I. Call to Order & Introductions

Chairperson Keshishian called the meeting to order at 9:35 a.m.

A. Members Present:

  Denise Brooks-Williams  
  Gail J. Clarkson, RN  
  James B. Falahhee, Jr., JD,  
  Robert Hughes  
  Marc Keshishian, MD, Chairperson  
  Jessica Kochin  
  Gay L. Landstrom, RN arrived at 9:46 a.m.  
  Suresh Mukherji, MD, Vice-Chairperson  
  Luis Tomatis, MD

B. Members Absent:

  Kathleen Cowling, DO  
  Charles Gayney

C. Department of Attorney General Staff:

  Joseph Potchen

D. Michigan Department of Health and Human Services Staff Present:

  Tulika Bhattacharya  
  Elizabeth Hertel  
  Natalie Kellogg  
  Amber Myers  
  Beth Nagel  
  Tania Rodriguez
II. Review of Agenda

Motion by Commissioner Tomatis, seconded by Commissioner Falahee, to approve the agenda as modified. Motion carried in a vote of 8-Yes, 0- No, and 0- Abstained.

Motion by Commissioner Brooks-Williams, and seconded by Commissioner Clarkson to approve the mailing of Commissioner Gayney’s Certificate of Appreciation and Service. Motion carried in a vote of 8-Yes, 0- No, and 0- Abstained.

III. Declaration of Conflicts of Interests

No conflicts of interest were declared.

IV. Review of Minutes of March 18, 2015

Motion by Vice-Chairperson Mukherji, seconded by Commissioner Tomatis, to approve the minutes of March 18, 2015 as presented. Motion carried in a vote of 8-Yes, 0- No, and 0- Abstained.

V. Cardiac Catheterization (CC) Services – April 9, 2015 Public Hearing Summary & Report

Ms. Nagel gave an overview of the public hearing summary and the Department’s recommendations (see Attachment A).

A. Public comment

None.

B. Commission Discussion

None.

C. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Brooks-Williams, to approve and move the CC standards forward to the Joint Legislative Committee (JLC) and Governor for the 45-day review period (see attachment B). Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

VI. Megavoltage Radiation Therapy (MRT) Services/Units – April 9, 2015 Public Hearing Summary & Report

Ms. Nagel gave an overview of the public’s hearing and the Department’s recommendations (see Attachment A).
A. Public Comment

Dennis McCaffert, Economic Alliance for Michigan (EAM)
Melissa Cupp on behalf of Barbara Bressack, HFHS

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Hughes, seconded by Commissioner Kochin, to amend the MRT standards to include “the percentage of cases treated with more than 10 fractions for bone metastasis and the percentage of breast cancer cases treated with IMRT.” Motion Failed in a vote of 4 - Yes, 5 - No, and 0 - Abstained.

Motion by Commissioner Falahee, seconded by Commissioner Landstrom, to approve the MRT standards as presented with acknowledgement that the Commission had an extensive discussion focused on quality metrics and move the MRT standards forward to the JLC and Governor for the 45-day review period. Motion passed in a vote of 6 - Yes, 3 - No, and 0 - Abstained.

VII. Positron Emission Tomography (PET) Scanner Services – April 9, 2015
Public Hearing Summary & Report

Ms. Nagel gave an overview of the public hearing and the Department’s recommendations (see Attachment A).

A. Public Comment

None.

B. Commission Discussion

None.

C. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Tomatis, to approve and move the PET standards (see Attachment D) forward to the JLC and Governor for the 45-day review period. Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

VIII. Public Comment – Certificate of Need Audit Response
IX. Certificate of Need Audit Response

Chairperson Keshishian gave an introduction to the response to the CON audit.

Motion by Commissioner Tomatis, seconded by Commissioner Falahee, to accept the preliminary response as follows, “The Commission agrees with the finding and will develop a plan to address the consistent documentation and evaluation of the CON program operations and assessment of the program effectiveness.” Chairperson Keshishian will draft a plan that will require the charge of every workgroup and Standard Advisory Committee (SAC) to address cost, quality, and access; Commission minutes will reflect discussion of cost, quality, and access; and the draft plan will be finalized at the September 24, 2015 meeting (see Attachment F). Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

X. Legislative Report

Ms. Hertel gave the legislative report.

XI. Administrative Update

A. Planning & Access to Care Section Update

Ms. Nagel gave an update on the Planning & Access to Care Section.

B. CON Evaluation Section Update


1. Compliance Report (Written Report & Compliance Update) (see Attachment G)
2. Quarterly Performance Measures (Written Report) (see Attachment H)

XIV. Legal Activity Report

Mr. Potchen gave an update on the legal activity report. There was no legal report.


XV. Public Comment

Melissa Cupp, RWC Advocacy

XVI. Review of Commission Work Plan

Ms. Nagel reviewed the upcoming work plan (see Attachment I)

A. Commission Discussion

None.

B. Commission Action

Motion by Commissioner Clarkson, seconded by Commissioner Kochin, to accept the work plan as presented. Motion carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

XVII. Adjournment

Motion by Commissioner Hughes, seconded by Vice-Chairperson Mukherji, to adjourn the meeting at 10:55 a.m. Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.
Date: April 28, 2015

TO: The Certificate of Need (CON) Commission

FROM: Beth Nagel, Manager, Planning and Access to Care Section, MDHHS

RE: Summary of Public Hearing Comments on CON Review Standards for Cardiac Catheterization Services, Megavoltage Radiation Therapy (MRT) Services/Units, and Positron Emission Tomography (PET) Scanner Services

Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission “...shall conduct a public hearing on its proposed action.” The Commission took proposed action on the Cardiac Catheterization Services, MRT Services/Units, and PET Scanner Services Standards at its March 18, 2015 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed Cardiac Catheterization Services, MRT Services/Units, and PET Scanner Services Standards on April 9, 2015. Written testimony was accepted for an additional seven days after the hearing via an electronic link on the Commission’s website. No testimony was received.

Department Recommendations – Cardiac Catheterization Services

The Department supports the language that was presented at the March 18, 2015 CON Commission meeting without any further modifications.

Department Recommendations – MRT Services/Units

The Department supports the language that was presented at the March 18, 2015 CON Commission meeting without any further modifications.

Department Recommendations – PET Scanner Services

The Department supports the language that was presented at the March 18, 2015 CON Commission meeting without any further modifications.
MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS
FOR CARDIAC CATHETERIZATION 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 approval of the initiation, replacement, expansion, or acquisition of cardiac catheterization services, and the delivery of these services under Part 222 of the Code. Pursuant to Part 222 of the Code, cardiac catheterization 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) "Cardiac catheterization laboratory" or "laboratory" means an individual radiological room equipped with a variety of x-ray machines and devices such as electronic image intensifiers, high speed film changers and digital subtraction units to assist in performing diagnostic or therapeutic cardiac catheterizations or electrophysiology studies.
(b) "Cardiac catheterization procedure" means any cardiac procedure, including diagnostic, therapeutic, and electrophysiology studies, performed on a patient during a single session in a laboratory. Cardiac catheterization is a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in a patient; subsequently the free end of the catheter is manipulated by a physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aides in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures in the heart. This term does not include "float catheters" that are performed at the bedside or in settings outside the laboratory or the implantation of cardiac permanent pacemakers and implantable cardioverter defibrillators (ICD) devices that are performed in an interventional radiology laboratory or operating room.
(c) "Cardiac catheterization service" means the provision of one or more of the following types of procedures: adult diagnostic cardiac catheterizations; pediatric diagnostic cardiac catheterizations; adult therapeutic cardiac catheterizations; and pediatric therapeutic cardiac catheterizations.
(d) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.
(e) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.
(f) "Department" means the Michigan Department of Community Health (MDCH).
(g) "Diagnostic cardiac catheterization service" means providing diagnostic cardiac catheterization procedures on an organized, regular basis in a laboratory to diagnose anatomical and/or physiological problems in the heart. Procedures include the intra coronary administration of drugs; left heart catheterization; right heart catheterization; coronary angiography; diagnostic electrophysiology studies; and cardiac biopsies (echo-guided or fluoroscopic). A hospital that provides diagnostic cardiac catheterization services may also perform implantations of cardiac permanent pacemakers and ICD devices.
(h) "ELECTIVE PERCUTANEOUS CORONARY INTERVENTION (PCI)" MEANS A PCI PROCEDURE PERFORMED ON A NON-EMERGENT BASIS.
(i) "ELECTIVE PCI SERVICES WITHOUT ON-SITE OPEN HEART SURGERY (OHS)" MEANS PERFORMING PCI, PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA), AND CORONARY STENT IMPLANTATION ON AN ORGANIZED, REGULAR BASIS IN A HOSPITAL HAVING A DIAGNOSTIC CARDIAC CATHETERIZATION SERVICE AND A PRIMARY PCI SERVICE BUT NOT HAVING OHS ON-SITE AND ADHERING TO PATIENT SELECTION AS OUTLINED IN THE SCAI/ACC/AHA EXPERT CONSENSUS DOCUMENT: 2014 UPDATED ON PCI WITHOUT ON-SITE SURGICAL BACKUP AND PUBLISHED IN CIRCULATION 2014, 129:2610-2626 AND ITS UPDATE OR FURTHER GUIDELINE CHANGES.

(hj) "Electrophysiology study" means a study of the electrical conduction activity of the heart and characterization of atrial and ventricular arrhythmias obtained by means of a cardiac catheterization procedure. The term also includes the implantation of permanent pacemakers and ICD devices.

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

(jj) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C. 1396 to 1396g and1396i to 1396u.

 mk) "Pediatric cardiac catheterization service" means providing cardiac catheterization services on an organized, regular basis to infants and children ages 18 and below, except for electrophysiology studies that are offered and provided to infants and children ages 14 and below, and others with congenital heart disease as defined by the ICD-9-CM codes (See Appendix B for ICD-10-CM Codes) of 426.7 (anomalous atrioventricular excitation), 427.0 (cardiac dysrythmias), and 745.0 through 747.99 (bulbus cordis anomalies and anomalies of cardiac septal closure, other congenital anomalies of heart, and other congenital anomalies of circulatory system).

( nl) "Primary percutaneous coronary intervention (PCI)" means a PCI performed on an acute myocardial infarction (AMI) patient with confirmed ST elevation or new left bundle branch block ON AN EMERGENT BASIS.

(o) "PRIMARY PCI SERVICE WITHOUT ON-SITE OHS" MEANS PERFORMING PRIMARY PCI ON AN EMERGENT BASIS IN A HOSPITAL HAVING A DIAGNOSTIC CARDIAC CATHETERIZATION SERVICE.

(mp) "Procedure equivalent" means a unit of measure that reflects the relative average length of time one patient spends in one session in a laboratory based on the type of procedures being performed.

(nq) "Therapeutic cardiac catheterization service" means providing therapeutic cardiac catheterizations on an organized, regular basis in a laboratory to treat and resolve anatomical and/or physiological problems in the heart. Procedures include PCI, PTCA, atherectomy, stent, laser, cardiac valvuloplasty, balloon atrial septostomy, catheter ablation, cardiac permanent pacemaker, ICD device implantations, transcatheter valve, other structural heart disease procedures, percutaneous transluminal coronary angioplasty (PTCA) and WITH coronary stent implantation and left sided arrhythmia therapeutic procedures. The term does not include the intra coronary administration of drugs where that is the only therapeutic intervention.

(2) Terms defined in the Code have the same meanings when used in these standards.

Section 3. Requirements to initiate cardiac catheterization services

Sec. 3. An applicant proposing to initiate cardiac catheterization services shall demonstrate the following, as applicable to the proposed project:

(1) An applicant proposing to initiate an adult diagnostic cardiac catheterization service shall demonstrate the following as applicable to the proposed project:

(a) An applicant proposing to initiate a diagnostic cardiac catheterization service with a single laboratory in a rural or micropolitan statistical area county shall project a minimum of 500 procedure equivalents including 300 procedure equivalents in the category of diagnostic cardiac catheterization procedures based on data from the most recent 12-month period preceding the date the application was submitted to the Department.
(b) An applicant proposing to initiate a diagnostic cardiac catheterization service with a single laboratory in a metropolitan statistical area county shall project a minimum of 750 procedure equivalents that includes 300 procedure equivalents in the category of diagnostic cardiac catheterization procedures based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

(c) An applicant proposing to initiate a diagnostic cardiac catheterization service with two or more laboratories shall project a minimum of 1,000 procedure equivalents per laboratory that includes 300 procedure equivalents in the category of diagnostic cardiac catheterization procedures based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

(2) An applicant proposing to initiate an adult therapeutic cardiac catheterization service shall demonstrate the following:

(a) The applicant provides, is approved to provide, or has applied to provide adult diagnostic cardiac catheterization services at the hospital. The applicant must be approved for adult diagnostic cardiac catheterization services in order to be approved for adult therapeutic cardiac catheterization services.

(b) An applicant operating an adult diagnostic cardiac catheterization service has performed a minimum of 300 procedure equivalents in the category of adult diagnostic cardiac catheterizations during the most recent 12-month period preceding the date the application was submitted to the Department if the service has been in operation more than 24 months.

(c) The applicant has applied to provide adult open heart surgeryOHS services at the hospital. The applicant must be approved for an adult open heart surgeryOHS service in order to be approved for an adult therapeutic cardiac catheterization service.

(d) The applicant shall project a minimum of 300 procedure equivalents in the category of adult therapeutic cardiac catheterizations based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

(3) An applicant proposing to initiate a pediatric cardiac catheterization service shall demonstrate the following:

(a) The applicant has a board certified pediatric cardiologist with training in pediatric catheterization procedures to direct the pediatric catheterization laboratory.

(b) The applicant has standardized BIPLANE equipment as defined in the most current American Academy of Pediatrics (AAP) AND AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION (ACCF)/SOCIETY FOR CARDIOVASCULAR ANGIOGRAPHY AND INTERVENTIONS (SCAI) guidelines for pediatric cardiovascular centers.

(c) The applicant has on-site PEDIATRIC AND NEONATAL ICU as outlined in the most current AAP AND ACCF/SCAI guidelines above.

(d) The applicant has applied to provide pediatric open heart surgeryOHS services at the hospital. The applicant must be approved for a pediatric open heart surgeryOHS service in order to be approved for pediatric cardiac catheterization services.

(e) THE APPLICANT HAS ON-SITE PEDIATRIC EXTRACORPOREAL MEMBRANE OXYGENATION (ECMO) CAPABILITY AS OUTLINED IN THE MOST CURRENT ACCF/SCAI GUIDELINES.

(f) A PEDIATRIC CARDIAC CATHETERIZATION SERVICES SHALL HAVE A QUALITY ASSURANCE PLAN AS OUTLINED IN THE MOST CURRENT ACCF/SCAI GUIDELINES.

(e) The applicant shall project a minimum of 600 procedure equivalents in the category of pediatric cardiac catheterizations based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

SECTION 4. REQUIREMENTS TO INITIATE PRIMARY OR ELECTIVE PCI SERVICES WITHOUT ON-SITE OHS SERVICES
(4) SEC. 4. An applicant proposing to initiate primary OR ELECTIVE PCI services without on-site open heart surgery OHS services shall demonstrate the following:

(a1) The applicant operates an adult diagnostic cardiac catheterization service that has performed a minimum of 500 procedure equivalents that includes 400 procedure equivalents in the category of cardiac catheterization procedures during the most recent 12 months preceding the date the application was submitted to the Department.

(b2) The applicant has at least two interventional cardiologists to perform the primary-PCI procedures and each cardiologist has performed at least 75 PCI sessions annually as the primary operator during the most recent 24-month period preceding the date the application was submitted to the Department.

(c3) The nursing and technical catheterization laboratory staff are experienced in handling acutely ill patients and comfortable with interventional equipment; have acquired experience in dedicated interventional laboratories at an open heart surgery OHS hospital; and participate in an un-interrupted 24-hour, 365-day call schedule. Competency shall be documented annually.

(d4) The laboratory or laboratories are equipped with optimal imaging systems, resuscitative equipment, and intra-aortic balloon pump (IABP) support, and stocked with a broad array of interventional equipment.

(e5) The cardiac care unit nurses are adept in hemodynamic monitoring and IABP management. Competency shall be documented annually.

(f6) A written agreement with an open heart surgery OHS hospital that includes all of the following:

(iia) Involvement in credentialing criteria and recommendations for physicians approved to perform primary-PCI procedures.

(iib) Provision for ongoing cross-training for professional and technical staff involved in the provision of primary-PCI to ensure familiarity with interventional equipment. Competency shall be documented annually.

(iic) Provision for ongoing cross training for emergency department, catheterization laboratory, and critical care unit staff to ensure experience in handling the high acuity status of primary-PCI patient candidates. Competency shall be documented annually.

(iid) Regularly held joint cardiology/cardiac surgery conferences to include review of all primary-PCI cases.

(ive) Development and ongoing review of patient selection criteria for primary-PCI patients and implementation of those criteria.

(vi) A mechanism to provide for appropriate patient transfers between facilities and an agreed plan for prompt care.

(vii) Written protocols, signed by the applicant and the open heart surgery OHS hospital, for the immediate transfer, within 1-hour 60 MINUTES TRAVEL TIME from the cardiac catheterization laboratory to evaluation on site in the open heart surgery OHS hospital, of patients requiring surgical evaluation and/or intervention 365 days a year. IF THE APPLICANT MEETS THE REQUIREMENTS OF SUB-SECTION (13)(c), THEN THE OHS HOSPITAL CAN BE MORE THAN 60 MINUTES TRAVEL TIME FROM THE PROPOSED SITE. The protocols shall be reviewed and tested on a quarterly basis.

(viii) Consultation on facilities, equipment, staffing, ancillary services, and policies and procedures for the provision of interventional procedures.

(g7) A written protocol must be established and maintained for case selection for the performance of primary-PCI.
(h) A system to ensure prompt and efficient identification of potential primary PCI patients and rapid transfer from the emergency department to the cardiac catheterization laboratory must be developed and maintained so that door-to-balloon targets are met.

(i) At least two physicians credentialed to perform primary PCI must commit to functioning as a coordinated group willing and able to provide this service at the hospital on a 24-hour per day, 365 day per year call schedule, with ability to be on-site and available to operate within 30 minutes of identifying the need for primary PCI. These physicians must be credentialed at the facility and actively collaborate with administrative and clinical staff in establishing and implementing protocols, call schedules, and quality assurance procedures pertaining to primary PCI designed to meet the requirements for this certification and in keeping with the current guidelines for the provision of primary PCI WITHOUT ON-SITE OHS SERVICES promulgated by the American College of Cardiology and American Heart Association.

(j) The applicant shall project a minimum of 36 primary PCI cases based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

(10) THE APPLICANT HOSPITAL SHALL PARTICIPATE IN A DATA REGISTRY ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE AS A MEANS TO MEASURE QUALITY AND RISK ADJUSTED OUTCOMES WITHIN PCI SERVICES WITHOUT ON-SITE OHS SERVICES, AND THE APPLICANT HOSPITAL SHALL IDENTIFY A PHYSICIAN POINT OF CONTACT FOR THE DATA REGISTRY.

(11) CATH LAB FACILITY REQUIREMENTS AND COLLABORATIVE CARDIOLOGISTS-HEART SURGEON RELATIONSHIP REQUIREMENTS SHALL CONFORM TO ALL SCAI/ACC GUIDELINES FOR PCI SERVICES WITHOUT ON-SITE OHS INCLUDING THE SCAI/ACC/AHA EXPERT CONSENSUS DOCUMENT. THE APPLICANT HOSPITAL SHALL BE LIABLE FOR THE COST OF DEMONSTRATING COMPLIANCE WITH THESE CRITERIA IN THEIR APPLICATION.

(12) The applicant shall project THE FOLLOWING based on data from the most recent 12-month period preceding the date the application was submitted to the Department, AS APPLICABLE.

(a) IF THE APPLICANT IS APPLYING FOR A PRIMARY PCI SERVICE WITHOUT OPEN HEART SURGERY, THE APPLICANT SHALL PROJECT A MINIMUM OF 36 PRIMARY PCI PROCEDURES PER YEAR.

(b) IF THE APPLICANT IS APPLYING FOR AN ELECTIVE PCI SERVICE WITHOUT ON-SITE OHS, THE APPLICANT SHALL PROJECT A MINIMUM OF 200 PCI PROCEDURES PER YEAR.

(13) IF THE APPLICANT IS APPLYING FOR AN ELECTIVE PCI SERVICE WITHOUT ON-SITE OHS, THE APPLICANT ALSO SHALL DEMONSTRATE THE FOLLOWING:

(a) THE APPLICANT OPERATED A PRIMARY PCI SERVICE FOR AT LEAST ONE YEAR PRIOR TO THE DATE OF APPLICATION.

(b) THE APPLICANT SUBMITTED DATA TO A DATA REGISTRY ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE AND BEEN FOUND TO HAVE ACCEPTABLE PERFORMANCE AS COMPARED TO THE REGISTRY BENCHMARKS FOR THE MOST RECENT 12 MONTHS PRIOR TO THE DATE OF APPLICATION.

(c) IF THE APPLICANT WAS NOT APPROVED AS A PRIMARY PCI SERVICE PRIOR TO (INSERT EFFECTIVE DATE OF THESE STANDARDS), THEN, IN ADDITION, THE APPLICANT SHALL DEMONSTRATE THAT THERE IS NO PCI OR OHS SERVICE WITHIN 60 RADIUS MILES OR 60 MINUTES TRAVEL TIME FROM THE PROPOSED SITE.

(14) IF THE APPLICANT IS CURRENTLY PROVIDING OHS SERVICES AND THERAPEUTIC CARDIAC CATHERIZATION SERVICES AND IS PROPOSING TO DISCONTINUE OHS SERVICES AND THERAPEUTIC CARDIAC CATHERIZATION SERVICES, THEN THE APPLICANT SHALL APPLY TO INITIATE PRIMARY OR ELECTIVE PCI SERVICES WITHOUT ON-SITE OHS USING THIS...
SECTION. THE APPLICANT SHALL DEMONSTRATE ALL OF THE REQUIREMENTS IN THIS SECTION EXCEPT FOR SUB-SECTION (13) AND IS SUBJECT TO ALL REQUIREMENTS IN SECTION 10.

Section 45. Requirements to replace an existing cardiac catheterization service or laboratory

Sec. 45. Replacing a cardiac catheterization laboratory means a change in the angiography x-ray equipment or a relocation of the service to a new site. The term does not include a change in any of the other equipment or software used in the laboratory. An applicant proposing to replace a cardiac catheterization laboratory or service shall demonstrate the following as applicable to the proposed project:

(1) An applicant proposing to replace cardiac catheterization laboratory equipment shall demonstrate the following:
   (a) The existing laboratory or laboratories to be replaced are fully depreciated according to generally accepted accounting principles or demonstrates either of the following:
      (i) The existing angiography x-ray equipment to be replaced poses a threat to the safety of the patients.
      (ii) The replacement angiography x-ray equipment offers technological improvements that enhance quality of care, increases efficiency, and reduces operating costs.
   (b) The existing angiography x-ray equipment to be replaced will be removed from service on or before beginning operation of the replacement equipment.

(2) An applicant proposing to replace a cardiac catheterization service to a new site shall demonstrate the following:
   (a) The proposed project is part of an application to replace the entire hospital.
   (b) The applicant has performed the following during the most recent 12-month period preceding the date the application was submitted to the Department as applicable to the proposed project:
      (i) A minimum of 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures.
      (ii) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac catheterization procedures.
      (iii) A minimum of 600 procedure equivalents in the category of pediatric cardiac catheterization procedures.
      (iv) A minimum of 500 procedure equivalents for a hospital in a rural or micropolitan county with one laboratory.
      (v) A minimum of 750 procedure equivalents for a hospital in a metropolitan county with one laboratory.
      (vi) A minimum of 1,000 procedure equivalents per cardiac catheterization laboratory for a hospital with two or more laboratories.
   (c) The existing cardiac catheterization service has been in operation for at least 36 months as of the date the application has been submitted to the Department.

Section 56. Requirements to expand a cardiac catheterization service

Sec. 56. An applicant proposing to add a laboratory to an existing cardiac catheterization service shall demonstrate the following:

(1) The applicant has performed the following during the most recent 12-month period preceding the date the application was submitted to the Department as applicable to the proposed project:
   (a) A minimum of 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures.
   (b) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac catheterization procedures.
(c) A minimum of 600 procedure equivalents in the category of pediatric cardiac catheterization procedures.

(2) The applicant has performed a minimum of 1,400 procedure equivalents per existing and approved laboratories during the most recent 12-month period preceding the date the application was submitted to the Department.

Section 67. Requirements to acquire a cardiac catheterization service

Sec. 67. Acquiring a cardiac catheterization service and its laboratories means obtaining possession and control by contract, ownership, lease or other comparable arrangement or renewal of a lease for existing angiography x-ray equipment. An applicant proposing to acquire a cardiac catheterization service or renew a lease for equipment shall demonstrate the following as applicable to the proposed project:

(1) An applicant proposing to acquire a cardiac catheterization service shall demonstrate the following:
   (a) The proposed project is part of an application to acquire the entire hospital.
   (b) An application for the first acquisition of an existing cardiac catheterization service after February 27, 2012 shall not be required to be in compliance with the applicable volume requirements in subsection SECTION (c)10. The cardiac catheterization 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.
   (c) FOR ANY APPLICATION PROPOSING TO ACQUIRE AN EXISTING CARDIAC CATHETERIZATION SERVICE, EXCEPT THE FIRST APPLICATION APPROVED PURSUANT TO SUBSECTION (B), AN APPLICANT SHALL BE REQUIRED TO DOCUMENT THAT THE CARDIAC CATHETERIZATION SERVICE TO BE ACQUIRED IS OPERATING IN COMPLIANCE WITH THE VOLUME REQUIREMENTS SET FORTH IN SECTION 10 OF THESE STANDARDS APPLICABLE TO AN EXISTING CARDIAC CATHETERIZATION SERVICE ON THE DATE THE APPLICATION IS SUBMITTED TO THE DEPARTMENT. The applicant has performed the following during the most recent 12-month period preceding the date the application was submitted to the Department as applicable to the proposed project:
      (i) A minimum of 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures.
      (ii) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac catheterization procedures.
      (iii) A minimum of 600 procedure equivalents in the category of pediatric cardiac catheterization procedures.
      (iv) A minimum of 500 procedure equivalents for a hospital in a rural or micropolitan county with one laboratory.
      (v) A minimum of 750 procedure equivalents for a hospital in a metropolitan county with one laboratory.
      (vi) A minimum of 1,000 procedure equivalents per cardiac catheterization laboratory for two or more laboratories.

(2) An applicant proposing to renew a lease for existing angiography x-ray equipment shall demonstrate the renewal of the lease is more cost effective than replacing the equipment.

Section 78. Requirements for a hybrid operating room/cardiac catheterization laboratory (OR/CCL)

Sec. 78. A hybrid OR/CCL means an operating room located on a sterile corridor and equipped with an angiography system permitting minimally invasive procedures of the heart and blood vessels with full
anesthesia capabilities. An applicant proposing to add one or more hybrid OR/CCLs at an existing cardiac catheterization service shall demonstrate each of the following:

1. The applicant operates an open heart surgery (OHS) service which is in full compliance with the current CON Review Standards for Open Heart Surgery (OHS) Services.

2. The applicant operates a therapeutic cardiac catheterization program which is in full compliance with section 45(2) of these standards.

3. If the hybrid OR/CCL(s) represents an increase in the number of cardiac catheterization laboratories at the facility, the applicant is in compliance with Section 5.6 of these standards.

4. If the hybrid OR/CCL(s) represents conversion of an existing cardiac catheterization laboratory(s), the applicant is in compliance with the provisions of Section 45, if applicable.

5. The applicant meets the applicable requirements of the CON Review Standards for Surgical Services.

6. Each case performed in a hybrid OR/CCL shall be included either in the surgical volume or the therapeutic cardiac catheterization volume of the facility. No case shall be counted more than once.

7. For each hybrid OR/CCL, a facility shall have 0.5 excluded from its inventory of cardiac catheterization laboratories for the purposes of computing the procedure equivalents per room. A facility will not be limited to the number of hybrid OR/CCLs within a single licensed facility.

**Section 89. Requirement for Medicaid participation**

Sec. 89. An applicant shall provide verification of Medicaid participation at the time the application is submitted to the Department. An applicant that is initiating a new service or is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved.

**Section 910. Project delivery requirements and terms of approval for all applicants**

Sec. 910. An applicant shall agree that, if approved, the cardiac catheterization service and all existing and approved laboratories shall be delivered in compliance with the following terms of approval:

1. Compliance with these standards.

2. Compliance with the following quality assurance standards:
   (a) Cardiac catheterization procedures shall be performed in a cardiac catheterization laboratory located within a hospital, and have within, or immediately available to the room, dedicated emergency equipment to manage cardiovascular emergencies.
   (b) The service shall be staffed with sufficient medical, nursing, technical and other personnel to permit regular scheduled hours of operation and continuous 24-hour on-call availability.
   (c) The medical staff and governing body shall receive and review at least annual reports describing the activities of the cardiac catheterization service including complication rates, morbidity and mortality, success rates and the number of procedures performed.
   (d) Each physician credentialed by a hospital to perform adult therapeutic cardiac catheterization procedures shall perform, as the primary operator, a minimum of 75.50 adult therapeutic cardiac catheterization procedures per year in the second 12 months after being credentialed to and annually thereafter. The annual case load for a physician means adult therapeutic cardiac catheterization procedures performed by that physician in any combination of hospitals.
(e) Each physician credentialed by a hospital to perform pediatric diagnostic cardiac catheterizations shall perform, as the primary operator, a minimum of 50 pediatric diagnostic cardiac catheterization procedures per year in the second 12 months after being credentialed and annually thereafter. The annual case load for a physician means pediatric diagnostic cardiac catheterization procedures performed by that physician in any combination of hospitals.

(f) Each physician credentialed by a hospital to perform pediatric therapeutic cardiac catheterizations shall perform, as the primary operator, a minimum of 25 pediatric therapeutic cardiac catheterizations per year in the second 12 months after being credentialed and annually thereafter. The annual case load for a physician means pediatric therapeutic cardiac catheterization procedures performed by that physician in any combination of hospitals.

(gf) An adult diagnostic cardiac catheterization service shall have a minimum of two appropriately trained physicians on its active hospital staff. The Department may accept other evidence or shall consider it appropriate training if the staff physicians:

(i) are trained consistent with the recommendations of the American College of Cardiology;

(ii) are credentialed by the hospital to perform adult diagnostic cardiac catheterizations; and

(iii) have each performed a minimum of 100 adult diagnostic cardiac catheterizations in the preceding 12 months.

(hg) An adult therapeutic cardiac catheterization service shall have a minimum of two appropriately trained physicians on its active hospital staff. The Department may accept other evidence or shall consider it appropriate training if the staff physicians:

(i) are trained consistent with the recommendations of the American College of Cardiology;

(ii) are credentialed by the hospital to perform adult therapeutic cardiac catheterizations; and

(iii) have each performed a minimum of 75 adult therapeutic cardiac catheterization procedures in the preceding 12 months.

(hi) A pediatric cardiac catheterization service shall have an appropriately trained physician on its active hospital staff. The Department may accept other evidence or shall consider it appropriate training if the staff physician:

(i) is board certified or board eligible in pediatric cardiology by the American Board of Pediatrics;

(ii) is credentialed by the hospital to perform pediatric cardiac catheterizations; and

(iii) has trained consistently with the recommendations of the American College of Cardiology.

(i) A PEDIATRIC CARDIAC CATHETERIZATION SERVICE SHALL MAINTAIN A QUALITY ASSURANCE PLAN AS OUTLINED IN THE MOST CURRENT ACCF/SCAI GUIDELINES.

(j) A cardiac catheterization service shall be directed by an appropriately trained physician. The Department shall consider appropriate training of the director if the physician is board certified in cardiology, cardiovascular radiology or cardiology, adult or pediatric, as applicable. The director of an adult cardiac catheterization service shall have performed at least 200 catheterizations per year during each of the five preceding years. The Department may accept other evidence that the director is appropriately trained.

(k) A cardiac catheterization service shall be operated consistently with the recommendations of the American College of Cardiology.

(l) THE APPLICANT HOSPITAL PROVIDING THERAPEUTIC CARDIAC CATHETERIZATION SERVICES, PRIMARY PCI SERVICES WITHOUT ON-SITE OHS SERVICE, OR ELECTIVE PCI SERVICES WITHOUT ON-SITE OHS SERVICE SHALL PARTICIPATE WITH A DATA REGISTRY ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE THAT MONITORS QUALITY AND RISK ADJUSTED OUTCOMES.

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

(a) The service shall accept referrals for cardiac catheterization from all appropriately licensed practitioners.

(b) The service shall participate in Medicaid at least 12 consecutive months within the first two years of operation and annually thereafter.

(c) The service shall not deny cardiac catheterization services to any individual based on ability to pay or source of payment.
(d) The operation of and referral of patients to the cardiac catheterization service shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.1621; MSA 14.15 (16221).

(4) Compliance with the following monitoring and reporting requirements:
(a) The service shall be operating at or above the applicable volumes in the second 12 months of operation of the service, or an additional laboratory, and annually thereafter:
   (i) 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures.
   (ii) 300 procedure equivalents in the category of adult therapeutic cardiac catheterization procedures.
   (iii) 600 procedure equivalents in the category of pediatric cardiac catheterization procedures.
   (iv) 500 procedure equivalents for a hospital in a rural or micropolitan county with one laboratory.
   (v) 750 procedure equivalents for a hospital in a metropolitan county with one laboratory.
   (vi) 1,000 procedure equivalents per cardiac catheterization laboratory for two or more laboratories.
   (vii) 36 adult primary PCI cases for a primary PCI service WITHOUT ON-SITE OHS SERVICE.
   (viii) 200 ADULT PCI PROCEDURES FOR AN ELECTIVE PCI SERVICE WITHOUT ON-SITE OHS SERVICE.
(b) The APPLICANT hospital shall participate in a data collection network established and administered by the Department or its designee. Data may include, but is not limited to, annual budget and cost information, operating schedules, patient demographics, morbidity and mortality information, and payor. The Department may verify the data through on-site review of appropriate records.
(c) The APPLICANT hospital PROVIDING THERAPEUTIC CARDIAC CATHETERIZATION SERVICES, PRIMARY PCI SERVICES WITHOUT ON-SITE OHS SERVICE, OR ELECTIVE PCI SERVICES WITHOUT ON-SITE OHS SERVICE shall participate in a quality improvement data registry administered by the Department or its designee AS A MEANS TO MEASURE QUALITY AND RISK ADJUSTED OUTCOMES WITHIN CARDIAC CATHETERIZATION SERVICES. The DEPARTMENT OR ITS DESIGNEE SHALL REQUIRE THAT THE APPLICANT hospital submit summary reports as required SPECIFIED by the Department. The APPLICANT hospital shall provide the required data in a format established by the Department or its designee. The APPLICANT hospital is SHALL BE liable for the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes and assure quality. The APPLICANT hospital must SHALL become a member of the data registry SPECIFIED BY THE DEPARTMENT upon initiation of the service and continue to participate annually thereafter for the life of that service.
(d) THE APPLICANT HOSPITAL SHALL PROVIDE THE DEPARTMENT WITH TIMELY NOTICE OF THE PROPOSED PROJECT IMPLEMENTATION CONSISTENT WITH APPLICABLE STATUTE AND PROMULGATED RULES.

(5) Compliance with the following primary AND ELECTIVE PCI requirements FOR HOSPITALS PROVIDING THERAPEUTIC CARDIAC CATHETERIZATION SERVICES, PRIMARY PCI SERVICES WITHOUT ON-SITE OHS SERVICE, OR ELECTIVE PCI SERVICES WITHOUT ON-SITE OHS SERVICE, if applicable:
(a) The requirements set forth in Section 3(4).
(b) The hospital shall immediately report to the Department any changes in the interventional cardiologists who perform the primary PCI procedures.
(c) The hospital shall perform a minimum of 36 primary PCI procedures at the hospital in the preceding 12-month period of operation of the service and annually thereafter.
(c) The hospital shall maintain a 90-minute door-to-balloon time or less in at least 75% of the primary PCI sessions.
(d) The APPLICANT hospital shall participate in a data registry, administered by the Department or its designee AS A MEANS TO MEASURE QUALITY AND RISK ADJUSTED OUTCOMES WITHIN PCI SERVICES BY SERVICE LEVEL. The Department or its designee shall require that the applicant HOSPITAL submit data on all consecutive cases of primary PCI CASES PERFORMED WITHIN THE HOSPITAL AND MEET DATA SUBMISSION TIMELINESS REQUIREMENTS AND THRESHOLD REQUIREMENTS.
Section 4011. Methodology for computing cardiac catheterization equivalents

Sec. 4011. The following shall be used in calculating procedure equivalents and evaluating utilization of a cardiac catheterization service and its laboratories:
### Procedure Type | Procedure equivalent
--- | ---
Diagnostic cardiac catheterization/peripheral sessions | 1.5 Adult, 2.7 Pediatric
Therapeutic cardiac catheterization/peripheral sessions | 2.7 Adult, 4.0 Pediatric
Complex percutaneous valvular sessions* | 4.0 Adult, 7.0 Pediatric

* Complex percutaneous valvular sessions includes, but is not limited to, procedures performed percutaneously or with surgical assistance to repair or replace aortic, mitral and pulmonary valves such as transcatheter aortic valvular implantation (Tavi) procedures. These sessions can only be performed at hospitals approved with open heart surgery (OHS) services.

### Section 4112. Documentation of projections

Sec. 4112. An applicant required to project volumes shall demonstrate the following as applicable to the proposed project:

1. The applicant shall specify how the volume projections were developed. Specification of the projections shall include a description of the data source(s) used and assessment of the accuracy of the data. The Department shall determine if the projections are reasonable.

2. An applicant proposing to initiate a primary PCI service shall demonstrate and certify that the hospital treated or transferred 36 ST segment elevation AMI cases during the most recent 12-month period preceding the date the application was submitted to the Department. Cases may include thrombolytic eligible patients documented through pharmacy records showing the number of doses of thrombolytic therapy ordered and medical records of emergency transfers of AMI patients to an appropriate hospital for a primary PCI procedure.

3. An applicant proposing to initiate an elective PCI service without on-site OHS services shall demonstrate and certify that the hospital shall treat 200 or more patients with PCI annually using data during the most recent 12-month period preceding the date the application was submitted to the Department as follows:
   - (a) All primary PCIs performed at the applicant hospital.
   - (b) All inpatients transferred from the applicant hospital to another hospital for PCI.
   - (c) 90% of patients who received diagnostic cardiac catheterizations at the applicant hospital and received an elective PCI at another hospital within 30 days of the diagnostic catheterization (based on physician commitments).
   - (d) 50% of the elective PCI procedures performed by the committing physician at another hospital within 120 radius miles or 120 minutes travel time from the applicant hospital for patients who did not receive diagnostic cardiac catheterization at the applicant hospital (based on physician commitments).

4. An applicant with current OHS services and therapeutic cardiac catheterization services that is proposing to discontinue OHS services and therapeutic cardiac catheterization services and is applying to initiate primary or elective PCI services without on-site OHS services may count all primary and elective PCI at the applicant hospital within the most recent 12-month period preceding the date the application was submitted to the Department.

### Section 4213. Comparative reviews; Effect on prior CON Review Standards
Sec. 4213. Proposed projects reviewed under these standards shall not be subject to comparative review. These CON Review Standards supercede and replace the CON Review Standards for Cardiac Catheterization Services approved by the CON Commission on December 15, 2011 and effective on February 27, 2012.

JUNE 2, 2014.
APPENDIX A

Rural Michigan counties are as follows:

<table>
<thead>
<tr>
<th>Rural Michigan Counties</th>
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</thead>
<tbody>
<tr>
<td>Alcona</td>
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Micropolitan statistical area Michigan counties are as follows:

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<th>Micropolitan statistical area Michigan Counties</th>
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<td>Allegan</td>
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<tr>
<td>Eaton</td>
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<tr>
<td>Genesee</td>
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<tr>
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</table>

Source:

6575 F.R., p. 82238-37245 (December 27, 2000)
## APPENDIX B

### ICD-9-CM TO ICD-10-CM Code Translation

<table>
<thead>
<tr>
<th>ICD-9 Code</th>
<th>Description</th>
<th>ICD-10 Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>426.7</td>
<td>Anomalous Atrioventricular Excitation</td>
<td>I45.6</td>
<td>Pre-Excitation Syndrome</td>
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<tr>
<td>427</td>
<td>Cardiac Dysrhythmias</td>
<td>I47.0-I47.9</td>
<td>Paroxysmal Tachycardia</td>
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<td></td>
<td></td>
<td>I48.0-I48.92</td>
<td>Atrial Fibrillation and Flutter</td>
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<td></td>
<td></td>
<td>I49.01-I49.9</td>
<td>Other Cardiac Arrhythmias</td>
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<tr>
<td></td>
<td></td>
<td>R00.1</td>
<td>Bradycardia, Unspecified</td>
</tr>
<tr>
<td>745.0</td>
<td>through 747.99 Bulbus Cordis Anomalies and Anomalies of Cardiac Septal Closure, Other Congenital Anomalies of Heart, and other Congenital Anomalies of Circulatory System</td>
<td>P29.3</td>
<td>Persistent Fetal Circulation</td>
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<td></td>
<td></td>
<td>Q20.0-Q28.9</td>
<td>Congenital Malformations of the Circulatory System</td>
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</tbody>
</table>

"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.
MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR MEGAVOLTAGE RADIATION THERAPY (MRT) SERVICES/UNITS


Section 1. Applicability

Sec. 1. These standards are requirements for approval to initiate, replace, expand, or acquire an MRT service under Part 222 of the Code. MRT services and units are a covered clinical service pursuant to Part 222 of the Code. The Department shall use these 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) "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.
(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) "Cyber knife" means a treatment device that is a frameless special stereotactic radiosurgery unit that consists of three key components: (i) an advanced, lightweight linear accelerator (linac) (this device is used to produce a high energy megavoltage of radiation), (ii) a robot which can point the linear accelerator from a wide variety of angles, and (iii) several x-ray cameras (imaging devices) that are combined with software to track patient position. The cameras obtain frequent pictures of the patient during treatment and use this information to target the radiation beam emitted by the linear accelerator.
(d) "DEDICATED STEREOTACTIC RADIOSURGERY UNIT" MEANS AN MRT UNIT FOR WHICH MORE THAN 90 PERCENT OF CASES WILL BE TREATED WITH RADIOSURGERY.
(e) "Department" means the Michigan Department of Community Health (MDCH).
(f) "Equivalent treatment visit" or "ETV" means a unit of measure, based on the type of treatment visit that reflects the relative average length of time one patient spends in one treatment visit in an MRT unit.
(g) "Excess ETVs" means the number of ETVs performed by an existing MRT service in excess of 10,000 per MRT unit. The number of MRT units used to compute excess ETVs shall include both existing and approved but not yet operational MRT units. In the case of an MRT service that operates or has a valid CON to operate that has more than one MRT unit at the same site; the term means number of ETVs in excess of 10,000 multiplied by the number of MRT units at the same site. For example, if an MRT service operates, or has a valid CON to operate, two MRT units at the same site, the excess ETVs is the number that is in excess of 20,000 (10,000 x 2) ETVs.
(h) "Gamma knife" means a special stereotactic radiosurgery unit consisting of multiple cobalt sources all simultaneously focused to irradiate cancer or other neoplasms in the brain or cerebrovascular system abnormalities.
(i) "Heavy particle accelerator" means a machine such as a cyclotron which produces beams of high energy particles such as protons, neutrons, pions, carbon ions, or other heavy ions with masses greater than that of an electron.
(j) "High MRT unit" or "HMRT unit" means a heavy particle accelerator or any other MRT unit operating at an energy level equal to or greater than 30.0 million electron volts (megavolts or MEV).

(k) "Intensity modulated radiation therapy" or "IMRT" means a visit utilizing only the computer controlled multi-leaf collimator part of the CMS definition for IMRT.

(l) "Intraoperative MRT unit" or "IORT unit" means an MRT unit that is designed to emit only electrons, located in an operating room in the surgical department of a licensed hospital and available for the treatment of a patient undergoing a surgical procedure with megavoltage radiation.

(m) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and1396r-8 to 1396v.

(n) "Megavoltage radiation therapy" or "MRT" means a clinical modality in which patients with cancer, other neoplasms, or cerebrovascular system abnormalities, OR CERTAIN BENIGN CONDITIONS are treated with radiation which is delivered by a MRT unit.

(o) "MRT service" means the CON approved MRT utilization of a MRT unit(s) at one geographic location.

(p) "MRT unit" or "unit" means a CON approved linear accelerator; cobalt unit; or other piece of medical equipment operating at an energy level equal to or greater than 1.0 million electron volts (megavolts or MEV) for the purpose of delivering doses of radiation to patients with cancer, other neoplasms, or cerebrovascular system abnormalities.

(q) "Michigan Cancer Surveillance Program" means the program for the collection and analysis of information on cancer in Michigan operated by the Department mandated by Act 82 of 1984, being Section 333.2619 of the Michigan Compiled Laws.

(r) "Non-special MRT unit" or "non-special unit" means an MRT unit other than an MRT unit meeting the definition of a special purpose MRT unit or an HMRT unit.

(s) "Simulation" means the precise mock-up of a patient treatment with an apparatus that uses a diagnostic x-ray tube, MAGNETIC RESONANCE IMAGING DEVICE, OR COMPUTED TOMOGRAPHY SCANNER, WHICH IS USED IN REPRODUCING THE TWO-DIMENSIONAL OR THREE-DIMENSIONAL INTERNAL OR EXTERNAL GEOMETRY OF THE PATIENT, FOR USE IN TREATMENT PLANNING AND DELIVERY and duplicates an MRT unit in terms of its geometrical, mechanical, and optical properties.

(t) "Special purpose MRT unit" or "special purpose unit" or "special unit" means any of the following types of MRT units: (i) gamma knife, (ii) dedicated stereotactic radiosurgery unit, (iii) dedicated total body irradiator (TBI), OR (iv) an OR-based IORT unit, or (v) cyber knife.

(u) "Total body irradiator" or "TBI" means a specially modified dedicated cobalt unit certified as a total body irradiator by the Nuclear Regulatory Commission (NRC) or a permanently modified dedicated linear accelerator that uses a very wide beam of gamma rays or x-rays to irradiate the entire body simultaneously.

(v) "Treatment site" means the anatomical location of the MRT treatment.

(w) "Treatment visit" means one patient encounter during which MRT is administered AND BILLED. One treatment visit may involve one or more treatment ports or fields. Each separate encounter by the same patient at different times of the same day shall be counted as a separate treatment visit.

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

Section 3. Requirements to initiate an MRT service

Sec. 3. Initiate means the establishment of an MRT service where an MRT service is not currently provided. The term does not include replacement of an existing MRT service. An applicant proposing to initiate an MRT service shall demonstrate the following, as applicable to the proposed project.

(1) An applicant proposing to initiate an MRT service shall demonstrate the following:

(a) The applicant projects 8,000 equivalent treatment visits for each proposed unit.

(b) The proposed MRT unit is not a special purpose MRT unit.

(2) An applicant that demonstrates all of the following shall not be required to be in compliance with the requirement in subsection (1):
(a) The site of the proposed MRT service is located in a rural or micropolitan statistical area county.

(b) The site of the proposed MRT service is 60 driving miles or more, verifiable by the Department, from the nearest MRT service.

(c) The applicant projects 5,500 equivalent treatment visits for each proposed unit.

(d) The proposed MRT unit is not a special purpose MRT unit.

(3) An applicant that demonstrates all of the following shall not be required to be in compliance with the requirement in subsection (1):

(a) The applicant is a hospital licensed under part 215 of the Code.

(b) The site of the proposed MRT service is a hospital licensed under part 215 of the Code and located in planning area 8.

(c) The site of the proposed MRT service is 90 driving miles or more, verifiable by the department, from the nearest MRT service.

(d) The applicant provides comprehensive imaging services including at least the following:

(i) Fixed magnetic resonance imaging (MRI) services,

(ii) Fixed computed tomography (CT) services, and

(iii) Mobile positron emission tomography (PET) services.

(e) The proposed MRT unit is not a special purpose MRT unit.

(4) An applicant proposing to initiate an MRT service with an HMRT unit shall demonstrate the following:

(a) The applicant is a single legal entity authorized to do business in the State of Michigan.

(b) The applicant is a collaborative that consists of at least 40% of all Michigan-based hospital MRT services with more than 30,000 equivalent treatment visits based on the most current data available to the Department. Hospital MRT service means an MRT service owned by a hospital or owned by a corporation that is itself wholly owned by hospital(s).

(c) The applicant shall include hospital MRT services from more than one planning area from one or both of the following:

(i) Hospital MRT services qualified under subsection (b).

(ii) Hospital MRT services with the highest number of equivalent treatment visits in a planning area.

(d) Equivalent treatment visits for this subsection shall be those from the most recent CON Annual Survey.

(e) An application shall not be approved if it includes an MRT service described in subsection (i) or (ii) except as provided in subsections (iii) or (iv).

(i) An MRT service that was part of another application under this subsection.

(ii) An MRT service owned by, under common control of, or has a common parent, as an MRT service under subsection (i).

(iii) The prior application, or the approved CON, were subsequently disapproved or withdrawn.

(iv) The application includes a commitment from the MRT service described in subsection (i) to surrender the CON, or application, described in subsection (i) and that commitment is fulfilled at the time the application under this section is approved.

(f) An application shall not be approved if it includes any of the following:

(i) An MRT service that is approved but not operational, or that has a pending application, for a heavy particle accelerator.

(ii) An MRT service that is owned by, under common control of, or has a common parent, as an MRT service described by subsection (i), unless the application under this subsection includes a commitment from the MRT service described in subsection (i) to surrender the CON, or application, described in subsection (i) and that commitment is fulfilled at the time the application under this section is approved.

(g) An application shall not be approved if it includes any of the following:

(i) An MRT service that is approved for a heavy particle accelerator that is operational.

(ii) An MRT service that is owned by, under common control of, or has a common parent, as an MRT service described by subsection (i), unless the application under this section includes a commitment from the MRT service described in subsection (i) to surrender the CON described in subsection (i), and that commitment is fulfilled at the time the HMRT unit is approved and operational under this subsection.
(h) The applicant shall provide documentation of its process, policies and procedures, acceptable to the Department that allows any other interested entities to participate in the collaborative utilization of the HMRT unit.

(i) The applicant shall provide an implementation plan, acceptable to the Department, for financing and operating the MRT service utilizing an HMRT that includes how physician staff privileges, patient review, patient selection, and patient care management shall be determined.

(j) The applicant shall indicate that its proposed HMRT unit will be available to both adult and pediatric patients.

(k) The applicant shall demonstrate simulation capabilities available for use in treatment planning.

(5) Applicants under this section shall demonstrate the following staff will be provided:

(a) One (1) FTE board-certified or board-qualified physician trained in radiation oncology.

(b) One (1) board-certified or board-qualified radiation physicist certified in therapeutic radiologic physics.

(c) One (1) dosimetrist, a person who is familiar with the physical and geometric characteristics of the radiation equipment and radioactive sources commonly employed and who has the training and expertise necessary to measure and generate radiation dose distributions and calculations under the direction of a medical physicist and/or a radiation oncologist.

(d) Two (2) FTE radiation therapists registered or eligible by the American Registry of Radiological Technologists (ARRT).

(e) One (1) program director who is a board-certified physician trained in radiation oncology who may also be the physician required under subsection (5)(a).

Section 4. Requirements to replace an existing MRT unit or service

Sec. 4. Replacement of an existing MRT unit means an equipment change that results in a new serial number or requiring the issuance of a new radiation safety certificate from the State of Michigan Radiation Safety Section. Replacement also means the relocation of an MRT service or unit to a new site. Replacement does not include an upgrade to an existing MRT unit with the addition or modification of equipment or software; the replacement components; or change for the purpose of maintaining or improving its efficiency, effectiveness, and/or functionality. An applicant requesting to replace an existing MRT unit(s) or MRT service shall demonstrate the following, as applicable to the proposed project.

(1) An applicant proposing to replace an existing MRT unit(s) shall demonstrate the following:

(a) The replacement unit(s) is the same type as the MRT unit(s) to be replaced A NON-SPECIAL UNIT AND IS REPLACING A NON-SPECIAL UNIT, OR IS A SPECIAL PURPOSE UNIT AND IS REPLACING A NON-SPECIAL PURPOSE UNIT OR A SPECIAL PURPOSE UNIT.

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

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

(ii) The replacement MRT unit(s) offers technological improvements that enhance quality of care, increased efficiency, and a reduction in operating costs and patient charges.

(c) The applicant agrees that the unit(s) to be replaced will be removed from service on or before beginning operation of the replacement unit(s).

(d) THE SITE AT WHICH A SPECIAL PURPOSE UNIT IS REPLACED SHALL CONTINUE TO OPERATE A NON-SPECIAL PURPOSE UNIT.

(2) An applicant proposing to replace an existing MRT service to a new site shall demonstrate the following:

(a) The proposed site is within the same planning area as the existing MRT service site.

(b) The existing MRT unit(s) shall be operating at the following volumes, as applicable to the proposed project:

(i) Non-special MRT unit(s) at 8,000 equivalent treatment visits per unit or 5,500 for a unit approved under Section 3(2) or 3(3).

(ii) HMRT unit(s) at 8,000 equivalent treatment visits per unit.
(iii) Special purpose unit(s) at 1,000 equivalent treatment visits per unit.

(3) An applicant proposing to replace an MRT unit(s) of an existing MRT service to a new site shall demonstrate the following:
(a) The applicant is the same legal entity as the existing MRT service.
(b) For volume purposes, the new site shall remain associated with the existing MRT service for a minimum of three years.
(c) The MRT unit(s) to be relocated is a non-special MRT unit(s).
(d) The existing non-special MRT unit(s) of the MRT services from where the unit is being relocated from shall be operating at a minimum average volume of 8,000 equivalent treatment visits per unit.

(e) The proposed site meets the requirements of Section 3(45).
(f) The proposed site is within the same planning area as the existing MRT service site.
(g) The existing MRT service has been in operation for at least 36 months as of the date the application was submitted to the Department.

Section 5. Requirements to expand an existing MRT service

Sec. 5. An applicant proposing to expand an existing MRT service by adding an MRT unit(s) shall demonstrate the following, as applicable to the proposed project.

(1) An applicant proposing to add a non-special MRT unit(s) shall demonstrate an average of 10,000 equivalent treatment visits was performed in the most recent 12-month period on each of the applicant's existing and approved non-special MRT units.

(2) An applicant proposing to expand an existing MRT service with a special purpose MRT unit shall demonstrate the following, as applicable to the proposed project:
(a) An average of 8,000 equivalent treatment visits was performed in the most recent 12-month period on each of the applicant's existing and approved non-special MRT units AND AN AVERAGE OF 1,000 EQUIVALENT TREATMENT VISITS WAS PERFORMED IN THE MOST RECENT 12-MONTH PERIOD ON EACH OF THE APPLICANT'S EXISTING AND APPROVED SPECIAL PURPOSE MRT UNITS.
(b) An applicant proposing to add a dedicated total body irradiator shall operate a bone marrow transplantation program or have a written agreement to provide total body irradiation services to a hospital that operates a bone marrow transplantation program.
(c) An applicant proposing to add a dedicated stereotactic radiosurgery unit such as a gamma knife or cyber knife, shall demonstrate that the applicant has a contractual relationship with a board-eligible or board-certified neurosurgeon(s) trained in stereotactic radiosurgery and on-site 3-dimensional imaging and 3-dimensional treatment planning capabilities.
(d) An applicant proposing to add an intraoperative MRT unit in an existing or proposed hospital operating room shall demonstrate that the unit is a linear accelerator with only electron beam capabilities.

Section 6. Requirements to acquire an existing MRT service

Sec. 6. Acquiring an existing MRT service means obtaining possession and control by contract, ownership, lease, or another comparable arrangement and renewal of lease for an existing MRT unit(s). An applicant proposing to acquire an MRT service shall demonstrate the following, as applicable to the proposed project.

(1) For the first application proposing to FOR THE FIRST acquire acquisition OF an existing MRT service, other than the renewal of a lease, on or after November 21, 2011, the existing MRT service shall not be required to be in compliance with the applicable volume requirements set forth in this section. THE MRT 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.

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(2) an applicant proposing to acquire an existing MRT service shall demonstrate the following:

   (a) The existing MRT unit(s) shall be operating at the following volumes, as applicable to the
       proposed project:
           (i) Non-special MRT unit(s) at 8,000 equivalent treatment visits per unit or 5,500 for a unit approved
               under Section 3(2) or 3(3).
           (ii) HMRT unit(s) at 8,000 equivalent treatment visits per unit.
           (iii) Special purpose unit(s) at 1,000 equivalent treatment visits per unit.

   FOR ANY APPLICATION PROPOSING TO ACQUIRE AN EXISTING MRT SERVICE, EXCEPT THE FIRST APPLICATION
   APPROVED PURSUANT TO SUBSECTION (1), AN APPLICANT SHALL BE REQUIRED TO
   DOCUMENT THAT THE MRT SERVICE TO BE ACQUIRED IS OPERATING IN COMPLIANCE WITH
   THE VOLUME REQUIREMENTS SET FORTH IN SECTION 11 OF THESE STANDARDS APPLICABLE
   TO AN EXISTING MRT SERVICE ON THE DATE THE APPLICATION IS SUBMITTED TO THE
   DEPARTMENT.

   (3) An applicant proposing to renew a lease for an existing MRT unit shall demonstrate the renewal
       of the lease is more cost effective than replacing the equipment.

Section 7. Requirements for a dedicated research MRT unit(s)

Sec. 7. An applicant proposing to add a dedicated research MRT unit shall demonstrate the
following:

(1) The applicant is an existing MRT service.

(2) The applicant agrees that the dedicated research MRT unit(s) will be used primarily (70% or more
    of treatments) for research purposes.

(3) The dedicated research MRT unit(s) shall operate under a protocol approved by the applicant’s
    Institutional Review Board (IRB), as defined by Public Law 93-348 and regulated by Title 45 CFR 46.

(4) The applicant operates a therapeutic radiation residency program approved by the American
    Medical Association, the American Osteopathic Association, or an equivalent organization.

(5) The proposed site can have no more than two dedicated research MRT units.

Section 8. Requirements for Medicaid participation

Sec. 8. 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 six (6) months from the offering of services, if a CON is approved.

Section 9. Methodology for projecting equivalent treatment visits

Sec. 9. An applicant being reviewed under Section 3 shall apply the methodology set forth in this
section in computing the projected number of equivalent treatment visits.

(1) An applicant shall demonstrate that the projection is based on the commitments of the
treatments provided by the treating physician(s) for the most recent 12-month period immediately
preceding the date of the application. The commitments of the treating physician(s) will be verified with
the data maintained by the Department through its “CON Annual Survey.”

(a) For the purposes of this section, treating physician means the staff physician of the MRT service
directing and providing the MRT treatment, not the referring physician.

(2) An applicant shall demonstrate that the projected number of commitments to be performed at the
proposed site under subsection (1) are from an existing MRT service that is in compliance with the
volume requirements applicable to that service, and will continue to be in compliance with the volume
requirements applicable to that service subsequent to the initiation of the proposed MRT service by an
applicant. Only excess ETVs equal to or greater than what is being committed pursuant to this
subsection may be used to document projections under subsection (1). In demonstrating compliance with
this subsection, an applicant shall provide each of the following:

(a) A written commitment from each treating physician that he or she will treat at least the volume of
MRT treatments to be transferred to the proposed MRT service for no less than 3 years subsequent to
the initiation of the MRT service proposed by an applicant.

(b) The number of treatments committed must have resulted in an actual treatment of the patient at
the existing MRT service from which the treatment will be transferred. The committing physician must
make available HIPAA compliant audit material if needed upon Department request to verify referral
sources and outcomes. Commitments must be verified by the most recent data set maintained by the
Department through its “CON Annual Survey.”

Section 10. Equivalent treatment visits

Sec. 10. Equivalent treatment visits shall be calculated as follows:

(1) For the time period specified in the applicable sections, assign each actual treatment visit
provided to one applicable treatment visit category set forth in Table 1.

(2) The number of treatment visits for each category in the time period specified in the applicable
section(s) of these standards shall be multiplied by the corresponding equivalent treatment visits weight in
Table 1 to determine the number of equivalent treatment visits for that category for that time period.

(3) The number of equivalent treatment visits for each category determined pursuant to subsection
(2) shall be summed to determine the total equivalent treatment visits for the time period specified in the
applicable sections of these standards.

TABLE 1
Equivalent Treatments

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<th>Treatment Visit Category</th>
<th>Non-Special Visit Weight</th>
<th>Special Visit Weight</th>
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<tr>
<td>Stereotactic radio-surgery/radio-therapy**</td>
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<tr>
<td>IORT (non-gamma knife and cyber knife**)</td>
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<tr>
<td>Gamma Knife**</td>
<td>8.00</td>
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</table>

All patients under 5 years of age receive a 2.00 additive factor.

GATING RECEIVES A 1.00 ADDITIVE FACTOR. GATING IS THE CAPTURING AND MONITORING
OF THE TARGET’S OR FIDUCIAL’S MOTION DURING RADIATION TREATMENT AND THE
MODULATION OF THE RADIATION BEAM IN ORDER TO MORE PRECISELY DELIVER RADIATION
TO THE TARGET AND/OR DECREASE THE RADIATION DOSE TO THE SURROUNDING NORMAL
TISSUE.
After the first visit, each additional visit receives 2.5 additional equivalent treatment visits with a maximum of five visits per course of therapy.

After the first isocenter, each additional isocenter receives 4-6 additional equivalent treatment visits. THERE IS A MAXIMUM OF FIVE VISITS PER COURSE OF THERAPY.

(4) “Simple treatment visit” means a treatment visit involving a single treatment site, single treatment field, or parallel opposed fields with the use of no more than simple blocks.

(5) “Intermediate treatment visit” means a treatment visit involving two separate treatment sites, three or more fields to a single treatment site, or the use of special blocking.

(6) “Complex treatment visit” means a treatment visit involving three or more treatment sites, tangential fields with wedges, rotational or arc techniques or other special arrangements, or custom blocking.

(7) “IMRT treatment visit” means a visit utilizing only the computer controlled multi-leaf collimator part of the CMS definition for IMRT.

(8) “Stereotactic treatment visit” means a visit involving the use of a stereotactic guiding device with radiotherapy for the ablation of a precisely defined intracranial and/or extracranial tumor or lesion.

(9) “Intraoperative treatment visit” means a treatment visit where a dose of megavoltage radiation is delivered to a surgically exposed neoplasm or cancerous organ/site using a dedicated unit.

(10) “Isocenter” means the virtual point in space about which the MRT unit operates and is placed at the center of the tumor for the delivery of the radiation treatment.

(11) “Course of treatment” means the planned series of visits that compose a plan for treatment of one or more cancer sites for a single patient.

Section 11. Project delivery requirements terms of approval for all applicants

Sec. 11. An applicant shall agree that, if approved, the MRT service, including all existing and approved MRT units, shall be delivered in compliance with the following:

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

(a) An applicant shall assure that the MRT service is staffed and operated by physicians and/or radiation therapists qualified by training and experience to operate the unit safely and effectively. The Department shall consider it prima facie evidence if the applicant requires the equipment to be operated by a physician who is board certified or board qualified in either radiation oncology or therapeutic radiology, and/or a radiation therapist certified by the American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT). The applicant may also submit, and the Department may accept, other evidence. An applicant approved to operate a dedicated stereotactic radiosurgery unit or a gamma knife has on the active medical staff a neurosurgeon(s) trained in the special type of MRT unit being operated.

(b) An applicant shall have the following staff:

(i) One (1) full-time equivalent (FTE) board-certified or board-qualified physician trained in radiation oncology for each 250 patients treated with MRT annually.

(ii) One (1) FTE board-certified or board-qualified radiation physicist, certified in therapeutic radiologic physics, immediately available during hours of operation.
(iii) One (1) dosimetrist for every 300 patients treated with MRT annually.

(iv) Two (2) radiation therapists registered or eligible by the American Registry of Radiological Technologists (ARRT), for every MRT unit per shift of operation (not including supervisory time).

(v) One (1) FTE program director who is a board-certified physician trained in radiation oncology who may also be the physician required under subsection (i). 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 radiation oncology and/or therapeutic radiology.

(c) All MRT treatments shall be performed pursuant to a radiation oncologist and at least one radiation oncologist will be immediately available during the operation of the unit(s).

(d) An applicant shall have equipment and supplies to handle clinical emergencies that might occur.

(e) An applicant shall operate a cancer treatment program. The Department shall consider it prima facie evidence if the applicant submits evidence of a cancer treatment program approved by the American College of Surgeons Commission on Cancer. A cancer treatment program is a coordinated, multi-disciplinary approach to the treatment of patients with cancer or other neoplasms, which must provide on-site simulation capability, and, either on-site or through written agreements with other providers, all of the following services: access to consultative services from all major disciplines needed to develop a comprehensive treatment plan, a computer-based treatment planning system, medical radiation physicist involvement, MRT capability including electron beam capability, treatment aid fabrication capability, brachytherapy, a multi-disciplinary cancer committee, a tumor registry, patient care evaluation studies, and cancer prevention and education programs. The applicant may also submit, and the Department may accept, other evidence. Patient care evaluation studies means a system of patient care evaluation, conducted at least twice annually, that documents the methods used to identify problems and the opportunities to improve patient care. Tumor registry means a manual or computerized data base containing information about all malignancies and only those that are diagnosed and/or treated at the applicant's facility. The malignancies must be reportable to the Michigan Cancer Surveillance Program as required pursuant to Public Act 82 of 1984, as amended.

(i) An applicant shall submit evidence of accreditation by the American College of Surgeons Commission on cancer, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), or the Healthcare Facilities Accreditation Program (HFAP) within the first three years of operation and continue to participate annually thereafter.

(ii) An applicant shall submit evidence of accreditation by the American Society for Radiation Oncology (ACR/ASTRO) or the American College of Radiation Oncology (ACRO) within the first three years of operation and continue to participate annually thereafter.

(f) The MRT service will have simulation capability at the same location.

(g) An applicant shall participate in the Michigan Cancer Surveillance Program.

(h) The applicant agrees to operate a special purpose MRT unit(s) only for the specific use for which it was approved.

(i) An applicant approved to operate a dedicated total body irradiator that uses cobalt as the source of radiation shall obtain and maintain Nuclear Regulatory Commission certification. An applicant approved to operate a dedicated total body irradiator that is a permanently modified linear accelerator, or an HMRT unit, shall meet any requirements specified by the State of Michigan Radiation Safety Section.

(j) All patients treated on an HMRT unit shall be evaluated for potential enrollment in research studies focusing on the applicability and efficacy of utilizing an HMRT unit for treatment of specific cancer conditions. The number of patients treated, number enrolled in research studies, and the types of cancer conditions involved shall be provided to the Department as part of the CON Annual Survey.

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

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

(a) The applicant shall accept referrals for MRT services from all appropriately licensed health care practitioners.
(b) To assure that the MRT service and its unit(s) will be utilized by all segments of the Michigan population, the applicant shall:

(i) not deny MRT services to any individual based on ability to pay or source of payment,

(ii) provide MRT services to an individual based on the clinical indications of need for the service, and

(iii) 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.

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

(4) Compliance with the following monitoring and reporting requirements:

(a) Non-special MRT units and HMRT units shall be operating at a minimum average volume of 8,000 Equivalent Treatment Visits per unit annually by the end of the third full year of operation, and annually thereafter. All special purpose MRT units shall be operating at a minimum average volume of 1,000 equivalent treatment visits per special purpose unit by the end of the third full year of operation, and annually thereafter. An applicant shall not include any treatments conducted on a dedicated research MRT unit.

(b) Non-special MRT units and HMRT units approved pursuant to Section 3(2) or 3(3) of these standards shall be operating at a minimum average volume of 5,500 equivalent treatment visits per unit by the end of the third full year of operation, and annually thereafter. An applicant shall not include any treatments conducted on a dedicated research MRT unit.

(c) An applicant is not required to be in compliance with subsections (4)(a) or (b) if the applicant is replacing an MRT unit under section 4(1).

(d) An applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, 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 and other data requested by the Department. Data shall be provided by each type of MRT unit in a format established by the Department and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(e) Services provided on a dedicated research MRT unit shall be delivered in compliance with the following terms:

(i) Capital and operating costs for research treatment visits shall be charged only to a specific research account(s) and not to any patient or third-party payor.

(ii) The dedicated research MRT unit shall not be used for any purposes other than as approved by the IRB.

(iii) The treatments on a dedicated research MRT unit shall not be used for any volume purposes.

(5) The applicable 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. Effect on prior CON review standards; comparative reviews

Sec. 12. proposed projects reviewed under these standards shall not be subject to comparative review. These standards supersede and replace the CON Review Standards for MRT Services/Units approved by the CON Commission on September 22, 2011/MARCH 28, 2013 and effective November 21, 2011/MAY 24, 2013.
## APPENDIX A

### PLANNING AREAS BY COUNTY

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## APPENDIX B

Rural Michigan counties are as follows:

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Micropolitan statistical area Michigan counties are as follows:

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Metropolitan statistical area Michigan counties are as follows:

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Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget
MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

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

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

Section 1. Applicability

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

Section 2. Definitions

Sec. 2. (1) For purposes of these standards:
(a) "Central service coordinator" means the legal entity that has operational responsibility for a mobile PET scanner service.
(b) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.
(c) "Department" means the Michigan Department of Community Health (MDCH).
(d) "Existing PET scanner" means an operational PET scanner used to provide PET services on the date an application is submitted to the Department.
(e) "Existing PET scanner service" means an operational PET scanner service providing PET scanner services at one site in the case of a fixed PET service or at each host site in the case of a mobile PET service on the date an application is submitted to the Department.
(f) "Health service area" or "HSA" means the groups of counties listed in Appendix A.
(g) "Hospital" means a health facility licensed under Part 215 of the Code.
(h) "Host site" means the geographic address at which a mobile PET scanner is authorized by CON to provide mobile PET scanner services.
(i) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C.1396 to 1396g and 1396i to 1396u.
(j) "Michigan Inpatient Data Base" or "MIDB" means the data base compiled by the Michigan Health and Hospital Association or successor organization. The data base consists of inpatient discharge records from all Michigan hospitals and Michigan residents discharged from hospitals in border states for a specific calendar year.
(k) "Mobile PET scanner" means a PET scanner unit and transporting equipment operated by a central service coordinator that serves two or more host sites.
(l) "Mobile PET scanner network" means the route (i.e., all host sites) that the central service coordinator is authorized to serve under CON.
(m) "Patient visit" means a single session utilizing a PET scanner during which 1 or more PET procedures are performed.
(n) "Pediatric patient" means any patient less than 18 years of age.
(o) "PET procedure" means the acquisition of a single image or image sequence involving a single injection of tracer.
(p) "PET scan" means one (1) or more PET procedures performed during a single patient visit.
(q) "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.

(r) "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.

(s) "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) 1,700 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 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.
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.

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. Requirement for Medicaid participation

Sec. 10. 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 11. Project delivery requirements and terms of approval for all applicants

Sec. 11. 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(45), 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. Methodology for computing the projected PET data units

Sec. 12. 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 13.

(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), 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 13.

(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 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, see Appendix D for ICD-10-CM Codes) 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. Commitment of diagnosis-specific new cancer cases

Sec. 13. 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 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 14. 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.
Section 15. 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.

Section 16. 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 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. Methodology for computing PET equivalents

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

<p>| TABLE 1 |
| PET EQUIVALENTS |</p>
<table>
<thead>
<tr>
<th>Scan Category</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simple 1</td>
<td>0.75</td>
</tr>
<tr>
<td>Standard 2</td>
<td>1.0</td>
</tr>
<tr>
<td>Complex 3</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 18. Department inventory of PET scanners

Sec. 18. The Department shall maintain and publicly post on its web site a list of PET scanner
services annually.

Section 19. Comparative reviews; effect on prior planning policies

Sec. 19. Proposed projects reviewed under these standards shall not be subject to comparative
review. These CON review standards supersede and replace the CON standards for PET scanner
services approved by the CON Commission on June 14, 2012, March 18, 2014 and effective September
APPENDIX A

Counties assigned to each health service area are as follows:

<table>
<thead>
<tr>
<th>HEALTH SERVICE AREA</th>
<th>COUNTIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Livingston        Monroe       St. Clair</td>
</tr>
<tr>
<td></td>
<td>Macomb            Oakland      Washtenaw</td>
</tr>
<tr>
<td></td>
<td>Wayne</td>
</tr>
<tr>
<td>2</td>
<td>Clinton           Hillsdale    Jackson</td>
</tr>
<tr>
<td></td>
<td>Eaton             Ingham       Lenawee</td>
</tr>
<tr>
<td>3</td>
<td>Barry             Calhoun      St. Joseph</td>
</tr>
<tr>
<td></td>
<td>Berrien           Cass         Van Buren</td>
</tr>
<tr>
<td></td>
<td>Branch            Kalamazoo</td>
</tr>
<tr>
<td>4</td>
<td>Allegan           Mason        Newaygo</td>
</tr>
<tr>
<td></td>
<td>Ionia             Mecosta      Oceana</td>
</tr>
<tr>
<td></td>
<td>Kent              Montcalm     Osceola</td>
</tr>
<tr>
<td></td>
<td>Lake              Muskegon     Ottawa</td>
</tr>
<tr>
<td>5</td>
<td>Genesee           Lapeer       Shiawassee</td>
</tr>
<tr>
<td>6</td>
<td>Arenac            Huron        Roscommon</td>
</tr>
<tr>
<td></td>
<td>Bay               Iosco        Saginaw</td>
</tr>
<tr>
<td></td>
<td>Clare             Isabella     Sanilac</td>
</tr>
<tr>
<td></td>
<td>Gladwin           Midland      Tuscola</td>
</tr>
<tr>
<td></td>
<td>Gratiot           Ogemaw</td>
</tr>
<tr>
<td>7</td>
<td>Alcona            Crawford     Missaukee</td>
</tr>
<tr>
<td></td>
<td>Alpena            Emmet        Montmorency</td>
</tr>
<tr>
<td></td>
<td>Antrim            Gd Traverse  Oscoda</td>
</tr>
<tr>
<td></td>
<td>Benzie            Kalkaska     Otsego</td>
</tr>
<tr>
<td></td>
<td>Charlevoix        Leelanau     Presque Isle</td>
</tr>
<tr>
<td></td>
<td>Cheboygan         Manistee     Wexford</td>
</tr>
<tr>
<td>8</td>
<td>Alger             Gogebic      Mackinac</td>
</tr>
<tr>
<td></td>
<td>Baraga            Houghton     Marquette</td>
</tr>
<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>
</tr>
</tbody>
</table>
Counties by Health service areas assigned to each planning area are as follows:

### APPENDIX B

<table>
<thead>
<tr>
<th>COUNTIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>COUNTY</td>
</tr>
<tr>
<td>Planning Area 1</td>
</tr>
<tr>
<td>Livingston</td>
</tr>
<tr>
<td>Macomb</td>
</tr>
<tr>
<td>Wayne</td>
</tr>
<tr>
<td>Planning Area 2</td>
</tr>
<tr>
<td>Clinton</td>
</tr>
<tr>
<td>Eaton</td>
</tr>
<tr>
<td>Barry</td>
</tr>
<tr>
<td>Berrien</td>
</tr>
<tr>
<td>Branch</td>
</tr>
<tr>
<td>Planning Area 3</td>
</tr>
<tr>
<td>Allegan</td>
</tr>
<tr>
<td>Ionia</td>
</tr>
<tr>
<td>Kent</td>
</tr>
<tr>
<td>Lake</td>
</tr>
<tr>
<td>Planning Area 4</td>
</tr>
<tr>
<td>Genesee</td>
</tr>
<tr>
<td>Arenac</td>
</tr>
<tr>
<td>Bay</td>
</tr>
<tr>
<td>Clare</td>
</tr>
<tr>
<td>Gladwin</td>
</tr>
<tr>
<td>Gratiot</td>
</tr>
<tr>
<td>Planning Area 5</td>
</tr>
<tr>
<td>Alcona</td>
</tr>
<tr>
<td>Alpena</td>
</tr>
<tr>
<td>Antrim</td>
</tr>
<tr>
<td>Benzie</td>
</tr>
<tr>
<td>Charlevoix</td>
</tr>
<tr>
<td>Cheboygan</td>
</tr>
<tr>
<td>Planning Area 6</td>
</tr>
<tr>
<td>Alger</td>
</tr>
<tr>
<td>Baraga</td>
</tr>
<tr>
<td>Chippewa</td>
</tr>
<tr>
<td>Delta</td>
</tr>
<tr>
<td>Dickinson</td>
</tr>
</tbody>
</table>
### APPENDIX C

Rural Michigan counties are as follows:

<table>
<thead>
<tr>
<th>Alcona</th>
<th>Hillsdale</th>
<th>Oceana</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alger</td>
<td>Huron</td>
<td>Ogemaw</td>
</tr>
<tr>
<td>Antrim</td>
<td>Iosco</td>
<td>Ontonagon</td>
</tr>
<tr>
<td>Arenac</td>
<td>Iron</td>
<td>Osceola</td>
</tr>
<tr>
<td>Baraga</td>
<td>Lake</td>
<td>Oscoda</td>
</tr>
<tr>
<td>Charlevoix</td>
<td>Luce</td>
<td>Otsego</td>
</tr>
<tr>
<td>Cheboygan</td>
<td>Mackinac</td>
<td>Presque Isle</td>
</tr>
<tr>
<td>Clare</td>
<td>Manistee</td>
<td>Roscommon</td>
</tr>
<tr>
<td>Crawford</td>
<td>Mason</td>
<td>Sanilac</td>
</tr>
<tr>
<td>Emmet</td>
<td>Montcalm</td>
<td>Schoolcraft</td>
</tr>
<tr>
<td>Gladwin</td>
<td>Montmorency</td>
<td>Tuscola</td>
</tr>
<tr>
<td>Gogebic</td>
<td>NEWAYGO</td>
<td></td>
</tr>
</tbody>
</table>

Micropolitan statistical area Michigan counties are as follows:

<table>
<thead>
<tr>
<th>Allegan</th>
<th>HILLSDALE</th>
<th>MASON</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpena</td>
<td>Houghton</td>
<td>Mecosta</td>
</tr>
<tr>
<td>Benzie</td>
<td>Ionia</td>
<td>Menominee</td>
</tr>
<tr>
<td>Branch</td>
<td>Isabella</td>
<td>Midland</td>
</tr>
<tr>
<td>Chippewa</td>
<td>Kalkaska</td>
<td>Missaukee</td>
</tr>
<tr>
<td>Delta</td>
<td>Keweenaw</td>
<td>St. Joseph</td>
</tr>
<tr>
<td>Dickinson</td>
<td>Leelanau</td>
<td>Shiawassee</td>
</tr>
<tr>
<td>Grand Traverse</td>
<td>Lenawee</td>
<td>Wexford</td>
</tr>
<tr>
<td>Gratiot</td>
<td>Marquette</td>
<td></td>
</tr>
</tbody>
</table>

Metropolitan statistical area Michigan counties are as follows:

<table>
<thead>
<tr>
<th>Barry</th>
<th>Ionia</th>
<th>MONTCALMNEWAYGO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bay</td>
<td>Jackson</td>
<td>Muskegon</td>
</tr>
<tr>
<td>Berrien</td>
<td>Kalamazoo</td>
<td>Oakland</td>
</tr>
<tr>
<td>Calhoun</td>
<td>Kent</td>
<td>Ottawa</td>
</tr>
<tr>
<td>Cass</td>
<td>Lapeer</td>
<td>Saginaw</td>
</tr>
<tr>
<td>Clinton</td>
<td>Livingston</td>
<td>St. Clair</td>
</tr>
<tr>
<td>Eaton</td>
<td>Macomb</td>
<td>Van Buren</td>
</tr>
<tr>
<td>Genesee</td>
<td>MIDLAND</td>
<td>Washtenaw</td>
</tr>
<tr>
<td>Ingham</td>
<td>Monroe</td>
<td>Wayne</td>
</tr>
</tbody>
</table>

Source:

65.75 F.R., p. 82238-37245 (December 27JUNE 28, 20002010)  
Statistical Policy Office  
Office of Information and Regulatory Affairs  
United States Office of Management and Budget
<table>
<thead>
<tr>
<th>ICD-9 CODE</th>
<th>DESCRIPTION</th>
<th>ICD-10 CODE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>345.01</td>
<td>Intractable Epilepsy Cases</td>
<td>G40.311</td>
<td>Generalized Idiopathic Epilepsy and Epileptic Syndromes, Intractable, with</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Status Epilepticus</td>
</tr>
<tr>
<td></td>
<td></td>
<td>G40.319</td>
<td>Generalized Idiopathic Epilepsy and Epileptic Syndromes, Intractable,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>without Status Epilepticus</td>
</tr>
<tr>
<td></td>
<td></td>
<td>G40.A11</td>
<td>Absence Epileptic Syndrome, Intractable, with Status Epilepticus</td>
</tr>
<tr>
<td>345.11</td>
<td>Intractable Epilepsy Cases</td>
<td>G40.311</td>
<td>Generalized Idiopathic Epilepsy and Epileptic Syndromes, Intractable, with</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Status Epilepticus</td>
</tr>
<tr>
<td></td>
<td></td>
<td>G40.319</td>
<td>Generalized Idiopathic Epilepsy and Epileptic Syndromes, Intractable,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>without Status Epilepticus</td>
</tr>
<tr>
<td>345.41</td>
<td>Intractable Epilepsy Cases</td>
<td>G40.211</td>
<td>Localization-Related (Focal) (Partial) Symptomatic Epilepsy and Epileptic</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Syndromes with Complex Partial Seizures, Intractable, with Status Epileptic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>G40.219</td>
<td>Localization-Related (Focal) (Partial) Symptomatic Epilepsy and Epileptic</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Syndromes with Complex Partial Seizures, Intractable, without Status Epileptic</td>
</tr>
<tr>
<td>345.51</td>
<td>Intractable Epilepsy Cases</td>
<td>G40.011</td>
<td>Localization-Related (Focal) (Partial) Idiopathic Epilepsy and Epileptic</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Syndromes with Seizures of Localized Onset, Intractable, with Status</td>
</tr>
<tr>
<td></td>
<td></td>
<td>G40.019</td>
<td>Localization-Related (Focal) (Partial) Idiopathic Epilepsy and Epileptic</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Syndromes with Seizures of Localized Onset, Intractable, without Status</td>
</tr>
<tr>
<td></td>
<td></td>
<td>G40.111</td>
<td>Localization-Related (Focal) (Partial) Symptomatic Epilepsy and Epileptic</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Syndromes with Simple Partial Seizures, Intractable, with Status Epileptic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>G40.119</td>
<td>Localization-Related (Focal) (Partial) Symptomatic Epilepsy and Epileptic</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Syndromes with Simple Partial Seizures, Intractable, without Status Epileptic</td>
</tr>
</tbody>
</table>
### APPENDIX D continued

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

"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.
June 11, 2015

Ascension – Michigan statement on OAG Performance Audit – Certificate of Need Program (MDHHS)

On behalf of Ascension – Michigan we applaud the CON Commission and the Michigan Department of Health and Human Services for your thoughtful and thorough response to the recommendations outlined in the April 2015 Performance Audit report of the Certificate of Need Program in your discussion earlier in today’s agenda. We recognize the significant work that the CON Commission undertakes to ensure that the overall objectives of the program in balancing cost, quality and access to healthcare services are achieved through development and modification of CON standards. Similarly, we acknowledge the diligent work the Department currently performs to ensure that these standards are implemented and that follow up activities and monitoring and enforcement activities are conducted.

Despite these current efforts we believe the recent Audit of the CON program identified areas of improvement that will serve to improve the program and provide additional transparency and accountability for all stakeholders. We support the findings of the Audit and and subsequently, we believe the Commission and Department’s response today illustrates your commitment to provide this enhanced accountability and integrity consistent with your responsibilities in your respective roles within the CON process. Specifically, by establishing a process to consistently document the Commission’s evaluation and assessment of the CON program and efforts by the Department to continue to improve its efforts to follow up approved CON projects in a timely manner to ensure that the applicants submit Project implementation progress reports and contracts on schedule and adequately document its monitoring of health facilities compliance with CON review standards to help ensure the quality of services provided by health facilities will achieve the aforementioned objectives.

Thank you for the opportunity to comment on the recent Office of Auditor General report on Michigan’s Certificate of Need Program
Please visit the link below for the OAG audit report:

This report is to update the Commission on Department activities to monitor compliance of all Certificates of Need recipients as required by Section 22247 of the Public Health Code.

**MCL 333.22247**

(1) The department shall monitor compliance with all certificates of need issued under this part and shall investigate allegations of noncompliance with a certificate of need or this part.

(2) If the department determines that the recipient of a certificate of need under this part is not in compliance with the terms of the certificate of need or that a person is in violation of this part or the rules promulgated under this part, the department shall do 1 or more of the following:
   (a) Revoke or suspend the certificate of need.
   (b) Impose a civil fine of not more than the amount of the billings for the services provided in violation of this part.
   (c) Take any action authorized under this article for a violation of this article or a rule promulgated under this article, including, but not limited to, issuance of a compliance order under section 20162(5), whether or not the person is licensed under this article.
   (d) Request enforcement action under section 22253.
   (e) Take any other enforcement action authorized by this code.
   (f) Publicize or report the violation or enforcement action, or both, to any person.
   (g) Take any other action as determined appropriate by the department.

(3) A person shall not charge to, or collect from, another person or otherwise recover costs for services provided or for equipment or facilities that are acquired in violation of this part. If a person has violated this subsection, in addition to the sanctions provided under subsection (2), the person shall, upon request of the person from whom the charges were collected, refund those charges, either directly or through a credit on a subsequent bill.

**Activity Report**

*Follow Up:* In accordance with Administrative Rules 325.9403 and 325.9417, the Department tracks approved Certificates of Need to determine if proposed projects have been implemented in accordance with Part 222. By rule, applicants are required to either implement a project within one year of approval or execute an enforceable contract to purchase the covered equipment or start construction, as applicable. In addition, an applicant must install the equipment or start construction within two years of approval.

<table>
<thead>
<tr>
<th>Activity</th>
<th>2nd Quarter</th>
<th>Year-to-Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved projects requiring 1-year follow up</td>
<td>61</td>
<td>139</td>
</tr>
<tr>
<td>Approved projects contacted on or before anniversary date</td>
<td>37</td>
<td>89</td>
</tr>
<tr>
<td>Approved projects completed on or before 1-year follow up</td>
<td>61%</td>
<td></td>
</tr>
<tr>
<td>CON approvals expired</td>
<td>38</td>
<td>53</td>
</tr>
<tr>
<td>Total follow up correspondence sent</td>
<td>324</td>
<td>517</td>
</tr>
<tr>
<td>Total approved projects still ongoing</td>
<td>296</td>
<td></td>
</tr>
</tbody>
</table>
Compliance: In accordance with Section 22247 and Rule 9419, the Department performs compliance checks on approved and operational Certificates of Need to determine if projects have been implemented, or if other applicable requirements have been met, in accordance with Part 222 of the Code.

The Department has taken the following actions:

- After a statewide review of the Open Heart Surgery data based on the 2010 Annual Survey, the Department opened 6 compliance investigations of Open Heart Surgery programs not meeting the approved volume requirement. The Department has investigated and conducted meetings with all 6 hospitals. A settlement proposal has been offered to all 6 hospitals with open compliance investigations. The Department has finalized settlement agreements with 4 of the 6 hospitals and is working to finalize the settlement agreements with the 2 remaining hospitals.

- After a statewide review of the Open Heart Surgery data based on the 2013 Annual Survey, the Department opened 5 additional compliance investigations of Open Heart Surgery programs not meeting the approved volume requirement. The Department has investigated and conducted meetings with all 5 hospitals and is in the process of determining proposed compliance actions.

- After a statewide review of the Psychiatric Beds and Services data based on the 2010 Annual Survey, the Department opened 14 compliance investigations of adult and child/adolescent psychiatric programs not meeting the approved occupancy rates. The Department has completed collection of information and investigation of the same. The Department has closed 4 investigations based on more recent data and updated information. The Department has conducted meetings with the remaining 10 psychiatric hospitals (10 adult programs and 1 child/adolescent program) and has determined proposed compliance actions. The Department is working to finalize settlement agreements with the 10 programs to resolve these investigations.

- Harper University Hospital – Facility self-reported operation of a hospital based portable CT scanner without CON approval. The facility was required to file a corrective CON, establish a corrective action plan, and paid a civil fine of $5,500.

- St. Joseph Mercy Ann Arbor Hospital – Facility self-reported operating 6 Cardiac Catheterization Laboratories (CCL) while approved for only 5 CCL. The facility was required to file a corrective CON, establish a corrective action plan, and paid a civil fine of $1,500.

- Northland Radiology – Facility received MRI services from a MRI Network that was not approved to provide service at this site. The facility was required to file a corrective notice CON, establish a corrective action plan, and paid a civil fine of $3,000.

- MRI Leasing, LLC – Facility provided MRI services to a non-approved host site. The facility was required to establish a corrective action plan and paid a civil fine of $2,000.

- Michigan Radiation Institute - Facility failed to offer MRT services for 12 months. The CON for this facility was expired.
CERTIFICATE OF NEED

2nd Quarter Program Activity Report to the CON Commission
October 1, 2014 through September 30, 2015 (FY 2015)

This quarterly report is designed to assist the CON Commission in monitoring and assessing the operations and effectiveness of the CON Program Section in accordance with Section 22215(1)(e) of the Public Health Code, 1978 PA 368.

Measures

Administrative Rule R325.9201 requires the Department to process a Letter of Intent within 15 days upon receipt of a Letter of Intent.

<table>
<thead>
<tr>
<th>Activity</th>
<th>2nd Quarter</th>
<th>Year-to-Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>Percent</td>
</tr>
<tr>
<td>Letters of Intent Received</td>
<td>128</td>
<td>N/A</td>
</tr>
<tr>
<td>Letters of Intent Processed within 15 days</td>
<td>128</td>
<td>100%</td>
</tr>
<tr>
<td>Letters of Intent Processed Online</td>
<td>128</td>
<td>100%</td>
</tr>
</tbody>
</table>

Administrative Rule R325.9201 requires the Department to request additional information from an applicant within 15 days upon receipt of an application, if additional information is needed.

<table>
<thead>
<tr>
<th>Activity</th>
<th>2nd Quarter</th>
<th>Year-to-Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>Percent</td>
</tr>
<tr>
<td>Applications Received</td>
<td>105</td>
<td>N/A</td>
</tr>
<tr>
<td>Applications Processed within 15 Days</td>
<td>105</td>
<td>100%</td>
</tr>
<tr>
<td>Applications Incomplete/More Information Needed</td>
<td>81</td>
<td>77%</td>
</tr>
<tr>
<td>Applications Filed Online*</td>
<td>101</td>
<td>100%</td>
</tr>
<tr>
<td>Application Fees Received Online*</td>
<td>28</td>
<td>28%</td>
</tr>
</tbody>
</table>

* Number/percent is for only those applications eligible to be filed online, potential comparative and comparative applications are not eligible to be filed online, and emergency applications have no fee.

Administrative rules R325.9206 and R325.9207 require the Department to issue a proposed decision for completed applications within 45 days for nonsubstantive, 120 days for substantive, and 150 days for comparative reviews.

<table>
<thead>
<tr>
<th>Activity</th>
<th>2nd Quarter</th>
<th>Year-to-Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Issued on Time</td>
<td>Percent</td>
</tr>
<tr>
<td>Nonsubstantive Applications</td>
<td>35</td>
<td>100%</td>
</tr>
<tr>
<td>Substantive Applications</td>
<td>26</td>
<td>100%</td>
</tr>
<tr>
<td>Comparative Applications</td>
<td>0</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Note: Data in this table may not total/correlate with application received table because receive and processed dates may carry over into next month/next quarter.
Measures – continued

Administrative Rule R325.9227 requires the Department to determine if an emergency application will be reviewed pursuant to Section 22235 of the Public Health Code within 10 working days upon receipt of the emergency application request.

<table>
<thead>
<tr>
<th>Activity</th>
<th>2nd Quarter</th>
<th>Year-to-Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Issued on</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Time</td>
<td>Percent</td>
</tr>
<tr>
<td>Emergency Applications Received</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Decisions Issued within 10 workings Days</td>
<td>1</td>
<td>100%</td>
</tr>
</tbody>
</table>

Administrative Rule R325.9413 requires the Department to process amendment requests within the same review period as the original application.

<table>
<thead>
<tr>
<th>Activity</th>
<th>2nd Quarter</th>
<th>Year-to-Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Issued on</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Time</td>
<td>Percent</td>
</tr>
<tr>
<td>Amendments</td>
<td>26</td>
<td>100%</td>
</tr>
</tbody>
</table>

Section 22231(10) of the Public Health Code requires the Department to issue a refund of the application fee, upon written request, if the Director exceeds the time set forth in this section for a final decision for other than good cause as determined by the Commission.

<table>
<thead>
<tr>
<th>Activity</th>
<th>2nd Quarter</th>
<th>Year-to-Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Refunds Issued Pursuant to Section 22231</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Other Measures

<table>
<thead>
<tr>
<th>Activity</th>
<th>2nd Quarter</th>
<th>Year-to-Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>Percent</td>
</tr>
<tr>
<td>FOIA Requests Received</td>
<td>52</td>
<td>N/A</td>
</tr>
<tr>
<td>FOIA Requests Processed on Time</td>
<td>50</td>
<td>96%</td>
</tr>
<tr>
<td>Number of Applications Viewed Onsite</td>
<td>1</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Source: Certificate of Need Evaluation Section, Michigan Department of Health & Human Services.
### CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

<table>
<thead>
<tr>
<th>Service Category</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Air Ambulance (AA)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Bone Marrow Transplantation (BMT) Services</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Cardiac Catheterization Services</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Computed Tomography (CT) Scanner</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Magnetic Resonance Imaging (MRI) Services</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Megavoltage Radiation Therapy (MRT) Services/Units</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Neonatal Intensive Care Services/Beds and Special Newborn Nursing Services</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Nursing Home and Hospital Long-Term-Care Unit (NH-HLTCU) Beds</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Positron Emission Tomography (PET) Scanner Services</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Psychiatric Beds and Services</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Urinary Extracorporeal Shock Wave Lithotripsy Services</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>New Medical Technology Standing Committee</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**KEY**
- Receipt of proposed standards/documents, proposed Commission action
- Commission meeting
- Staff work/Standard advisory committee meetings
- Consider Public/Legislative comment
- Current in-process standard advisory committee or Informal Workgroup
- Staff work/Informal Workgroup/Commission Liaison Work/Standing Committee Work

**Attachment I**

The CON Commission may revise this work plan at each meeting. For information about the CON Commission work plan or how to be notified of CON Commission meetings, contact the Michigan Department of Community Health, Office of Health Policy and Innovation, Planning and Access to Care Section, 7th Floor Capitol View Bldg., 201 Townsend St., Lansing, MI 48913, 517-335-6708, www.michigan.gov/con.
# Schedule for Updating Certificate of Need (CON) Standards Every Three Years

<table>
<thead>
<tr>
<th>Standards</th>
<th>Effective Date</th>
<th>Next Scheduled Update**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air Ambulance Services</td>
<td>June 2, 2014</td>
<td>2016</td>
</tr>
<tr>
<td>Bone Marrow Transplantation Services</td>
<td>September 29, 2014</td>
<td>2018</td>
</tr>
<tr>
<td>Cardiac Catheterization Services</td>
<td>June 2, 2014</td>
<td>2017</td>
</tr>
<tr>
<td>Computed Tomography (CT) Scanner Services</td>
<td>December 22, 2014</td>
<td>2016</td>
</tr>
<tr>
<td>Heart/Lung and Liver Transplantation Services</td>
<td>September 28, 2012</td>
<td>2018</td>
</tr>
<tr>
<td>Hospital Beds</td>
<td>March 20, 2015</td>
<td>2017</td>
</tr>
<tr>
<td>Megavoltage Radiation Therapy (MRT) Services/Units</td>
<td>May 24, 2013</td>
<td>2017</td>
</tr>
<tr>
<td>Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups</td>
<td>March 20, 2015</td>
<td>2016</td>
</tr>
<tr>
<td>Open Heart Surgery Services</td>
<td>June 2, 2014</td>
<td>2017</td>
</tr>
<tr>
<td>Positron Emission Tomography (PET) Scanner Services</td>
<td>June 2, 2014</td>
<td>2017</td>
</tr>
<tr>
<td>Psychiatric Beds and Services</td>
<td>March 22, 2013</td>
<td>2018</td>
</tr>
<tr>
<td>Surgical Services</td>
<td>December 22, 2014</td>
<td>2017</td>
</tr>
</tbody>
</table>

*Pursuant to MCL 333.22215 (1)(m): "In addition to subdivision (b), review and, if necessary, revise each set of certificate of need review standards at least every 3 years."

**A Public Comment Period will be held in October prior to the review year to determine what, if any, changes need to be made for each standard scheduled for review. If it is determined that changes are necessary, then the standards can be deferred to a standard advisory committee (SAC), workgroup, or the Department for further review and recommendation to the CON Commission. If no changes are determined, then the standards are scheduled for review in another three years.