Section 3. Requirements to initiate a PET scanner service

Sec. 3. An applicant proposing to initiate PET scanner services shall demonstrate the following, as applicable to the proposed project.

(1) The applicant shall demonstrate the proposed site provides the following services and specialties:

(a) nuclear medicine services as documented by a certificate from the US Nuclear Regulatory Commission,

(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 proposed site does not provide any of the services listed in subsection (1) on-site, the applicant shall provide 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.

(3) The applicant shall demonstrate the proposed site has an on-site source of radiopharmaceuticals. If the proposed site does not provide an on-site source of radiopharmaceuticals,

the applicant shall provide a written contract or agreement that demonstrates a reliable supply of radiopharmaceuticals.

(4) 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) 1,500 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) 1,325 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 shall install the fixed PET unit at the same site as the existing host site or within a 10-mile radius of the existing host site for a metropolitan statistical area county or a 25-mile radius for a rural or micropolitan statistical area.

(d) 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. This requirement shall not apply if the applicant is installing an FDA-approved PET/MRI scanner hybrid.

(5) 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.

(6) 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(4) 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.

(7) 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 existing host site.

Section 4. Requirements to replace an existing PET scanner(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 replace a PET scanner(s) shall demonstrate each of the following:

(a) The replacement scanner(s) is the same type (fixed or mobile) as the scanner(s) to be replaced.

(b) The scanner(s) to be replaced is fully depreciated according to generally accepted accounting principles or either of the following:

(i) The existing scanner(s) poses a threat to the safety of the patients.

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

(c) 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).

(2) An applicant proposing to replace a fixed PET scanner service to a new site shall demonstrate the following:

(a) The 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.

(b) The existing fixed PET scanner(s) performed 500 PET equivalents per fixed scanner in the most recent 12-month period verifiable by the Department.

(c) 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.

Section 5. Requirements to expand a PET scanner service

Sec. 5. An applicant proposing to expand a PET scanner service shall demonstrate the following, as applicable to the proposed project. This section does not apply to dedicated research, dedicated pediatric, or positron emission mammography (PEM) scanners.

(1) An applicant proposing to add a fixed PET scanner(s) to an existing fixed PET scanner service shall demonstrate the following:

(a) 1,900 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 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.

(c) The additional PET scanner(s) shall be located at the same site.

(2) An applicant proposing to add a mobile PET scanner(s) to an existing mobile PET scanner service shall demonstrate the following:

(a) 2,000 PET equivalents were performed per existing and approved mobile scanner(s) in the most recent 12-month period verifiable by the Department 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 scanner(s) in the most recent 12-month period verifiable by the Department 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 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) An average of 1,900 pet equivalents for the host site and each of the existing and approved fixed scanners in the most recent 12-month period verifiable by the Department for a host site in a metropolitan statistical area county, or

(ii) An average of 1,700 PET equivalents for the host site and each of the existing and approved fixed scanners 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 scanner becomes operational.

Section 6. Requirements to acquire a PET scanner service or scanner(s)

Sec. 6. Acquiring a PET scanner service and its scanner(s) means obtaining possession and control by contract, ownership, lease, or other comparable arrangement and renewal of lease for an existing fixed or mobile PET scanner. An applicant proposing to acquire a PET scanner service shall demonstrate the following, as applicable to the proposed project.

(1) For the first application proposing to acquire an existing fixed, mobile, or host site PET scanner service, other than a renewal of lease, on or after November 21, 2011, the existing PET service and its scanner(s) shall not be required to be in compliance with the applicable volume requirements set forth in this section. The PET scanner service shall be operating at the applicable volumes set forth in the project delivery requirements in the second 12 months of operation of the service by the applicant and annually thereafter.

(2) For any application proposing to acquire an existing PET scanner service, except the first application approved pursuant to subsection (1), an applicant shall be required to document that the PET scanner service to be acquired is operating in compliance with the volume requirements set forth in Section 11 of these standards applicable to an existing PET scanner service on the date the application is submitted to the Department.

(3) An applicant 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.

(4) An applicant proposing to acquire an existing host site shall demonstrate that the existing host site has performed 50 PET equivalents in the most recent 12-month period verifiable by the Department.

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

Section 7. Requirements for a dedicated research fixed PET scanner

Sec. 7. An applicant proposing to add a fixed PET scanner to an existing PET scanner service for exclusive research use shall demonstrate 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.

(2) The 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.

(3) The applicant has access to a cyclotron for accelerating charged particles to high energies by means of electromagnetic fields.

(4) The proposed site can have no more than three dedicated research fixed PET scanners approved under this Section.

Section 8. Requirements for a dedicated pediatric PET scanner

Sec. 8. An applicant proposing to initiate a PET scanner service, or add a fixed PET scanner to expand an existing PET scanner service, for dedicated pediatric PET use shall demonstrate the following:

(1) The applicant agrees that the dedicated pediatric PET scanner will be used primarily (70% or more of the scans) for patients under 18 years of age.

(2) The applicant shall demonstrate the existing site provided the following for the most recent calendar year or a continuous 12-month period at the time the application is submitted to the Department:

(a) at least 7,000 pediatric (< 18 years old) discharges, excluding normal newborns,
(b) at least 5,000 pediatric (< 18 years old) surgeries, and
(c) at least 50 new pediatric cancer cases on its cancer registry.

(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 a positron emission mammography (PEM) scanner

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 a fixed PET scanner service and 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 and contracts with a facility that has a fixed PET scanner service.

(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 a fixed PET scanner site or host site and 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 and contracts with a facility that has a fixed or mobile PET scanner service.

(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.

Section 10. Pilot program requirements for all applicants proposing to initiate, replace, expand or acquire a comprehensive fixed PET referral service

(1) An applicant proposing to initiate a comprehensive fixed PET referral service shall demonstrate all of the following:

(a) The applicant shall provide a signed letter(s) of support from a hospital(s) and/or physician practice(s) indicating the willingness of the hospital(s) and/or physician practice(s) to provide referrals and consulting services to the applicant for the specialties listed below:

(i) cardiology

(ii) oncology

(iii) radiation oncology/therapy

(iv) neurology

(b) The applicant shall have a fixed cyclotron.

(c) The applicant shall have a radiopharmacy onsite that will combine cyclotron-produced radionuclide tracers with pharmaceutical components for purposes of onsite patient administration.

(d) The applicant's radiopharmacy shall support the development of radiopharmaceuticals for use in diagnostic and theranostic applications.

(e) The applicant is proposing no more than two fixed PET scanners.

(f) The applicant agrees to operate the comprehensive fixed PET referral service in accordance with all applicable project delivery requirements set forth in Section 12 of these standards including, but not limited to, the following:

(i) The applicant shall become accredited by the American College of Radiology (ACR), the Intersocietal Accreditation Commission (IAC) OR any other national accreditation body acceptable to the Department.

(ii) The applicant's radiopharmacy shall be licensed by the Michigan Board of Pharmacy.

(2) An applicant proposing to initiate a comprehensive fixed PET referral service shall not be required to project PET data units.

(3) An applicant proposing to replace a comprehensive fixed PET referral service shall demonstrate any one of the following:

(a) The applicant meets the requirements of Section 4(1).

(b) The applicant is proposing to replace a comprehensive fixed PET referral service and its existing PET scanner unit(s) to a new site and meets the following:

(i) The proposed site is within the planning area.

(ii) The existing fixed PET scanner(s) performed 500 PET equivalents per fixed scanner in the most recent 12-month period verifiable by the Department.

(iii) The existing comprehensive fixed PET referral service has been in operation for at least 36 months as of the date on which the application was submitted to the Department.

(iv) The fixed PET scanner(s) will be located in the same building or in a contiguous building as a fixed cyclotron-equipped radiopharmacy.

(4) An applicant proposing to expand a comprehensive fixed PET referral service shall demonstrate that it meets the requirements of Section 5.

(5) An applicant proposing to acquire a comprehensive fixed PET referral service or its scanner(s) shall demonstrate that it meets the requirements of Section 6.

(6) The Commission may decide to have the requirements of the pilot program described in this section become a permanent part of the PET Scanner Services Standards. If the Commission does not take action to make the pilot program a permanent part of the standards, the provisions of this section will expire on September 30, 2027 and after that date will be of no further force and effect. Any applicant seeking to participate in the pilot program described in this section must submit its application on or before September 1, 2025~~ 2023~~. These provisions shall not be applicable to any application submitted after September 1,~~ 2025~~~~2023~~.

Section 11. Requirement for Medicaid participation

Sec. 11. An applicant shall 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 12. Project delivery requirements and terms of approval for all applicants

Sec. 12. An applicant shall agree that, if approved, the PET scanner services shall be delivered in compliance with the following terms of approval.

(1) Compliance with these standards.

(2) Compliance with the following quality assurance requirements:

(a) 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.

(b) The PET scanner service shall include the following 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.

(c) The 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.

(d) The applicant maintains the services and specialties as set forth in Section 3(1) through 3(4).

(3) Compliance with the following access to care requirements:

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

(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(5), 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) For a comprehensive fixed PET referral service approved under Section 10, compliance with the following terms:

(a) The applicant shall become accredited by American College of Radiology (ACR), Intersocietal Accreditation Commission (IAC) or any other national accreditation body acceptable to the Department within 18 months of operation and shall maintain accreditation on an on-going basis.

(b) The applicant meets the requirements listed in Section 12(1) – (8), as applicable.

(c) The applicant's radiopharmacy shall be licensed by the Michigan Board of Pharmacy within 12 months of operation and shall continue to be licensed on an ongoing basis.

(d) The applicant shall have equipment and supplies onsite to handle clinical emergencies that might occur in the unit.

(e) PET service staff shall be trained in CPR and other appropriate emergency interventions.

(f) The applicant shall establish and maintain: (i) a standing medical staff and governing body (or its equivalent) that provides for the medical and administrative control of the ordering and utilization of PET patient procedures, and (ii) a formal program of utilization review and quality assurance.

(g) By April 30th of each year, the applicant shall provide annual reports to the Department regarding all diagnostic scans performed using radioisotopes other than FDG in the preceding calendar year. This reporting requirement shall continue for a period of 7 years and is in addition to the requirements of Section 12(4)(b). The data in the report shall, at a minimum, include:

(i) patient and referring physician zip codes,
(ii) number of scans by diagnosis and/or radiotracer,
(iii) number of pediatric (less than 18 years old) and adult scans,
(iv) average equipment time by visit type, as available, and
(v) number of scans performed as part of a research study.

(10) 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 13. Methodology for computing the projected PET data units

Sec. 13. An applicant being reviewed under Section 3 shall apply the methodology set forth in this section in computing the projected number of PET data units.

(1) Identify the number of diagnosis-specific new cancer cases documented in accordance with the requirements of Section 14.

(a) Combine the number of cancer cases for lung (site codes C340-C349), esophagus (site codes C150-C159), colorectal (site codes C180-C209), lymphoma (morphology codes 9590-9729), melanoma (morphology codes 8720-8790), prostate (site code C619), neuroendocrine tumors (small intestine: site codes C170-C179; pancreas: site codes C250-C259; and intestinal tract, NOS: site code C260; which

have any of the following morphology codes: 8240/3, 8574/3, 8249/3, 8246/3, 8013/3, 8041/3, 8151/3, 8152/3, and 8150/3), and head & neck [site codes C000-C148, C300-C329, C410, C411, C470 or C490 excluding C440-C444 (skin of head and neck), and additional codes approved by national coverage determination]. Use the name "combined" for this grouping.

(b) Multiply the number resulting from the calculation in "combined" cancer cases identified in subsection (1)(a) by 0.8, which is the estimated probability that a "combined" cancer case will require a PET scan.

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

(2) Identify the number of diagnosis-specific new cancer cases documented in accord with the requirements of section 14.

(a) 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) Multiply the number resulting from the calculation in subsection (2)(a) 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 16 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, see Appendix D for ICD-10-CM Codes) identified in accord with the requirements of Section 17 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 14. Commitment of diagnosis-specific new cancer cases

Sec. 14. An applicant proposing to use diagnosis-specific new cancer cases shall demonstrate all of the following:

(1) Only those cancer diagnoses identified in Section 13(1) and 13(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 cases.

(4) 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. 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 15. Documentation of diagnosis-specific new cancer case data

Sec. 15. 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.

Section 16. Commitment and documentation of diagnostic cardiac catheterization data

Sec. 16. 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.

Section 17. Commitment and documentation of intractable epilepsy data

Sec. 17. 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 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 18. Methodology for computing PET equivalents

Sec. 18. PET equivalents shall be calculated as follows:

TABLE 1 **PET EQUIVALENTS**	
Scan Category	**Weight**
Simple [1]	0.75
Standard [2]	1.0
Complex [3]	1.5

[1] Brain and single cardiac scans.

[2] Mid-skull to mid-thigh scans.

[3] Inpatient, radiation treatment when patient position device is used, cardiac rest/stress perfusion and metabolism, standard study with additional limited scan, pediatric, and total body scans.

Section 19. Department inventory of PET scanners

Sec. 19. The Department shall maintain and publicly post on its web site a list of PET scanner services annually.

Section 20. Comparative reviews; effect on prior planning policies

Sec. 20. 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 September 16, 2021 and effective November 12, 2021.

APPENDIX A

Counties assigned to each health service area are as follows:

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

APPENDIX B

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
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

APPENDIX C

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

75 F.R., p. 37245 (June 28, 2010)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

APPENDIX D

ICD-9-CM TO ICD-10-CM CODE TRANSLATION

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
345.01	Intractable Epilepsy Cases	G40.311	Generalized Idiopathic Epilepsy and Epileptic Syndromes, Intractable, with Status Epilepticus
		G40.319	Generalized Idiopathic Epilepsy and Epileptic Syndromes, Intractable, without Status Epilepticus
		G40.A11	Absence Epileptic Syndrome, Intractable, with Status Epilepticus
345.11	Intractable Epilepsy Cases	G40.311	Generalized Idiopathic Epilepsy and Epileptic Syndromes, Intractable, with Status Epilepticus
		G40.319	Generalized Idiopathic Epilepsy and Epileptic Syndromes, Intractable, without Status Epilepticus
345.41	Intractable Epilepsy Cases	G40.211	Localization-Related (Focal) (Partial) Symptomatic Epilepsy and Epileptic Syndromes with Complex Partial Seizures, Intractable, with Status Epilepticus
		G40.219	Localization-Related (Focal) (Partial) Symptomatic Epilepsy and Epileptic Syndromes with Complex Partial Seizures, Intractable, without Status Epilepticus
345.51	Intractable Epilepsy Cases	G40.011	Localization-Related (Focal) (Partial) Idiopathic Epilepsy and Epileptic Syndromes with Seizures of Localized Onset, Intractable, with Status Epilepticus
		G40.019	Localization-Related (Focal) (Partial) Idiopathic Epilepsy and Epileptic Syndromes with Seizures of Localized Onset, Intractable, without Status Epilepticus
		G40.111	Localization-Related (Focal) (Partial) Symptomatic Epilepsy and Epileptic Syndromes with Simple Partial Seizures, Intractable, with Status Epilepticus
		G40.119	Localization-Related (Focal) (Partial) Symptomatic Epilepsy and Epileptic Syndromes with Simple Partial Seizures, Intractable, without Status Epilepticus

APPENDIX D CONTINUED

ICD-9 Code	Description	ICD-10 Code	Description
345.61	Intractable Epilepsy Cases	G40.411	Other Generalized Epilepsy and Epileptic Syndromes, Intractable, with Status Epilepticus
		G40.419	Other Generalized Epilepsy and Epileptic Syndromes, Intractable, Without Status Epilepticus
345.71	Intractable Epilepsy Cases	G40.111	Localization-Related (Focal)(Partial) Symptomatic Epilepsy and Epileptic Syndromes with Simple Partial Seizures, Intractable, with Status Epilepticus
		G40.119	Localization-Related (Focal) (Partial) Symptomatic Epilepsy and Epileptic Syndromes With Simple Partial Seizures, Intractable, without Status Epilepticus
345.81	INTRACTABLE EPILEPSY CASES	G40.803	Other Epilepsy, Intractable, with Status Epilepticus
		G40.804	Other Epilepsy, Intractable, without Status Epilepticus
		G40.89	Other Seizures
345.91	INTRACTABLE EPILEPSY CASES	G40.411	Other Generalized Epilepsy and Epileptic Syndromes, Intractable, with Status Epilepticus
		G40.419	Other Generalized Epilepsy and Epileptic Syndromes, Intractable, without Status Epilepticus
		G40.911	Epilepsy, Unspecified, Intractable, with Status Epilepticus
		G40.919	Epilepsy, Unspecified, Intractable, without Status Epilepticus

"ICD-9-CM CODE" means the disease codes and nomenclature found in the International Classification of Diseases - 9th Revision - Clinical Modification**,** prepared by the Commission on Professional and Hospital Activities for the U.S. National Center for Health statistics.

"ICD-10-CM CODE" means the disease codes and nomenclature found in the International Classification of Diseases - 10th Revision - Clinical Modification, National Center for Health Statistics.